# SkyePharma PLC Preliminary statement of annual results for the year ended 31 December 2008

SkyePharma PLC (LSE: SKP), LONDON, ENGLAND, 26 March 2009

# **Summary of Results**

	2008*	2007*
		(restated)
	£'m	£'m
Results		
Revenue	62.2	41.6
Research and development expenses	(25.1)	(30.3)
Pre-exceptional operating profit / (loss)	10.9	(15.2)
Pre-exceptional profit/(loss) before tax for the period	0.4	(23.7)
Continuing and discontinued operations: Net loss after tax (post exceptional)	(28.7)	(27.0)
Net debt and liquidity		
Total debt less cash including convertible bonds at face value	142.7	122.4
Liquidity - cash and cash equivalents plus undrawn facilities	37.5	33.1

<sup>\*</sup> All figures, unless otherwise noted, relate to continuing operations

# **Financial Highlights**

- Revenues up 49% to £62.2m (2007: £41.6m); revenues at constant currency up 23%
- Pre-exceptional operating profit of £10.9m (2007: loss of £15.2m), reflecting growth in revenues, lower operating costs and currency effects
- Pre-exceptional pre-tax profit of £0.4m (2007: loss of £23.7m)
- Net loss of £28.7m (2007: loss of £24.0m), post exceptional items of £28.5m (2007: £Nil) of which £26.2m is non-cash
- Cash and undrawn facilities of £37.5m at 31 December 2008 (2007: £33.1m)

# **Operating Highlights**

- United States Phase III clinical programmes for Flutiform<sup>™</sup> completed during 2008
- New Drug Application (NDA) for Flutiform<sup>™</sup> submitted to FDA in United States on 20 March 2009
- EU filing for Flutiform<sup>™</sup> expected in Q1 2010
- Development agreement signed with Kyorin for Flutiform™ in Japan
- Good progress on other pipeline products
- Balance sheet restructuring completed in September 2008 which significantly improved the Group's debt maturities

Commenting on the results, Jeremy Scudamore, Non-Executive Chairman, said:

"Further significant progress was made in the turnaround of SkyePharma during 2008. The clinical work necessary for the submission of the NDA in the United States for Flutiform™ was completed and the marketing application was submitted to the FDA on 20 March 2009. In addition, completion of the renegotiation of the convertible bonds and the related fundraising was a major achievement and gives the Group a debt maturity profile which enables it to continue to build its core oral and inhalation business and generate shareholder value from Flutiform™ and other pipeline products. The approval and commercial success of Flutiform™ is expected to be transformational for the Group."

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

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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 approved 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 <a href="https://www.skyepharma.com">www.skyepharma.com</a>.

### **CHAIRMAN'S STATEMENT**

### Overview

In 2008 further significant progress has been made in the turnaround of SkyePharma. The clinical work necessary for the submission of the New Drug Application ("NDA") in the United States for Flutiform™ was completed during 2008, and the application was submitted to the United States Food & Drug Administration ("FDA") on 20 March 2009. The completion of the renegotiation of the terms of the convertible bonds and the related fundraising in September 2008 was a major achievement and gives the Group a debt maturity profile which enables it to continue to build its core oral and inhalation business and generate shareholder value from Flutiform™ and other pipeline products. The Board continues to believe that the approval and commercial success of Flutiform™ will be transformational for the Group.

# **Financial Highlights**

The Group achieved revenues of £62.2 million in the year, 49 per cent. above the £41.6 million reported for the Continuing Operations in 2007. Approximately half of the increase is due to foreign exchange translation effects and the balance has arisen from additional revenues from contract research and development, an increase in royalty income following the launches of Pulmicort® HFA-MDI, Sular® and Requip® Once-a-day, and higher manufacturing revenues,

mainly from Sular®. Revenues would have increased 23 per cent. if monthly average foreign exchange rates in 2008 had been the same as 2007.

The improvement in the pre-exceptional operating result to a profit of £10.9 million in 2008 compared with a loss of £15.2 million (restated) in 2007 reflects the growth in revenues, continuing reduction in operating costs and foreign exchange translation effects. The profit was after costs including £25.1 million (2007 restated: £30.3 million) for research and development, mainly on the continuing development of Flutiform $^{TM}$ . After net finance costs, the Group incurred a profit before exceptional items and tax of £0.4 million (2007: loss of £23.7 million).

Exceptional charges for 2008 total £28.5 million (2007: £Nil) of which £26.2 million is non-cash. This primarily consists of a non-cash goodwill impairment charge of £19.5 million relating to the IDD® technology. The charge has arisen due to lower expectations for future sales of Triglide® as a result of the effects of competition in the second half of 2008 and the overall economic environment making it less likely that other potential applications for the technology will result in the development of viable products in the foreseeable future. A total charge of £5.9 million relates to the write-down of assets and other costs associated with the termination of contracts to supply Foradil® Certihaler™ as detailed in the Chief Executive's Review.

The remaining charge of £3.1 million consists of £1.5 million for legal, taxation, accounting and other professional costs related to work on the aborted refinancing transaction, £0.8 million for the write-down of assets related to the Flutiform™ supply chain to their net realisable value, and a further £0.8 million for other restructuring provisions.

The net result for the Continuing Operations after exceptional items, net finance charges and tax was a loss of £28.7 million (2007: £24.0 million).

### **Financial Position**

In September 2008, SkyePharma announced that renegotiated terms for the convertible bonds had been approved by bondholders. The new terms deferred the earliest dates at which the bondholders may call for repayment to November 2013 for the £69.6 million 2024 bonds and December 2014 for the £20 million 2025 bonds. In conjunction with this, the conversion prices were amended to £3.71 and £3.82 per share respectively. Completed at the same time was a Placing and Open Offer of new Ordinary Shares raising £18.4 million (net of expenses of the fundraising). The Ordinary Shares were consolidated on the basis of 1 new share replacing 100 original shares.

As at 31 December 2008, SkyePharma had cash of £35.7 million compared with £31.9 million at 31 December 2007.

### **Board**

In line with the Board succession plan Frank Condella stepped down from his position as Chief Executive Officer on 1 September 2008 and was replaced by Ken Cunningham, previously the Chief Operating Officer. This ensured a seamless transition. On 1 November 2008 Frank Condella became Non-Executive Director and has ioined а since the Remuneration Committee. The Board thanks Frank for steering the Company through some challenging times and is delighted that he is remaining on the Board in a non-executive capacity. Jerry Karabelas, who has served on the Board since 2000, as Chairman from February 2006 until November 2007, has decided not to seek re-election at the forthcoming Annual General Meeting which is taking place on 15 May 2009 and will step down from the Board on that date. His industry experience and perspective will be missed and we thank him for his services to the Group over many years.

#### Outlook

SkyePharma continues to make good progress, including filing the NDA for Flutiform™ in the United States, and the Directors remain confident of the Group's future prospects.

Revenues in 2008 included a number of non-recurring items, in particular the recognition of deferred revenues and development milestones of £6.4 million relating to Flutiform™ and manufacturing revenues of £6.2 million in respect of Foradil® Certihaler™. In 2009, the Directors are anticipating further growth in contract development revenues whilst royalty revenues are expected to be at a similar level to those in 2008 as growth from Requip® Onceaday, ZYFLO CR® and Lodotra™ offsets the continued decline in revenues from Paxil CR™ and Triglide® due to generic competition. Overall, 2009 revenues are expected to be lower than those in 2008.

As explained in the Chief Executive Officer's Review, underlying operating costs are being tightly controlled and headcount reductions have taken place or are under consultation. This will lead to some exceptional costs in 2009 but also operational cost savings in 2009 and future years. Now that the Flutiform™ NDA has been filed, the level of research and development costs borne by the Group will be significantly lower in 2009 compared with 2008. External costs re-charged to customers are likely to increase with the anticipated growth in contract research and development revenues.

As the Group's operations are in a number of different currencies, reported numbers may be significantly affected if the recent volatility in exchange rates continues. For example, if the current weakness of Sterling persists, reported costs will be higher than would have been the case at constant exchange rates but revenues would be positively impacted.

The Board believes that existing liquidity (£37.5 million as at 31 December 2008) is sufficient to meet the needs of the business for the foreseeable future.

Once  $\mathsf{Flutiform}^\mathsf{TM}$  is approved and launched in the United States and Europe, the Board continues to believe that there are exciting prospects for growth in both revenues and positive cash flow in the longer term.

We thank all our shareholders, bondholders, debt holders, employees and partners for their support during 2008.

Jeremy Scudamore Non-Executive Chairman

### **BUSINESS AND FINANCIAL REVIEW**

# **Chief Executive Officer's Review**

2008 saw the achievement of two key milestones for SkyePharma. The first was the completion of the Flutiform<sup>™</sup> Phase III clinical program, including three clinical efficacy studies completed by SkyePharma, and the completion of a fourth efficacy study by our United States partner, Abbott Respiratory LLC ("Abbott"). This has enabled us to meet our previously announced target of filing the NDA for the United States in Q1, 2009.

The second milestone was the successful renegotiation of the terms of the convertible bonds

and the placing and open offer. As a result the Group improved its debt maturity profile, with the first payment dates for the bonds falling in 2013 for the £69.6 million 2024 bonds and 2014 for the £20 million 2025 bonds. The successful conclusion of these negotiations allows the Group to focus on securing the approval of Flutiform™ whilst also building the pipeline and entering into new partnerships to broaden and strengthen the business.

### **Pipeline Update**

The European development of Flutiform™, in partnership with Mundipharma International Corporation Limited ("Mundipharma"), continued to move forward, with three studies completed during 2008. As previously announced, the final study results were delayed after some patients were assigned to the wrong study arm due to a randomisation issue. However substantial efforts are being made to minimise the impact of this with a view to filing the European Marketing Authorisation Application ("EMAA") in Q1, 2010.

During 2008, a development agreement was signed with Kyorin Pharmaceutical Company Ltd ("Kyorin") for the development of Flutiform™ in Japan, for which the Group is due to receive milestones worth several millions of pounds, and a high mid-single digit percentage royalty on net sales. In December 2008, recruitment for the Phase II study commenced.

Good progress continues to be made with other pipeline products, including confirmation that Lodotra<sup>TM</sup> was approvable in 15 European countries, and its subsequent approval in Germany. In addition, a Phase I study has been completed for SKP-1041, a controlled release sleep maintenance drug being developed with Somnus Therapeutics Inc ("Somnus").

Also in 2008, two new feasibility studies utilising SkyePharma's proprietary technology were commenced with two major pharmaceutical companies.

### **Approved Products**

SkyePharma currently has a portfolio of 12 approved products. New launches in 2008 include several additional countries for Pulmicort® HFA-MDI to replace the previous formulation of the CFC MDI formulation of Pulmicort®, Requip® Once-a-day and Sular®, all of which have contributed to the 49 per cent. increase in revenues to £62.2 million. Lodotra™ is expected to receive its first European launch in Q2 2009. Further detail on the performance of the approved products in 2008 is given in the Business Review - Products.

As announced in December 2008, discussions on commercialising the formoterol Certihaler ceased as a result of the recommendation of the Joint Advisory Committee to the FDA. This has resulted in a non-cash exceptional charge of £5.9 million being included in the 2008 consolidated income statement, which comprises a £4.5 million write-down of property, plant and equipment, £0.9 million for the associated intellectual property and £0.5 million for additional restructuring costs to be incurred.

Following this decision, Novartis gave notice of termination of its contract with the Group for the supply of Foradil® Certihaler™, and the Group also gave notice of termination of its agreement with the sub-contractor which manufactured the device. Negotiations are currently underway to determine any compensation arising from these events as detailed in Note 13: Contingencies, to the preliminary announcement.

# **Financial Strength**

In the current challenging market conditions it is important that the Group focuses on maintaining its increasingly robust balance sheet, and moving towards a cash generative position. Our cash balance at the end of the year was £35.7 million, an increase from the £31.9 million reported as at 31 December 2007. The increase in cash balances arose due to

exchange rate effects and the September 2008 fundraising which raised £18.4 million (net of equity expenses) which more than offset the costs incurred on renegotiating the terms of the convertible bonds and operating cash outflows during the year. Although overall borrowing levels remain substantial, having renegotiated the convertible bonds, the due dates for scheduled repayments have now been brought in line with reasonable expectations of future cash inflows. In 2009 the Group will continue to maintain a tight control on cash utilisation and is reducing costs where appropriate to ensure that existing cash resources remain sufficient to bring the business through to sustainable profitability. In connection with this a small number of redundancies have been made at the research and development facility in Muttenz, Switzerland and in March 2009 consultations commenced in France about potentially reducing the workforce there by approximately one-third.

### Strategy

Our primary focus for 2009 will remain on Flutiform™, where we will support Abbott with the registration process in the United States and Mundipharma with the completion of the development programme in Europe and the preparation of the European Marketing Authorisation Application ("EMAA"). We are also working on a number of line extensions related to Flutiform™.

We also continue to seek new partnerships, based on a contract development approach where we apply our drug delivery technology to a partner's product. Additionally, we continue with our early stage research and development activity, including further work on the two feasibility studies in progress, to provide further pipeline products.

Ken Cunningham
Chief Executive Officer

**Business Review - Products** 

### **INHALATION PRODUCTS**

# Flutiform™

Flutiform™ is a fixed-dose combination of fluticasone, an inhaled corticosteroid ("ICS"), and formoterol, a long-acting beta agonist ("LABA") in a Metered Dose Inhaler ("MDI"). ICS/LABA combinations are the fastest growing segment of the global asthma and chronic pulmonary ("COPD") market, which generated an obstructive disease 2007. Flutiform™ estimated U.S.\$28.8 billion globally in is aimed combination ICS/LABA inhalers' market which is forecast to generate approximately U.S.\$10 billion worldwide by 2010, which is when, subject to approval, Flutiform™ is planned to be launched in the United States. The Board has a target of achieving a 10 per cent. market share, as the third entrant to the market in the United States and fourth in the European Union.

Flutiform<sup>™</sup> is licensed to Abbott in the United States, to Mundipharma in the rest of the world (apart from Japan and the Americas) and to Kyorin for Japan. Discussions are continuing to out-license Flutiform<sup>™</sup> for Canada, and now that the NDA has been filed in the United States, licensees will also be sought for Latin America.

Progress with Flutiform™ in the United States

As previously announced, all clinical work for the submission of the NDA in the United States for Flutiform™ was completed during 2008 and the application was submitted on 20 March 2009.

Primary endpoints were met in all of the clinical programmes required for the submission of the NDA, comprising a long-term safety study and four efficacy studies, covering nearly 2,300

### patients.

Abbott 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) signing payment, the agreement with Abbott provides for SkyePharma to receive time-dependent milestones on acceptance of filing and approval together with up to U.S.\$60 million (£41.4 million) in sales related milestones. The royalty rate on sales in the United States escalates upwards from a mid teens percentage.

An amount of U.S.\$2 million (£1.4 million) is due to the Group upon acceptance of the NDA by the FDA from which the filing fee of approximately U.S.\$1.2 million (£0.8 million) will be deducted. Assuming a 2010 approval date, a milestone of U.S.\$25.0 million (£17.3 million) will be due. To the extent that certain of Abbott's development costs exceed U.S.\$20.5 million (£14.2 million) the excess is recoverable out of up to 25 per cent. of any approval or post-approval milestone and royalty payments until such time as 100 per cent. of the excess is recovered. If Flutiform™ were to be approved in the United States in 2010 these additional costs could reduce the net milestone payment to U.S.\$18.75 million (£13.0 million). As described in detail in the Financial Review, the first U.S.\$20 million (£13.8 million) of net milestone payments received after 1 January 2009 in respect of Flutiform™ (from all territories) are to be paid in equal shares to Paul Capital and CRC in accordance with the finance agreements.

The Group is carrying out additional contract development work for line extensions of Flutiform™.

# Progress with Flutiform™ in Europe

In addition to the data supporting the NDA for the United States, a number of additional clinical studies are being conducted by Mundipharma to support the EMAA for Flutiform™. Three of these studies have been completed and one higher dose strength study is currently in recruitment. In July 2008, Mundipharma advised SkyePharma that it had revised its plans for the filing and marketing of Flutiform™. This would have had the effect of bringing forward the likely launch timing for the higher dose strength by six to nine months, whilst holding back the launch of the low and middle strengths by a similar amount of time. The expected filing date for then Q3, 2009. A likely further delay announced in January 2009 as Mundipharma advised that some patients were assigned to the wrong study arm of the four armed study due to a randomisation issue, and that additional patients would need to be recruited into the high dose strength study. There is no cost implication for the additional work to SkyePharma as a result of this but it has delayed the likely filing of the EMAA by a few months. Mundipharma is now targeting to file the EMAA in Q1, 2010.

The completed studies comprise a 12-week open-label non-inferiority comparator study in 211 paediatric patients, a 12-week open-label non-inferiority comparator study in 182 adult and teenage patients, and a 12-week open-label non-inferiority study comparing with the two active components in 196 adult and teenage patients. The on-going study is an 8-week double-blind higher dose strength study to demonstrate the superiority of Flutiform™ over fluticasone and comparing its non-inferiority with the two active components (fluticasone and formoterol) administered concurrently. Following the randomisation issue noted above this study will now have over 900 subjects.

Mundipharma has exclusive rights to Flutiform<sup>™</sup> in Europe and other territories outside the Americas and Japan. The licensing agreement provides for the Group to earn up to €73 million (£66.5 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 (£14.6 million) is due on launch and up to €40 million (£38.9 million) is sales related. In addition,

the Group is entitled to royalties as a percentage of net sales escalating upwards from 10 per cent.. 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.

Also in July 2008, the Group entered into an amendment agreement with Mundipharma to make a number of changes to its existing license agreement. It was agreed that €3 million (£2.9 million) would be paid to the Group as the agreed balance of a €12 million (£11.7 million) milestone due from Mundipharma, less the Group's reimbursement to Mundipharma to contribute to the cost of the European clinical studies to support regulatory approval in adults (lower and middle strengths) and paediatrics. SkyePharma and Mundipharma also agreed that in the event that the Paediatric Committee ("PDCO") of the European Medicines Agency requests additional work to obtain a paediatric indication, SkyePharma would reimburse Mundipharma for half of the cost of this work up to €3.5 million (£3.4 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. The amendment also allowed Mundipharma to develop, at its cost, and market Flutiform™ with specific, new, breath-actuated actuator, which the Directors believe will enhance the sales of the product. Mundipharma will pay SkyePharma royalties escalating upwards from 10 per cent. on net sales of Flutiform™ whether or not incorporating the new actuator, but the rate of escalation of royalties was reduced to reflect the additional sales potential of the enhanced device and Mundipharma's costs to acquire and develop the actuator. Mundipharma and SkyePharma have agreed to negotiate an agreement for SkyePharma to manufacture and supply, or have manufactured and supplied, the filled canister product for use with the new actuator.

Under new EU regulations, there is a requirement to have an agreed Paediatric Investigation Plan ("PIP"). The recently formed PDCO has reviewed the plans for Flutiform<sup>™</sup> and a double blind study in children aged 4-12 years is required to be completed by December 2013.

### Progress with Flutiform™ in Japan

In April 2008, the Group entered into an exclusive development, distribution and license agreement for Flutiform<sup>™</sup> with Kyorin for Japan and has received an upfront milestone payment. Development and approval milestones worth several millions of 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. In December 2008, recruitment for the Phase II study commenced.

# Supply of Flutiform<sup>™</sup>

Under the agreements with Abbott, Mundipharma and Kyorin, the Group is responsible for supplying Flutiform™, and has committed to capital expenditure on tooling at two subcontractors as well as certain minimum volume commitments. The Group has entered into an agreement for the product to be manufactured in a sanofi-aventis 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 is in discussions with a view to transferring the responsibility and most of the risks and rewards of the Flutiform™ supply chain to a third party.

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

#### **Pulmicort® HFA-MDI**

This new HFA-MDI containing AstraZeneca's inhaled corticosteroid Pulmicort® (budesonide), which was developed for territories outside the United States, was filed for marketing authorisation between June and September 2005 on a country-by-country basis in Europe for the treatment of asthma. The HFA-MDI is intended to replace the currently available CFC-MDI formulation of Pulmicort®. Pulmicort® HFA-MDI has now been approved and launched in a large number of markets in which the CFC-MDI formulation of Pulmicort® has previously been sold. The target market for Pulmicort® HFA-MDI represents a low single digit percentage of AstraZeneca's global sales of Pulmicort®. SkyePharma earns a mid teens' royalty on AstraZeneca's net sales of Pulmicort® HFA-MDI.

### Foradil® Certihaler™

As announced in December 2008, discussions on commercialising the formoterol Certihaler™ ceased following the recommendation by the Joint Advisory Committees to the FDA that the benefits did not outweigh the risks in the current asthma indications for long acting beta-agonists administered alone. Novartis has given notice of termination of its contract for the supply of Foradil® Certihaler™ and, in light of this, the production line is being closed. The cessation of production capability has resulted in asset write-downs and a related non-cash charge of £5.9 million in the 2008 results.

# ORAL AND TOPICAL PRODUCTS Paxil $\mathsf{CR}^\mathsf{TM}$

Paxil CR™ is an advanced formulation of the anti-depressant Paxil® and was developed by SkyePharma with GlaxoSmithKline ("GSK") using SkyePharma's Geomatrix™ technology. Sales of Paxil® in the United States, including Paxil CR™, in 2008 were £79.0 million, down by 49 per cent. (using constant exchange rates) compared with 2007 following the entry of generic competition to Paxil CR™.

On 14 May 2008, Mylan Pharmaceuticals ("Mylan") announced that it had launched a generic version of Paxil CR™. Mylan stated that, as the first company to successfully file an abbreviated new drug application ("ANDA") containing a paragraph IV certification for the 12.5mg and 25mg tablets, it earned 180 days of marketing exclusivity for these two strengths. Reflecting a supply and distribution agreement with GSK, Mylan also has the right to market the 37.5mg strength. Of the three strengths launched, the 37.5mg strength will be manufactured by GSK using the Group's Geomatrix™ technology and, therefore, GSK's sales to Mylan will give rise to royalty payments to the Group. Generic erosion has been, as expected, quite rapid with approximately 80 per cent. of prescriptions being written for the generic form of the product.

### 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 2008, reported sales of all forms of Xatral® were €331 million (£262.7 million), up 3.4 per cent. (using constant exchange rates) compared with 2007. European sales have been affected by generic competition after the expiry of European patents starting in May 2006, with sales for 2008 reported as €148 million (£117.5 million), down 10.3 per cent. compared with 2007. This decline was offset by strong growth in the United States, where sales of Uroxatral® were €119 million (£94.5 million), up 20.2 per cent. compared with 2007. Sales in other countries were also up 14.3 per cent. to €64.0 million (£50.8 million). The term of the United States use patent has been extended to January 2011 (Geomatrix™ formulation patent reaching to August 2017). A number of companies have filed ANDA's with the FDA seeking approval to market a generic alfuzosin hydrochloride drug product in the United States. Sanofi-aventis has taken legal action in response to most of these ANDA's, and such legal action remains pending. SkyePharma earns low single digit royalties on net sales of Xatral® OD (Uroxatral®).

#### **Solaraze®**

Solaraze® (diclofenac), a topical gel treatment of actinic keratosis, is marketed in the United States by Nycomed. Nycomed acquired Bradley, the Group's previous licensee for the United States, in February 2008. Sales in 2008 were approximately U.S.\$37.6 million (£20.3 million), up by approximately 22 per cent. on 2007. The acquisition of Bradley has added further branded dermatologics to the PharmaDerm division of Nycomed and has provided an enhanced platform for in-licensing and co-promotion of dermatology products. SkyePharma's low teens royalty rate on net sales was unaffected by the acquisition. In 2007, Almirall acquired the distribution and marketing rights for Solaraze from Shire, together with a portfolio of other products. Sales in 2008 in Europe and certain other territories by Almirall were €16.8 million (£13.3 million) compared with the €11.3 million (£7.7 million) reported by Shire in 2007, up by 49 per cent. Sales were particularly strong in the key markets of Germany and the United Kingdom. In the third quarter of 2007, the product was launched in Australia by CSL Biotherapies under an agreement with Shire (now taken over by Almirall). SkyePharma's low teens royalty on relevant net sales was not affected by the transfer from Shire to Almirall.

### Triglide

Triglide® (fenofibrate), an oral treatment for elevated blood lipid disorders, is marketed in the United States by Sciele Pharma Inc. ("Sciele"), a Shionogi company, and is now being sold by Sciele alongside Fenoglide®, a fenofibrate product in-licensed from LifeCycle. Triglide® was launched in 2005 and Fenoglide® was launched in February 2008. The effect of competition led to a sharp drop in the rate of Triglide® total prescriptions during the second half of 2008. SkyePharma is entitled to receive 25 per cent. of Sciele'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 Sciele allowing the launch of Fenoglide® a few months earlier than the Triglide® licence agreement otherwise allowed, SkyePharma ceased making further marketing contributions in respect of Triglide® to Sciele, and Sciele agreed to purchase and distribute minimum numbers of samples of Triglide® and to share revenues from Fenoglide® with SkyePharma. The share of net sales of Fenoglide® starts at 8 per cent. and reduces to 4 per cent. from 1 August 2008 to 31 December 2009.

### 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 SkyePharma's patented Geomatrix™ technology and is designed to provide smoother blood levels of ropinirole 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. It also provides for a convenient, once-daily dosing schedule compared with immediate-release ropinirole, which is dosed three times a day. Extended release Requip® is currently approved in 34 countries worldwide and 29 countries in Europe, and has been launched in France, Germany, UK and a number of other European markets.

The FDA approved Requip® XL™ extended release tablets in June 2008 and the product was launched in the United States in July 2008. Requip® XL™ is the first and only once-daily oral non-ergot dopamine agonist indicated for Parkinson's disease in the United States.

In 2008, an ANDA was filed by a manufacturer for 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-aday. In 2008 sales of Requip® Once-a-day were £43.0 million, with £9.0 million generated in the United States and £34.0 million in Europe.

# **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 chronic treatment of asthma in adults and children aged 12 years and older. ZYFLO CR® and ZYFLO® (zileuton tablets) are the only FDA-approved leukotriene synthesis inhibitors. Cornerstone Therapeutics launched ZYFLO CR® in the United States together with its co-promotion partner, Dey, L.P., at the end of September 2007. SkyePharma receives a high mid single digit percentage royalty on net sales of ZYFLO CR® and also manufactures the product.

The previously announced product release issues have been investigated by Cornerstone Therapeutics in conjunction with its three manufacturing partners. These issues have been resolved and routine production has been resumed.

### **Sular®**

In May 2006, the Group entered into an agreement with Sciele (the United States licensee for Triglide®) to develop a new lower-dose formulation of Sciele's product Sular® (nisoldipine), a calcium channel blocker antihypertensive agent using the Group's proprietary Geomatrix™ drug delivery system. The clinical study programme was successfully completed in May 2007 and the new formulation was filed for approval in the United States, as planned, at the end of June 2007. FDA approval was given on 2 January 2008 for all four dosage strengths as bioequivalents to the old formulations and the product was launched in March 2008.

In July 2008, the FDA approved a generic version of the old formulation of Sular® for the 20mg, 30mg and 40mg doses. In February 2009, a paragraph IV certification was filed by a generic manufacturer in respect of the 25.5mg and 34mg strengths of the new formulation of Sular®. In March 2009, a further certification was filed for the 8.5mg and 17mg strengths of the new formulation. Entry of potential generic competition could be delayed by any patent infringement action.

For the full year to 2008, 39 per cent. of total prescriptions for the Sular® franchise were written for new Sular® according to IMS Health NPA data. In 2008 new prescriptions for new and old formulations of Sular® decreased 7 per cent. compared with 2007, and total prescriptions for both formulations decreased 17 per cent. SkyePharma received a milestone of U.S.\$2.0 million (£1.0 million) in January 2008 following approval in the United States. SkyePharma receives a low mid single digit percentage royalty on net sales and is manufacturing the new formulation of Sular® at its plant in Lyon, France.

# Lodotra™

Lodotra<sup>TM</sup>, developed together with Nitec Pharma AG ("Nitec"), is a novel delayed release night-time release formulation of low dose prednisone, a well-characterised glucocorticoid used in the treatment of a number of inflammatory conditions, including rheumatoid arthritis, where it is used as a core treatment. In rheumatoid arthritis, nocturnally elevated cytokines, such as interleukin-6 (IL-6) and tumour necrosis factor-alpha (TNF-a), are known pro-inflammatory factors involved in morning stiffness, one of the most disabling symptoms of rheumatoid arthritis. Using the Group's proprietary Geoclock<sup>TM</sup> delivery system, Lodotra<sup>TM</sup> can be taken at bedtime, but the active pharmaceutical is only released in the early hours of the morning. In this way prednisone release is synchronised with the sufferer's circadian cytokine rhythm and thus is designed to take effect at a physiologically optimal time to inhibit cytokine over-production and hence treat morning stiffness and pain. Phase-III studies were carried out on 288 patients in 26 European centres. The primary endpoint of the studies was to show significantly reduced morning stiffness. The results have been published and, in a

recent article in The Lancet (Lancet 2008; 371: 205-214), Buttgereit et al. concluded "... that modified release prednisone provides an improvement with respect to conventional glucocorticoids for the treatment of rheumatoid arthritis." Nitec received the final assessment report from the German BfArM in December 2008 concluding that Lodotra™ is approvable for the treatment of rheumatoid arthritis and associated morning stiffness in 15 European countries including Germany. Marketing authorisations are to be granted on a country by country basis under the EMEA's decentralised procedure. The first national European launch is expected to take place in Germany by Merck KGaA in Q2 2009 following the issuance of a marketing authorisation by the German authorities on 17 March 2009. The Directors believe that Nitec is in the process of establishing co-promotion or sub-licensing arrangements to distribute Lodotra™ in other European countries.

In the United States, Nitec has completed recruitment for the second pivotal Phase III study (a 12-week, multicentre, double blind trial involving 300 patients) required for filing the NDA. Nitec is targeting an NDA filing in Q1 2010.

SkyePharma will receive a mid single digit percentage royalty on net sales and is manufacturing the product at its plant in Lyon, France.

#### SKP-104<sup>2</sup>

In December 2008 SkyePharma and its partner, Somnus, announced the successful completion of a Phase I trial of the controlled release sleep maintenance drug SKP-1041, triggering a U.S.\$1 million development milestone. 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 daytime drowsiness.

Under the agreement with Somnus, SkyePharma could receive up to U.S.\$35 million (£23.4 million) in milestone payments, of which U.S.\$4 million (£2.0 million) was received on signature, up to U.S.\$11 million (£7.6 million) is payable during the development phase, mainly on product approval, and U.S.\$20 million (£13.8 million) is sales related.

SkyePharma is entitled to receive a royalty on future sales escalating upwards from a high mid single digit percentage. The project is progressing in line with the Board's expectations and, like most oral drug delivery programmes, the development is expected to take several years.

# 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. In order to conserve cash ahead of the approval and successful commercialisation of Flutiform™ the Board does not intend to finance any late phase clinical studies and will, therefore, tend to outlicense new developments at an early stage and work on further development on a contract development basis.

# Share of sales from Pacira

The terms of the sale of the injectable business included up to U.S.\$62 million (£42.8 million) in contingent milestone payments and a percentage of sales of certain future products for a fixed period of time. The milestones of up to U.S.\$62 million (£42.8 million) depend on the completion of Phase III studies and the achievement of certain launch and various substantial sales targets of DepoBupivacaine<sup>™</sup>. In addition, subject to the successful development and launch of the relevant products, the Continuing Group will receive 3 per cent. of net sales worldwide of DepoBupivacaine<sup>™</sup>. DepoBupivacaine<sup>™</sup> is currently in Phase II and Phase III clinical development for a number of indications with

Pacira Pharmaceuticals Inc ("Pacira Pharmaceuticals"). Pacira Pharmaceuticals announced in January 2008 that it had completed enrolment in two pivotal Phase 3 trials to evaluate the safety and effectiveness of DepoBupivacaine $^{\text{TM}}$ . In February 2009 Pacira Pharmaceuticals announced a setback in one of the clinical trials of DepoBupivacaine $^{\text{TM}}$ . No further details of the setback were given.

#### **MANUFACTURING**

Manufacturing operations in Europe take place at the Group's Lyon facility in France and Muttenz facility in Switzerland. The Group presently manufactures five Geomatrix™ products, Madopar DR® (at its Muttenz facility) and Diclofenac-ratiopharm®-uno, Coruno®, ZYFLO CR® and the new formulation of Sular® (at its Lyon facility). In addition, the Group manufactures one other oral product, Triglide®, based on its solubilisation technology, at its Lyon facility. The Group produces bio-batches for its internal development products and its collaborative partners in both facilities. The Lyon factory has cGMP status, with approvals from EMEA and United States (FDA).

During 2007 and 2008, Sciele has made a substantial investment in implementing a high capacity line, owned by Sciele, for the manufacture of the recently approved new formulation of Sular® in the Lyon facility. This has been a significant project for the factory, including adding to the existing buildings and relocating a number of operations on the site, whilst maintaining GMP status and quality production output.

As a result of the termination of the contract by Novartis for the supply of Foradil® Certihaler™, the production line in Lyon for this product is being closed.

### **Financial Review**

# **Continuing and Discontinued Operations**

The Injectable Business, which was sold on 23 March 2007, is included as Discontinued Operations in the 2007 comparatives in line with its classification in the 2006 accounts. Accordingly the consolidated income statement shows the net results of the Injectable Business separately (described as Discontinued Operations) and all other lines (including revenues, gross profit and operating loss) are for the Continuing Operations. Except where otherwise stated, all commentary in the Chairman's Statement and the Operating and Financial Review relates to Continuing Operations.

# Restatement of comparative information

During 2008 a review of the accounting policies relating to expenses was undertaken to better present the costs associated with each activity within the Group.

As detailed in Note 1(b) to the preliminary announcement, indirect costs which were previously recorded under administration costs have now been included in the expense headings to which they related - cost of sales (manufacturing costs), selling, marketing and distribution or research and development. Administration expenses now comprise expenditure not directly related to manufacturing, sales and marketing or research and development. In addition, share-based payment charges are now disclosed as an individual line item on the face of the income statement and translation gains and losses on net debt (cash and borrowings) are included in 'Translation gain on net debt' on the face of the consolidated income statement. All 2007 comparatives have been restated accordingly, as specified in Note 1(b) to the preliminary announcement.

In addition, 2007 comparatives have been restated, where necessary, to reflect the 2008 share

capital reorganisation as set out in Note 12: Share Capital to the preliminary announcement.

#### Revenue

Revenues of £62.2 million for 2008 were 49 per cent. above the £41.6 million reported in 2007. At constant exchange rates, using 2007 rates, revenue would have increased 23 per cent. year on year.

Revenues recognised from signing and milestone payments amounted to £12.4 million in 2008 compared with £10.4 million in 2007. For 2008, the Group has recognised a further £3.7 million (2007: £7.1 million) of the upfront payments received in 2006 relating to Flutiform  $^{\text{TM}}$ . These comprised recognition of the remaining £3.0 million of the upfront payment by Kos (now Abbott) (the full U.S.\$25.0 million received on signing has now been recognised) and £0.7 million from the upfront payment by Mundipharma (cumulatively £4.2 million from a total of £10.2 million (€15 million)). A large part of the balance of the Mundipharma upfront payment has been deferred to be released post-launch to offset a temporary royalty reduction which will represent the Group's contribution towards Mundipharma's costs for developing the higher strength version. Additionally the remaining deferred upfront revenue of £1.3 million relating to a development agreement with Baxter was recognised in full in 2008, due to the termination of the agreement.

Contract research and development costs recharged increased £4.8 million to £8.0 million (2007: £3.2 million), primarily relating to costs of the extra Flutiform $^{\text{TM}}$  study required by the FDA being recharged to Abbott and work on the partnership development recharged to Dr. Reddy's.

Royalty income was £22.4 million (2007: £17.8 million), an increase of £4.6 million (26 per cent.) largely due to exchange rate effects and growth in royalties mainly due to launches of Pulmicort® HFA-MDI in several countries, Requip® Once-a-day, the new formulation of Sular® and growth in Solaraze® offsetting the decline in revenues from Paxil CR™ due to generic competition.

Manufacturing and distribution revenue increased by £9.2 million to £19.4 million, compared with £10.2 million in 2007. This includes a £6.2 million (2007: £5.4 million) contribution from Novartis towards maintaining manufacturing capacity for Foradil® Certihaler™, of which a substantial part was passed on to a sub-contractor for maintaining its capacity to produce devices. Manufacturing revenues also benefited from the manufacture of launch stocks of the new formulation of Sular®.

# **Deferred income**

During 2008, of there net increase deferred income was £1.0 million, due primarily to exchange held. These gains on balances gains result from translation gains on consolidation into Sterling since deferred income is translated into the local functional currency at the prevailing rate on the date the balance is received in the subsidiary's local accounts.

The movement in deferred income was as follows:

	31 December 2007	Received	Recognised	Exchange Translation	31 December 2008
	£m	£m	£m	£m	£m
Contract development and licensing revenue	13.0	3.9	(7.6)	4.7	14.(

### Cost of sales

Cost of sales comprises the direct and indirect costs of manufacturing, agents' commissions and royalties payable. Cost of sales increased by £3.9 million to £19.6 million in 2008; and gross profit increased 65 per cent. to £42.6 million compared with £25.9 million in 2007 (restated).

# Selling, marketing & distribution and administration expenses

Selling, marketing and distribution expenses comprise the direct and indirect costs of business development, marketing and distribution. They increased to £1.5 million in 2008, compared with £1.0 million in 2007 (restated) as additional commercial resources were deployed.

Amortisation and impairment of intangibles totalled £0.7 million (2007: £2.7 million). The non-cash charge for 2007 included a goodwill impairment loss of £1.9 million related to the Insoluble Drug Delivery ("IDD®") technology business unit acquired in 2001. The 2008 impairment charge is included within exceptional items in the income statement due to the magnitude of the impairment as explained in Note 5: Exceptional Items.

Other administration expenses for the Continuing Operations of the Group were £3.5 million (2007 restated: £5.9 million), consisting primarily of corporate administration expenses.

# Research and development expenses

Research and development expenses comprise the direct and indirect costs on projects, feasibility studies and technology development; costs of chemistry, manufacturing and control development and clinical work and costs related to the registration and maintenance of intellectual property.

Research and development expenses in the year decreased to £25.1 million (2007 restated: £30.3 million) and included £13.8 million (including attributable overheads) on developing Flutiform<sup>TM</sup> (2007 restated: £24.6 million) in preparation for the NDA filing in the United States. As at 31 December 2008 the Group had obligations to purchase assets relating to the Flutiform<sup>TM</sup> supply chain to the value of £5.4 million. As noted in the review of products the Group is in discussions with a view to transferring the responsibility and certain of the risks and rewards of the Flutiform<sup>TM</sup> supply chain to a third party. If this transfer takes place in line with the current negotiations the Directors expect that the third party will take over the outstanding obligations for the supply chain assets as well as purchasing the assets already purchased by the Group. These assets have therefore been shown as 'non-current assets classified as held for sale' in 2008.

# **Operating results**

The operating profit before exceptional items was £10.9 million (2007 restated: loss of £15.2 million). Pre-exceptional earnings before interest, tax, depreciation and amortisation were £16.3 million (2007: loss of £10.3 million) as follows:

	2008	
	£m	
Operating profit/(loss) before exceptional items	10.9	
Pre-exceptional depreciation and amortisation	5.4	
Pre-exceptional earnings/(loss) before interest, tax, depreciation and amortisation (EBITDA)	16.3	

### **Exceptional Charges**

Exceptional charges for 2008 total £28.5 million (2007:£Nil) of which £26.2 million is non-cash. A non-cash charge of £19.5 million has arisen on the impairment of the goodwill which arose on the acquisition of RTP Canada in 2001. As described in Note 8: Goodwill, the remaining value is supported by the Directors' assessment of the value of the technologies acquired with that business, mainly the Insoluble Drug Delivery (IDD®) technology, which is used in Triglide®. The charge has arisen due to lower expectations for future sales of Triglide® as a result of the effects of competition in the second half of 2008 and the overall economic environment making it less likely that other potential applications for that technology will result in viable products in the foreseeable future.

A total of £5.9 million relates to the write-down of assets, and other costs incurred associated with the termination of Foradil® Certihaler™ as described in the Chief Executive Officer's review.

The remaining charge of £3.1 million includes a charge of £1.5 million for legal, taxation, accounting and other professional costs related to work on the aborted refinancing transaction in the first half year; £0.8 million for the write-down of assets, related to the Flutiform™ supply chain, to their net realisable value; and a further £0.8 million for other restructuring provisions.

# Finance income and expense

The finance costs of £17.1 million (2007: £12.4 million) comprise £14.1 million of interest costs and £3.0 million (2007: £Nil) of non-recurring finance charges. The interest charge comprises £4.5 million (2007:£3.1 million) interest payable on the CRC finance, £2.7 million (2007: £2.6 million) interest attributable to the Paul Capital finance, £6.5 million (2007: £6.3 million) interest payable on the convertible bonds and £0.4 million (2007: £0.4 million) on other bank borrowings. The non-recurring charges of £3.0 million represent the costs of providing for the net present value of future prepayments expected to be made to Paul Capital and future make whole payments expected to be made to CRC on receipt of future Flutiform™ milestones (as described in the borrowings and liquidity section below).

The exchange gain on net debt totalling £5.7 million (restated 2007: £2.3 million) consists of a £1.6 million (2007: £1.7 million) gain on the U.S.\$ denominated Paul Capital financing, a £3.7 million (2007: £1.1 million) gain on the Euro and U.S.\$ denominated CRC financing and a £0.4 million net gain (2007: loss of £0.5 million) on foreign currency denominated cash balances. The gain on net debt has arisen as the debt is held in the books of Jagotec AG, a Swiss subsidiary, which has a functional currency of Swiss Francs. During 2008 the Swiss Franc strengthened compared with the U.S. Dollar and Euro, giving rise to a gain in the books of Jagotec AG. In the consolidated accounts total net debt has increased as a result of the weakening of Sterling and a substantial debit has been charged directly to translation reserves on consolidation to reflect this increase in the liabilities. The net gain arose on cash balances denominated in foreign currency, largely U.S. Dollars, due to the weakening of Sterling during 2008.

### **Taxation**

The Group's tax expense was £0.6 million (2007: £0.3 million), mainly relating to provisions for irrecoverable withholding taxes.

# Result

The loss for the year after exceptionals from Continuing and Discontinued Operations increased by £4.7 million to £28.7 million, primarily due to the £28.5 million exceptional charges in 2008, and higher finance charges of £4.7 million offset by the increase in revenue of £20.6 million, and the decrease in research and development expenses of £5.2 million.

# Earnings per share

2007 earnings per share have been restated to reflect the September 2008 share consolidation, as set out in Note 12: Share Capital, to the preliminary announcement.

The loss per share from Continuing Operations amounted to 247.4 pence (2007 restated: 279.1 pence). The pre-exceptional loss per share from Continuing Operations amounted to 1.7 pence (2007 restated: 279.1 pence). As at 31 December 2008 there were 22,167,695 Ordinary £1.00 Shares, 12,000,000 deferred 10 pence "B" shares and 7,334,899,200 deferred 1 pence "C" shares in issue. The deferred "B" and "C" shares have negligible participation rights in the Company. As of 25 March 2009, since 31 December an additional 530,995 ordinary £1.00 shares have been or are being issued following the conversion of £2.0 million of 2024 6% Convertible Bonds. These conversions will reduce interest costs by approximately £118,000 per annum and strengthen the Group's balance sheet through the reduction in debt.

In addition as at 31 December 2008 there were outstanding a number of options, bond conversion rights and employee share schemes as follows:

Description	Number of ordinary £1.00 shares	Exercise price (per share)	Expiry conditions
Deferred consideration (Krypton)	375,000	£2.77 increasing at 10% per annum	None
Employee share option schemes	80,775	£22.90-£41.76	Various dates 2009 to 2013
Employee share schemes*	404,028	Nil	Various performance and service conditions
Convertible bonds 2024	18,758,490	£3.71	May 2024
Convertible bonds 2025	5,235,602	£3.82	June 2025
Total at 31 December 2008	24,853,895		
Total at 31 December 2007 (restated)	108,826,151		

<sup>\*</sup> Employee share schemes include the deferred share bonus plan, long term incentive plans and international share purchase plan.

As at 25 March 2009, the Company's mid-market share price was 155.75 pence.

# **Cash flows**

During 2008 there was a cash inflow from operating activities of £4.5 million, compared with an outflow of £17.9 million in 2007. During the year the Group spent £4.2 million on property, plant and equipment, mainly relating to the Flutiform™ supply chain.

The Group received cash of £18.4 million (net of expenses of the fund raising) from the share issue in September 2008 and incurred costs of £4.3 million in respect of the renegotiation of the bonds.

Borrowings of £3.0 million were repaid in the year, primarily comprising amortisation payments of the Paul Capital finance. In addition, the Group paid £13.2 million of interest during 2008, mainly relating to the convertible bonds, Paul Capital, CRC Finance and the mortgages. Interest received on cash deposits amounted to £0.9 million.

### **Key performance indicators**

We consider the following Key Performance Indicators (KPIs) to be the most relevant to our Continuing Operations, which are monitored on an actual and forecast basis:

Key financial performance indicators for the Continuing Operations		2004	2005	2006	2007	2008
Revenue excluding milestones	£'m	33.8	34.4	30.3	31.2	49.8
Signing and milestone payments received	£'m	26.6	24.1	30.0	3.0	3.9
Research and development expenditure (restated)	£'m	25.1	20.7	26.3	30.3	25.1
Liquidity	£'m	15.3	35.6	46.2	33.1	37.5

Key non-financial performance indicators for the Continuing Operations		2004	2005	2006	2007	2008
Number of approved and marketable products at year end		9	10	9	11	12
Manufacturing output	Units (millions)	120	103	98	94	234

The above figures exclude the Injectable Business which is included in Discontinued Operations.

# **Description of Key Performance Indicators**

# Revenue excluding milestones

Revenue reflects the levels 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 £49.8 million for 2008 excludes milestone revenue of £12.4 million and is shown in Note 2 to the preliminary announcement.

# Signing and milestone payments received

This KPI shows progress with pipeline products and product sales. The figure of £3.9 million for 2008 represents the cash milestones received in the year.

### Research and development

Research and development reflects the cost, including direct and indirect overheads, of all research and development activities. A breakdown of the 2008 costs is shown in Note 4 to the preliminary announcement.

### Liquidity

A key focal point for managing the operations of the business is the adequacy of finance to fund current and future activities and to meet debt servicing requirements. Liquidity consists of cash and cash equivalents of £35.7 million, as per the balance sheet, and undrawn facilities of £1.8 million.

# Approved products

This consists of products which have been approved and are available for sale as of 31 December. This demonstrates the number of different products which generate royalty

#### revenues.

# Manufacturing Output

Manufacturing output includes output from the sites in Lyon and Switzerland. Units represent the number of tablets and devices manufactured in the year and is an indication of the volume of throughput in manufacturing operations.

### **Balance sheet**

As at 31 December 2008, the Group balance sheet shows a total shareholders' equity of £89.8 million deficit (2007: £59.2 million deficit). The decrease in shareholders' equity has arisen mainly due to the £28.7 million loss from Continuing and Discontinued Operations and £20.7 million exchange translation effects due to the weakening of Sterling in 2008 offset by a £18.4 million net increase from the share issue in September 2008.

# **Borrowings and liquidity**

The Group's total net debt including convertible debt at face value comprises:

	2008	2007
	£m	£m
Convertible bonds at face value	89.6	89.6
Paul Capital funding liabilities (included at amortised	28.6	21.0
cost)		
CRC funding liabilities	49.5	36.2
Property mortgages	9.0	6.4
Bank borrowings	1.2	0.8
Finance lease liabilities	0.3	0.1
Bank overdraft	0.2	0.2
Total debt	178.4	154.3
Less cash and cash equivalents	(35.7)	(31.9)
Net debt	142.7	122.4

The total debt outstanding has increased, notwithstanding scheduled repayments totalling £3.0 million, due to exchange translation effects.

### Convertible bonds

The convertible bonds comprise £69.6 million 6 per cent. convertible bonds due May 2024 and £20.0 million 8 per cent. convertible bonds due June 2025 outstanding as at 31 December 2008.

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

As disclosed in Note 14: Post balance sheet events, £2.0 million of convertible bonds have been converted into Ordinary Shares in 2009 between 1 January 2009 and 25 March 2009.

# **Paul Capital Finance**

In March 2007, in conjunction with the disposal of the Injectable Business, the Group restructured its arrangements with Paul Capital from the sharing of royalties from a number of specified products into a fixed amortisable note ("Note") of U.S.\$92.5 million (£63.9 million) with up to an additional U.S.\$12.5 million (£8.6 million) payable if worldwide sales of DepoDur™ (a product of the Injectable Business) reach certain thresholds. The note is repayable in accordance with an amortisation schedule through to 2015.

The Injectable Business 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 continuing 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 the Injectable Business, now called Pacira Pharmaceuticals Inc. ("Pacira Pharmaceuticals").

As at 31 December 2008, 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 per cent. is U.S.\$41.5 million (£28.6 million) compared with the value of U.S.\$41.9 million (£21.0 million) included in the 31 December 2007 balance sheet. As at 31 December 2008 a cumulative total of U.S.\$18.6 million (£10.0 million) had been paid against the Note, including payments made by Pacira Pharmaceuticals totalling U.S.\$2.8 million (£1.5 million).

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

	Notional interest	Repayment of principal	Total
	U.S.\$m	U.S.\$m	U.S.\$m
2007 (actual)	6.7	2.9	9.6
2008 (actual)	5.9	3.1	9.0
2009	4.5	4.9	9.4
2010	3.1	15.0	18.1
2011	2.2	6.8	9.0
2012	1.4	7.3	8.7
2013	0.5	7.9	8.4
2014	(0.1)	(0.5)	(0.6)
2015	-	ı	1
Total	24.2	47.4	71.6

### The above table:

- shows interest and principal payments on a cash basis (no discounting applied) using the notional interest rate of 11.2 per cent. which has been applied from inception (based on benchmarking equivalent rates at that time),
- (ii) excludes the additional payments due if sales of DepoDur™ reach certain thresholds,
- (iii) includes reductions for estimated future sales-related payments by Pacira Pharmaceuticals for DepoDur™ and DepoCyt®,
- (iv) includes prepayment of the Note to an aggregate amount of U.S.\$10 million out of 50 per cent. of milestones and signing fees forecast to be received in respect of Flutiform™ in 2009 and 2010.

The negative interest and principal payments shown in 2014 arise because, once the Note has been repaid, payments received from Pacira Pharmaceuticals related to DepoDur™ and DepoCyt® are retained by the Group.

### **CRC Finance**

The CRC finance facility was taken out in 2006 and is a 10 year secured amortising loan facility at inception totalling approximately £35.0 million. 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. Half of the committed principal on each loan was drawn down in January 2007 and a further U.S.\$11.5 million and €9.0 million were drawn down in March 2007. The remaining U.S.\$6.0 million and €4.25 million were drawn down on 31 December 2007.

The amortisation schedule determines the interest payable and principal outstanding under the CRC Financing as follows (using exchange rates ruling as at 31 December 2008):

	Euro component of Ioan		U.S.\$ comp	onent 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	36.0
2009	3.0	24.5	3.1	32.6
2010	2.8	21.4	2.2	20.6
2011	2.4	17.4	1.7	16.8
2012	2.0	13.4	1.3	12.9
2013	1.6	9.9	1.0	9.4
2014	1.2	6.5	0.7	6.2
2015	0.9	3.2	0.4	3.0
2016	0.3	ı	0.1	-
Total	19.8		16.6	-

### The above table:

- (i) shows interest on a cash basis (no discounting is applied). The interest rates applicable at 31 December 2008 were 10.99 per cent. on the Euro component (plus an additional 5% on the first €7.5 million (£7.3 million)) and 9.61 per cent. 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 these when the principal would be paid off earlier without penalty,
- (iii) includes prepayment of the U.S.\$ loan to an aggregate amount of U.S.\$10 million out of 50 per cent. of milestones and signing fees forecast to be received in respect of Flutiform™ in 2009 and 2010.

Approximately half of the facility is denominated in U.S. Dollars and half in Euro. The amounts above are translated into U.S. Dollars and Euros using the exchange rates applicable at 31 December 2008.

# Other borrowings and cash

Bank and other borrowings amounted to £10.7 million at 31 December 2008 (2007:

£7.5 million), consisting principally of £9.0 million property mortgages secured on the assets of SkyePharma AG (2007: £6.4 million). The increase in the amount of the mortgages is entirely due to exchange translation effects.

As at 31 December 2008 SkyePharma had net cash of £35.5 million, comprising cash and cash equivalents of £35.7 million net of a bank overdraft of £0.2 million, compared with £31.7 million net cash at 31 December 2007.

### 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, 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. The auditors report on the accounts for 2007 and the auditors' conclusion on the unaudited interim financial statements to 30 June 2008 included an emphasis of matter paragraph to draw attention to the disclosures made in Note 2 to the accounts indicating material uncertainties. The auditors' report on the accounts for the year ended 31 December 2008 contains no emphasis of matter paragraph.

Whilst not a significant uncertainty affecting going concern, the Directors have reasonable expectations that the working capital position will be further enhanced by transferring the responsibility and most of the risks and rewards of Flutiform™ supply chain to a third party which, as described in Note 10 to the preliminary statement, could result in a recovery of £3.9m for assets held for sale and alleviate a further €5.6 million (£5.4 million) of capital commitments. The likely timing of approval and launch of Flutiform™ is outside the formal period for the assessment of going concern.

### Foreign exchange risks

Almost all of the Group's Continuing Operations are based overseas in Continental Europe and license 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 U.S. 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 finance income, 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 longterm 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. Use has been made of currency options and forward currency contracts during 2007 and 2008 to minimise the currency exposure on certain operational transactions.

### Injectable Business

In March 2007, SkyePharma sold the Injectable Business to Blue Acquisition Corp (now Pacira Inc.) for an initial cash consideration of U.S.\$20 million (£10 million) (less costs of U.S.\$2 million (£1.0 million) paid into escrow, a working capital adjustment and certain liabilities) and deferred consideration of up to U.S.\$62 million (£31 million) of contingent milestone payments and a percentage of sales for certain future products for a defined period of time. Subsequent to

the sale the working capital adjustment was agreed in 2007 and resulted in a reduction of the purchase price of U.S.\$0.3 million (£0.1 million) which has been settled from the escrow account. As noted above, the Injectable Business also retained responsibility for certain royalty based payments which, when made, will reduce SkyePharma's debt to Paul Capital. Following the impairment of goodwill of £37.0 million in 2006, the residual gain on sale was £1.4 million.

The gain on sale, which is shown as an exceptional gain from Discontinued Operations, has been calculated without taking account of any deferred consideration in respect of DepoBupivacaine<sup>™</sup> and Biologics products, since this depends on the successful outcome of the long-term development programme for DepoBupivacaine<sup>™</sup> and identification, initiation and completion of programmes for Biologics. The Injectable Business generated a loss of £4.4 million from 1 January 2007 until the date of sale of 23 March 2007.

### 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 timings for Flutiform™, the statements under "Outlook" including the timescales for the approval and launch of new products and the target for becoming cash flow positive, 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 2008

		Year to 31 December 2008	(Restated) Year to 31 December 2007
	Notes		
Continuing operations		£m	£m
Revenue	2	62.2	41.6
Cost of sales	1(b),3	(19.6)	(15.7)
Gross profit		42.6	25.9
Selling, marketing and distribution expenses	1(b)	(1.5)	(1.0)
Research and development expenses	1(b),4	(25.1)	(30.3)
Amortisation of intangible assets		(0.7)	(2.7)
Administration expenses	1(b)	(3.5)	(5.9)
Share based payment charge	1(b)	(0.8)	(1.2)
Other expense	. ,	(0.1)	-
Pre-exceptional operating profit/(loss)		10.9	(15.2)

Exceptional items	5	(28.5)	-
Operating loss		(17.6)	(15.2)
Finance costs	6	(17.1)	(12.4)
Finance income	1(b),6	0.9	1.6
Foreign exchange gain on net debt	1(b),6	5.7	2.3
Loss before tax		(28.1)	(23.7)
Taxation		(0.6)	(0.3)
Loss for the period		(28.7)	(24.0)
Pre-exceptional profit/(loss) for the period before tax		0.4	(23.7)
Discontinued operations			
Pre-exceptional loss for the period		-	(4.4)
Exceptional items		-	1.4
Loss for the period		-	(3.0)
Loss for the period from continuing and discontinued operations		(28.7)	(27.0)
Basic and diluted earnings per share	7		
Continuing operations	-	(247.4)p	(279.1)p
Continuing and discontinued operations		(247.4)p	(314.0)p

See Notes to the preliminary announcement

# **CONSOLIDATED BALANCE SHEET**

as at 31 December 2008

	Notes	As at 31 December 2008	As at 31 December 2007
A005T0	Notes	£m	£m
ASSETS			
Non-current assets			
Goodwill	8	7.8	27.3
Intangible assets		10.8	8.7
Property, plant and equipment		26.3	26.1
Available-for-sale financial assets		-	0.1
		44.9	62.2
Current assets			
Inventories		1.5	0.9
Trade and other receivables		19.4	11.7
Financial assets at fair value through profit or loss		-	0.1
Cash and cash equivalents	9	35.7	31.9
	_	56.6	44.6
Non current assets classified as held for sale	10	3.9	-
Total Assets		105.4	106.8

LIABILITIES			
Current liabilities			
Trade and other payables		(26.0)	(21.4)
Borrowings Deferred income	11	(12.8) (1.6)	(6.8) (5.0)
		(40.4)	(33.2)
Non-current liabilities			
Convertible bonds Other Borrowings Deferred income	11 11	(62.7) (76.0) (12.4)	(64.7) (57.9) (8.0)
Provisions		(3.7)	(2.2)
		(154.8)	(132.8)
Total Liabilities		(195.2)	(166.0)
Net Liabilities		(89.8)	(59.2)
SHAREHOLDERS' EQUITY			
Share capital Share premium	12	96.7 387.2	82.7 382.8
Translation reserve		(24.8)	(4.1)
Fair value reserve		(0.3)	(0.2)
Treasury share reserve		(0.2)	-
Retained losses		(557.8)	(529.8)
Other reserves		9.4	9.4
Total Shareholders' Equity		(89.8)	(59.2)

See Notes to the preliminary announcement

# CONSOLIDATED STATEMENT OF RECOGNISED INCOME AND EXPENSE

for the year ended 31 December 2008

	Year to 31 December 2008 £m	Year to 31 December 2007 £m
Net currency translation effect Available for sale financial assets	(20.7)	(7.4)
Fair value movement taken to equity Actuarial losses on defined benefit plans	(0.1) (0.1)	-
Net losses recognised directly in equity	(20.9)	(7.4)
Loss for the year from continuing operations	(28.7)	(24.0)
Loss for the year from discontinued operations	<u> </u>	(3.0)
Total recognised income and expense for the year	(49.6)	(34.4)

# **CONSOLIDATED CASH FLOW STATEMENT**

for the year ended 31 December 2008

Notes	Year ended	Year ended
	31 December	31 December

	2008	2007
	£m	£m
(a)	<b>5.1</b> (0.6)	<b>(17.6)</b> (0.3)
s	4.5	(17.9)
	(4.2)	(3.6)
	(0.1)	-
its	-	1.2
	-	4.6
	0.9	1.6
5	(3.4)	3.8
	(3.0)	(3.5)
	(13.2)	(11.1)
	18.4	14.8
	(4.3)	-
	-	35.8
6	(2.1)	36.0
	4.8	(8.0)
	3.8	21.1
r	31.7	10.6
	3.8	21.1
	35.5	31.7
9	35.7	31.9
11	(0.2) 35.5	(0.2)
	s s	£m  (a) 5.1 (0.6)  s 4.5  (4.2) (0.1)  onts -  0.9  (3.0) (13.2)  18.4 (4.3) - s (2.1)  4.8  3.8  3.8  3.8  3.8  3.8  3.8

See Notes to the preliminary announcement

# NOTE TO THE CONSOLIDATED CASH FLOW STATEMENT

# (a) Cash flow from operating activities

Year ended	Year ended
31 December	31 December
2008	2007
£m	£m

Loss for the year from continuing operations	(28.7)	(24.0)
Loss for the year from discontinued operations	<u>-</u>	(3.0)
Loss for the year from continuing and discontinued operations	(28.7)	(27.0)
Adjustments for:		
Tax	0.6	0.3
Depreciation	4.7	4.4
Amortisation	0.7	0.9
Impairments	25.7	1.9
Finance costs	17.1	13.2
Finance income	(0.9)	(1.6)
Gain on sale of subsidiary	-	(1.4)
Aborted transaction costs	1.5	-
Share based payments charge	0.8	1.2
Exchange gains on translation	(5.3)	(2.8)
Other non-cash charges	(1.5)	(1.1)
Operating cash flows before movements in working capital	14.7	(12.0)
Changes in working capital		
(Increase)/decrease in inventories	(0.1)	0.1
Increase in trade and other receivables	(2.3)	(1.5)
(Decrease)/increase in trade and other payables	(3.2)	1.2
Decrease in deferred income	(4.0)	(5.5)
Increase in provisions	( )	0.1
Cash generated by/(used in) operations	5.1	(17.6)
	<del>-</del>	\ /

# Notes to the preliminary announcement

The preliminary announcement for the year ended 31 December 2008 was approved by the Board on 25 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 1985 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 2007 to which no material changes were made except as described in Note 1(b).

The financial information in this preliminary announcement does not constitute statutory accounts within the meaning of Section 240 of the Companies Act 1985 for the years ended 31 December 2007 and 2008. The financial information for the years ended 31 December 2007 and 2008 has been extracted from the Group's audited consolidated accounts for the year ended 31 December 2008. The auditors' report on those accounts was unqualified and did not contain a statement under Section 237 (2) or (3) of the Companies Act 1985. Certain comparative figures as at 31 December 2007 have been restated to include prior period reclassifications, as detailed in Note 1(b).

The audited accounts for the year ended 31 December 2007 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.

### (a) 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 Financial 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, 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 annual report and accounts.

Whilst not a significant uncertainty affecting going concern, the Directors have reasonable expectations that the working capital position will be further enhanced by transferring the responsibility and most of the risks and rewards of the Flutiform™ supply chain to a third party which, as described in Note 10, could result in a recovery of £3.9m for assets held for sale and alleviate a further €5.6 million (£5.4 million) of capital commitments. The likely timing of approval and launch of Flutiform™ is outside the formal period of assessment for going concern.

# (b) Changes in accounting policies and reclassification of 2007 income statement

During 2008 a review of the accounting policies relating to expenses was undertaken to better present the costs associated with each activity within the Group. Indirect costs which were previously recorded under administration costs have now been included in the expense headings to which they relate - cost of sales (manufacturing costs), selling and marketing or research and development. Administration expenses now comprise expenditure not directly related to manufacturing, sales and marketing or research and development. In addition share-based payment charges are now disclosed as an individual line item on the face of the income statement and foreign exchange gains and losses on net debt (cash and borrowings) are all included in 'Foreign exchange gain on net debt' in the consolidated income statement. All 2007 comparatives have been restated accordingly, the financial effect of which has been to restate the 2007 comparatives as follows:

- Cost of sales has decreased by £0.4 million to £15.7 million
- Selling, marketing and distribution has increased by £0.5 million to £1.0 million
- Research and development expenses have increased by £5.1 million to £30.3 million
- Administration expenses have decreased by £6.9 million to £5.9 million
- Share based payment charge of £1.2 million has been disclosed separately

As a result of the above changes operating loss has decreased £0.5 million to £15.2 million. In addition the following changes have been made:

- Finance income has decreased by £2.8 million to £1.6 million
- Foreign exchange gain on net debt of £2.3 million has been disclosed separately.

# 2 Segment information

# Revenue by income stream:

	Year ended	Year ended
	31 December 2008	31 December 2007
	£m	£m
Continuing operations	62.2	41.6
Discontinued operations	-	0.8
Total revenue from continuing and discontinued operations	62.2	42.4
Revenue earned is analysed as follows:		
Signing and milestone payments	12.4	10.4
Contract research and development costs recharged	8.0	3.2
Royalties	22.4	17.8
Manufacturing and distribution	19.4	10.2
Continuing operations	62.2	41.6
Discontinued operations	-	0.8
Total revenue from continuing and discontinued operations	62.2	42.4

# Secondary reporting format - geographic

# Revenue by location of customer:

	Year ended	Year ended	
	31 December 2008	31 December 2007	
	£m	£m	
UK	9.0	11.3	
Rest of Europe	27.1	17.9	
North America	20.4	11.4	
Rest of World	5.7	1.0	
Continuing operations	62.2	41.6	
Discontinued operations	-	0.8	
Total revenue from continuing and discontinued operations	62.2	42.4	

# 3 Cost of sales

	Year ended	(restated) Year ended
	31 December 2008	31 December 2007
	£m	£m
Manufacturing and distribution	19.0	14.8
Other cost of sales	0.6	0.9
Total cost of sales	19.6	15.7

# 4 Research & development

	Year ended	(restated) Year ended
	31 December 2008	31 December 2007
	£m	£m
Clinical trials, supplies and other external costs directly recharged to development partners	3.3	1.9
Other external clinical trial and supply costs	7.0	15.8
Other research and development costs	14.8	12.6
Total research and development	25.1	30.3

### 5 Exceptional items

	Year ended	Year ended
	31 December 2008	31 December 2007
Continuing operations	£m	£m
Goodwill impairment	19.5	-
Impairment of assets associated with Foradil® Certihaler™	5.9	-
Aborted transaction costs	1.5	-
Impairment of non-current assets classified as held for sale	0.8	
Other restructuring charges	0.8	-
Total exceptional items	28.5	-

The goodwill impairment charge of £19.5 million relates to the IDD® goodwill as explained in Note 8: Goodwill. The charge has arisen due to lower expectations for future sales of Triglide® as a result of the effects of competition in the second half of 2008 and the overall economic environment making it less likely that other potential applications for that technology will result in the development of viable products in the foreseeable future.

Of the £5.9 million impairment charge associated with the termination of Foradil® Certihaler™, £4.5 million is to write down the associated property, plant and equipment, £0.9 million to write down the related intellectual property and a £0.5 million provision for additional restructuring costs relating to the termination. A claim for compensation for the wind-down period has been made as disclosed in Note 13: Contingencies.

Aborted transaction costs of £1.5 million incurred in 2008 comprise legal, taxation, accounting and other professional costs relating to work on the aborted refinancing transaction.

The charge of £0.8 million for the impairment of non-current assets classified as held for sale is the write-down of the assets to their net realisable value as detailed in Note 10.

The remaining £0.8 million are charges for other restructuring provisions.

# 6 Finance costs, income and foreign exchange gains on net debt

Υ	Year ended	Year ended
31	December	31 December 2007
	2008	

Continuing operations	£m	£m
Interest and similar expense:		_
Interest:		
Bank borrowings	(0.4)	(0.4)
Paul Capital finance	(2.7)	(2.6)
CRC finance	(4.5)	(3.1)
Convertible bonds	(6.5)	(6.3)
Total interest expense	(14.1)	(12.4)
Loss on revaluation of liabilities due to Paul Capital and CRC	(3.0)	-
Total finance costs	(17.1)	(12.4)

The non-recurring charges of £3.0 million represent the costs of providing for the net present value of future prepayments expected to be made to Paul Capital and future make whole payments expected to be made to CRC on receipt of future Flutiform™ milestones as disclosed in full in Note 11: Borrowings.

	Year ended	(restated) Year ended
	31 December 2008	31 December 2007
Continuing operations	£m	£m
Finance income:		
Interest income	0.9	1.6
Total finance income	0.9	1.6
Foreign exchange gain on net debt:		
Gain on Paul Capital finance	1.6	1.7
Gain on CRC finance	3.7	1.1
Gain/(loss) on foreign denominated cash balances	0.4	(0.5)
Total foreign exchange gain on net debt	5.7	2.3

# 7 Earnings per share

Earnings per share is calculated based on the following information

		(restated)
	Year ended	Year ended
	31 December 2008	31 December 2007
Continuing operations	£m	£m
Attributable loss before exceptional items	(0.2)	(24.0)
Exceptional items	(28.5)	` -
Basic and diluted attributable loss	(28.7)	(24.0)
Continuing and discontinued operations Attributable loss before exceptional items	(0.2)	(28.4)
Exceptional items	(28.5)	1.4
Basic and diluted attributable loss	(28.7)	(27.0)
	Number	(restated) Number
	m	m
Basic and diluted weighted average number of shares in issue	11.6	8.6

### **Continuing operations**

Loss per Ordinary Share before exceptional items	(1.7)p	(279.1)p
Exceptional items	(245.7)p	-
Basic and diluted loss per Ordinary Share	(247.4)p	(279.1)p
Continuing and discontinued operations		
Continuing and discontinued operations  Loss per Ordinary Share before exceptional items	(1.7)p	(330.2)p
	(1.7)p (245.7)p	(330.2)p 16.2p

For 2007 the number of shares for the calculation of EPS has been restated to reflect the capital reconstruction which took place in September 2008. See Note 12: Share Capital.

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.

Shares held by the SkyePharma PLC General Employee Benefit Trust (2008: 86,990; 2007 (restated): 25,452), deferred 'B' Shares and deferred 'C' shares have been excluded from the weighted average number of shares.

# 8 Goodwill

	Total
Group	£m
Cost	
At 1 January 2007	33.7
At 1 January 2008 and 31 December 2008	33.7
Accumulated amortisation	
At 1 January 2007	4.5
Impairment	1.9
At 1 January 2008	6.4
Impairment	19.5
At 31 December 2008	25.9
Net book value	
At 31 December 2007	27.3
At 31 December 2008	7.8

Goodwill is not amortised but is tested annually for impairment or more frequently if there are indications that goodwill might be impaired. Fair value, less costs to sell, and 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 projections, using partner information where available
- Discount rates The discount rate is calculated using the Capital Asset Pricing Model, giving a rate of 15 per cent. This rate is adjusted to reflect the specific risk associated with the related product. Approved products discount rates may be reduced below 15

per cent..

- Cash Flow projections Cash flow projections are usually for 10 years (or to the expiry of the patent if shorter). 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 2008 and 2007.

Goodwill at 31 December 2008 and 31 December 2007 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:

	As at 31 December 2008	As at 31 December 2007
Goodwill	£m	£m
Beginning of the year	27.3	29.2
Impairment	(19.5)	(1.9)
End of the year	7.8	27.3

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 covering a period of 10 years. The pre-tax discount rate used is 12% (2007: 12%) for approved products, which is the Group's average pre-tax discount rate derived from a capital asset pricing model adjusted to reflect specific risk. The business plans are based on management projections, using partner information where available. Based on these assumptions, the recoverable amount has been calculated as £7.8 million.

The impairment charge of £19.5 million has arisen due to lower expectations for future sales of Triglide® as a result of the effects of competition in the second half of 2008 and the overall economic environment making it less likely that other potential applications for that technology will result in the development of viable products in the foreseeable future. The 2008 impairment charge is included within exceptional items in the income statement due to the magnitude of the impairment, as disclosed in Note 5: Exceptional items.

At 31 December 2007, the Group incurred an impairment charge of £1.9 million relating to the IDD® technology goodwill.

Unless products under development 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% the recoverable amount would reduce to £4.8 million, resulting in a further impairment charge of £3.0 million.

# 9 Cash and cash equivalents

	Group As at 31 December 2008	Group As at 31 December 2007
	£m	£m
Cash at bank and in hand	30.7	31.9
Short term deposits	5.0	-
	35.7	31.9

# 10 Non current assets classified as held for sale

The Group is currently in discussions, and is currently reviewing draft terms, with a view to transferring the responsibility and most of the risks and rewards of the Flutiform $^{\text{TM}}$  supply chain to a third party.

As at 31 December 2008 the Group had capitalised assets held at their net realisable value of £3.9 million related to the supply chain. The £3.9 million includes £0.8 million for foreign exchange losses expected to be incurred on the sale, and other associated selling costs.

The charge for the reduction is included within exceptional items in the Income Statement.

# 11 Borrowings

	Group As at	Group As at
	31 December 2008	31 December 2007
	£m	£m
Current		
Bank overdraft & borrowings	1.4	1.0
Property mortgage	0.4	0.3
Paul Capital finance	7.4	5.4
CRC finance	3.5	0.1
Finance lease liabilities	0.1	-
Total current borrowings	12.8	6.8
Non-current		
Convertible bonds due May 2024	50.5	51.7
Convertible bonds due June 2025	12.2	13.0
Convertible bonds	62.7	64.7
Property mortgage	8.6	6.1
Paul Capital finance	21.2	15.6
CRC finance	46.0	36.1
Finance lease liabilities	0.2	0.1
Other non-current borrowings	76.0	57.9
Total non-current borrowings	138.7	122.6
Total borrowings	151.5	129.4

# Bank overdraft and borrowings

At 31 December 2008 bank borrowings include an overdraft of £0.2 million (CHF 0.3 million) (2007: £0.2 million) and loan due of £1.2 million (CHF 2.0 million) (2007: £0.8 million) with the

Basellandschaftliche Kantonalbank. This loan can be terminated on six weeks' notice by either party and bears interest at 6.5 per cent. per annum. Both amounts are secured on the assets of Skyepharma AG.

#### Convertible bonds

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

The conversion price for the £69.6 million 6% 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) being equivalent to 3.71 pence per share prior to the share consolidation 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% 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) being equivalent to 3.82 pence per share prior to the share consolidation 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 terms of the bonds represents a modification to the existing liability, and has been 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 (2008: £62.7 million, 2007: £64.7 million) and partly in share premium (2008 and 2007: £28.5 million). The total face value of the convertible bonds is £89.6 million.

# **Property mortgages**

At 31 December 2008, the Group had two property mortgage facilities with the Basellandschaftliche Kantonalbank totalling £9.0 million (CHF 13.7 million) (2007: £6.4 million (CHF 14.4 million)). The mortgage is in two tranches, both secured by the assets of SkyePharma AG. Both bear interest at 3.875 per cent. per annum and are fully repayable in February 2011.

# **Paul Capital finance**

The Group entered into two transactions with Paul Capital Royalty Fund, L.P. ("Paul Capital"), formerly known as Paul Capital Royalty Acquisition Fund, L.P., in 2000 and 2002. Under these transactions Paul Capital provided a total of U.S.\$60 million in return for the sale of a portion of the potential future royalty and revenue streams on Solaraze®, Xatral® OD, Triglide®, Pulmicort® HFA-MDI, Foradil® Certihaler™ and Paxil CR™ and certain other minor or early stage products ("Products"). On the sale of the Injectable Business in March 2007, the Paul Capital debt was restructured as described below.

On 23 March 2007, SkyePharma PLC and its subsidiary, Jagotec AG entered into a Private Note Purchase and Exchange of Interests Agreement (the "Note Purchase Agreement") with Royalty Securitization Group I, a Delaware statutory trust and subsidiary of Paul Capital ("RST"), and, with respect to certain sections therein, Paul Capital, pursuant to which each of Paul Capital and RST assigned its interests in the royalty and revenue streams described in the preceding paragraph in respect of the Products in exchange for a fixed amortisable senior note (the "Note") in the amount U.S.\$105.0 million (£52.5million) issued by Jagotec to RST. Under the terms of Note Purchase Agreement, minimum amortization payments are U.S.\$92.5 million (£46.3 million) and these payments are increased by U.S.\$12.5 million (£6.3 million) beginning

on 31 March 2011 if worldwide sales of DepoDur<sup>™</sup> 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 2008 is U.S.\$83.6 million (£57.7 million) (2007: U.S.\$94.3 million (£47.2 million)).

The Note must be prepaid in certain circumstances, including 50% of any milestone payments for any Flutiform<sup>™</sup> license agreements or 50% of any signing fees with respect to Flutiform<sup>™</sup> license agreements entered into with regard to any unlicensed territory, in each case received after 1 January 2009 (or on FDA approval if earlier), in an amount up to U.S.\$10.0 million. Jagotec AG must also prepay the Note in an amount equal to 50% of the proceeds received upon the disposal of any of the intellectual property related to the Products. The Injectable Business was sold on the basis that it retains its obligations to RST 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 U.S. Dollar LIBOR plus 75 basis points.

The Note Purchase Agreement contains 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 RST for certain transactions that could affect RST's security and risk. The Note is secured by milestone payments and royalty receipts receivable by Jagotec AG under license agreements related to the Products. SkyePharma PLC has guaranteed all of the obligations of Jagotec AG under the Note Purchase Agreement pursuant to a guarantee, dated 23 March 2007, by SkyePharma PLC to the noteholders of the Note (as defined in the Note Purchase Agreement).

In connection with the Note Purchase Agreement, Jagotec AG granted RST 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 certain other circumstances, pursuant to a License Agreement dated as of 23 March 2007.

The restructuring of the Paul Capital debt was on substantially different terms from those applying to the previous royalty sharing arrangement and therefore was treated as a new financial liability arising in 2007 on extinguishment of an original financial liability. The new liability was initially recorded at fair value, calculated by discounting the expected cash flows based on management's estimation of a fair market rate. 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 per cent. per annum (the effective comparable interest rate at inception).

In 2008, following the filing of the Flutiform<sup>TM</sup> NDA the prepayments forecast to be due on receipt of the Flutiform<sup>TM</sup> milestones have been included in the amortised cost calculation. Previously they were not included as the NDA had not been filed. The prepayment reduces future liabilities in accordance with an agreed schedule. As such these prepayments have no effect on the cash flows, but will affect the timing of the payments and, due to the acceleration of payments results in an increase in the current valuation (at amortised cost). The increase in the carrying value is U.S\$3.6million (£2.2 million). This amount has been recorded in Note 6: Finance costs, income and foreign exchange gains on net debt.

At 31 December 2008, the carrying value of the Note was £28.6 million (2007: £21.0 million).

#### **CRC Loan**

On 22 December 2006 SkyePharma PLC, SkyePharma AG, Jagotec AG, SkyePharma Holding AG, SkyePharma Production SAS, Jago Holding AG and SkyePharma Management AG entered into a facility agreement and associated documentation with a specialist lending entity, domiciled in Ireland ("CRC"), advised by Christofferson, Robb & Company LLC, for a 10 year secured amortising loan facility.

The transaction included the following elements:

- (i) initial commitments of U.S.\$35.0 million and €26.5 million are repayable over 10 years based on a minimum amortisation schedule. Such schedule was based on expected receipts from milestones and royalties in respect of Coruno®, Lodotra<sup>TM</sup> and Requip® Once-a-day; In the event that the cumulative milestones and royalties from these products exceed the minimum principal and interest payments, the excess will be applied to repay principal early without penalty;
- (ii) interest was charged on a quarterly basis at the respective three month U.S. Dollar LIBOR and EURIBOR rates plus a 5.85 per cent. margin;
- (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 an assignment (once certain consents are obtained) of receivables in respect of Coruno®, Lodotra<sup>™</sup> and Requip® Once-a-day. Flutiform™ is not directly included in the security package;
- (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; and
- (v) provision for the facility to be increased by a further \$15.0 million subject to due diligence and progress with a specific product development.

The facility agreement was amended on 23 March 2007 to include the following additional elements:

- (i) the interest rate on the first €7.5 million of the Euro facility was increased to three month EURIBOR plus 10.85%;
- (ii) charges over receivables in respect of Coruno®, Lodotra<sup>TM</sup> and Requip® Once-a-day until assignments over these receivable were implemented;
- (iii) an assignment or charge over receivables in respect of Sular® and ZYFLO CR®;
- (iv) charges over bank accounts into which receivables of Coruno®, Lodotra<sup>TM</sup>, Requip® Onceaday, Sular® and ZYFLO CR® are paid;
- (v) the loan must be prepaid in certain circumstances, including 50% of any milestone payments for any Flutiform<sup>TM</sup> license agreements or 50% of any signing fees with respect to Flutiform<sup>TM</sup> license agreements entered into with regard to any unlicensed territory, in each case received after 1 January 2009 (or on FDA approval if earlier), in an amount up to \$10.0 million. Any such repayment would be part principal and part a make-whole amount based on a pre-agreed calculation designed to compensate for loss of future margin;
- (vi) a number of additional covenants and consents that are in line with the Paul Capital refinancing;
- (vii) 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 Coruno®, Lodotra<sup>TM</sup> and Requip®, which becomes operable following an event of default and certain other circumstances.

The Directors believe that these changes did not substantially modify the liability.

Half of the committed principal on each loan was drawn down in January 2007 and a further U.S.\$11.5 million and €9.0 million was drawn down in March 2007. The balance of approximately £6.5 million was drawn down in December 2007.

In 2008 following the filing of the Flutiform™ NDA the prepayments forecast to be due on receipt of the Flutiform™ milestones have been included in the amortised cost calculation. The prepayment is to be split into part principal and part make whole to compensate for the loss of future interest. The make whole amount is specified as a percentage (which reduces over time) in the agreement. As such, the carrying value (at amortised cost) will increase to reflect the make whole cost. The increase in the carrying value of U.S.\$1.3 million (£0.8 million) has been recorded in Note 6: Finance costs, income and foreign exchange gains on net debt.

The balance as at 31 December 2008 is £49.5 million (net of £1.0 million of costs) (2007: £36.2 million net of £0.9 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 2008 £0.3 million (2007: £0.1 million) is guaranteed by SkyePharma PLC.

# 12 Share capital

### Company

The Company's authorised share capital is as follows:

	Authorise	d Shares
Ordinary Shares	31 December 2008 £m	31 December 2007 £m
140,000,000 Ordinary Shares of £1.00 each (2007: 1,188,000,000 shares of 10p each)	140	118.8
Deferred 'B' Shares		
12,000,000 Deferred 'B' shares of 10p each (2007: 12,000,000 shares of 10p each)	1.2	1.2
Deferred 'C' Shares		
7,334,899,200 Deferred 'C' shares of 1p each (2007: Nil)	73.3	-

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

	Ordinary S	hares Deferred 'B		Deferred 'B' shares Deferred 'C' s		Deferred 'B' shares Deferred 'C' shares		shares
Issued and fully paid	Number	Nominal value £m	Number	Nominal value £m	Number	Nominal value £m		
At 1 January 2007	753,764,146	75.4	12,000,000	1.2	-	-		

Share Placing	61,224,490	6.1	-	-	-	-
At 1 January 2008	814,988,636	81.5	12,000,000	1.2	-	-
Share Split	814,988,636	8.2	-	-	7,334,899,200	73.3
Share consolidation	8,149,888	8.2	-	-	-	-
Shares issued	14,017,807	14.0	-	-	-	-
At 31 December 2008	22,167,695	22.2	12,000,000	1.2	7,334,899,200	73.3

# 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 1,188,000,000 Ordinary Shares of 10 pence to 140,000,000 Ordinary Shares of £1.00 each.

# Issue of shares

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.

In June 2007 the authorised share capital was increased by £8.6 million by the creation of 86 million Ordinary Shares of 10 pence (pre consolidation).

In March 2007 SkyePharma issued 61.2 million new Ordinary Shares of 10 pence (pre consolidation) raising £14.8 million net of expenses.

As disclosed in Note 14: Post balance sheet events, in February and March 2009 Ordinary Share capital was increased by 530,995 by the conversion of certain convertible bonds.

# 13 Contingencies

At 31 December 2008 the Company had provided guarantees on various bank borrowings of its subsidiaries as set out in Note 11: 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 11: Borrowings, the Injectable Business has been sold on the basis that it retains responsibility to Paul Capital for its existing obligations to make payments based on sales of DepoCyt<sup>®</sup> and DepoDur<sup>™</sup>. The Group retains responsibility for the full liability under the Paul Capital Note whether or not these payments are made.

Following the FDA advisory committee decisions, in December 2008 Novartis gave notice of its intention to terminate the collaboration, manufacturing and supply agreements for the supply of Foradil® Certihaler™ and no further production will occur from 1 January 2009. This agreement requires two years notice of termination and the Group has entered into negotiations with Novartis for compensation to agree a suitable wind-down plan during the two year notice period. The Group also gave notice of its intention to terminate its supply agreement with a sub-contractor in respect of the supply of components for the product. This agreement also requires two years' notice of termination. A preliminary assessment has been made of amounts due from Novartis and amounts payable to the sub-contractor.

Discussions are currently underway with Novartis and the sub-contractor to discuss settlement of these amounts. Due to the back-to-back nature of the agreements the directors expect that any amounts receivable agreed with Novartis will exceed any liability due to the sub-contractor. No amounts have been recorded in 2008.

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.

# 14 Post Balance Sheet Events

In February and March 2009 a total of 1,970 6% 2024 Convertible Bonds with a principal value of £2.0 million were converted into ordinary shares at a conversion price of £3.71. This resulted in the issue of 530,995 ordinary shares. These conversions will reduce interest costs by approximately £118,000 per annum and strengthen the Group's balance sheet through the reduction in debt.

In March 2009 the Group announced that the management of its French subsidiary, SkyePharma Production SAS, had entered into a consultation process with the company's works council about potentially reducing its workforce of 129 employees by approximately one-third. The proposed reduction would improve the competitiveness of the Lyon factory, and, if implemented as envisaged, is expected to save approximately €1.8 million (£1.6 million) of operating costs each year.

The NDA for Flutiform™ was filed with the United States FDA on 20 March 2009.