



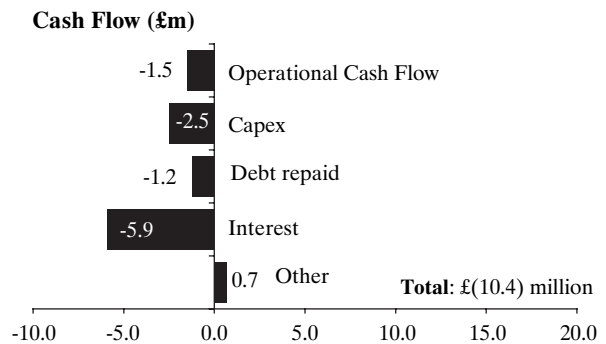
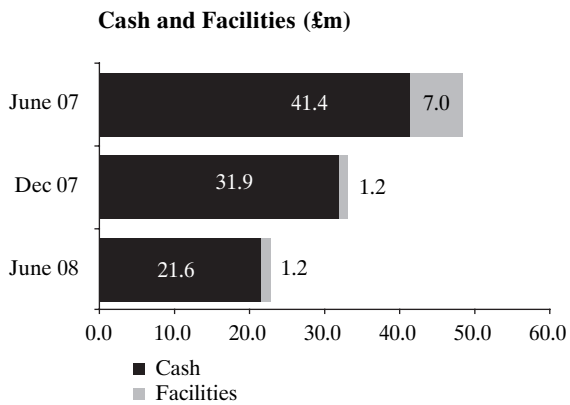
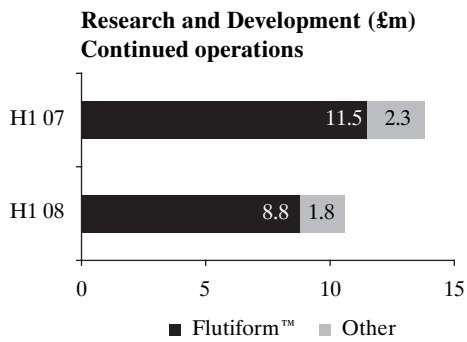
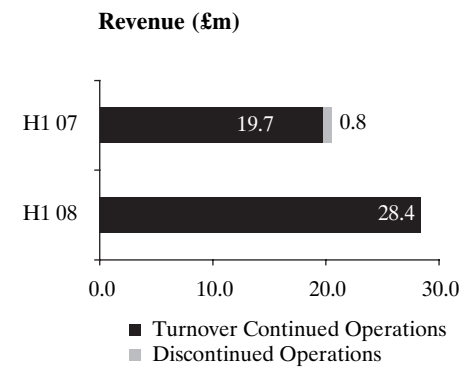
SkyePharma PLC  
Making good drugs better

Interim Report 2008  
[www.skyepharma.com](http://www.skyepharma.com)

## FINANCIAL HIGHLIGHTS

	H1: 2008	H1: 2007
	£m	£m
<b>Continuing operations</b>		
Revenue from continuing operations . . . . .	28.4	19.7
Research and development expenditure . . . . .	(10.6)	(13.8)
Operating loss from continuing operations before exceptionals . . . . .	(2.2)	(8.8)
Loss before tax from continuing operations after exceptionals . . . . .	(6.4)	(14.1)
<b>Discontinued operations</b>		
Revenue from discontinued operations . . . . .	—	0.8
Operating loss from discontinued operations (before exceptionals) . . . . .	—	(4.4)
Loss before tax from discontinued operations after exceptionals . . . . .	—	(5.4)
<b>Continuing and discontinued operations: net loss after tax . . . . .</b>	<b>(6.8)</b>	<b>(19.6)</b>
<b>Net debt and liquidity</b>		
Total debt less cash including convertible bonds* . . . . .	<b>134.0</b>	105.7
Liquidity—cash and cash equivalents plus undrawn facilities . . . . .	<b>22.8</b>	48.4

\* Total debt less cash including convertible bonds includes convertible bonds at face value.



## CHAIRMAN'S STATEMENT

Excellent progress has been made with the development of Flutiform™, the Company's lead product for the treatment of asthma. Positive top line data has now been announced for seven Phase III clinical studies for Flutiform™ across Europe and North America covering about 2,450 patients. We are also pleased that we are making good progress with proposals for renegotiating the convertible bonds which we expect to announce shortly. Once the bonds have been renegotiated, the Directors remain optimistic about the prospects for growth of the business ahead of Flutiform™ coming to market, supported by the recent approvals and launches of both the new formulation of Sular® and Requip® Once-a-day.

### Consolidated results

The Group achieved revenues of £28.4 million in the first half of 2008, 44 per cent. above the £19.7 million reported for the Continuing Operations in the first half of 2007. The increase was due to growth in royalties and manufacturing revenues from the launch of recently approved products and additional contract development revenues.

The pre-exceptional operating loss of £2.2 million was 75 per cent. lower than the operating loss for the Continuing Operations recorded in the first half of 2007. The loss was after charging £10.6 million (2007: £13.8 million) on research and development, mainly on the continuing development of Flutiform™. After net finance costs, the Group incurred a loss before tax and exceptional items of £4.0 million (2007: £14.1 million).

An exceptional charge of £2.4 million has been taken in the first half year for legal, taxation, accounting and other professional costs relating to work on the convertible bonds. Additional costs are being incurred in the second half of 2008.

The net result for the continuing business after exceptional items, net finance charges and tax was a loss of £6.8 million (2007: £14.2 million).

### Products

Selected product highlights are given below. More detailed information is provided in the Operating and Financial Review section.

#### Flutiform™

Excellent progress has been made with the development for the United States of Flutiform™, the Company's lead product for the treatment of asthma. As previously announced, the primary endpoints have been met in all of the studies in the core clinical programme, comprising a long-term safety study and three efficacy studies, covering over 1,850 patients. The additional clinical efficacy study required for the New Drug Application ("NDA") was fully recruited in July 2008. Work on the Chemistry, Manufacturing and Control ("CMC") package is well advanced. In the light of this significant progress and the nature of the outstanding steps to be completed, the Directors continue to have confidence in the likelihood of the NDA being filed in the United States in Q1 2009.

The development programme for Flutiform™ has also continued to advance in Europe, with positive results reported from three Phase III studies involving 589 patients. As previously announced Mundipharma, which is responsible for the clinical programme for regulatory approval in Europe, has been reviewing its plans for filing and marketing the product in light of discussions with regulatory authorities and advisers. The previous plan was to file for approval of the lower and middle strengths for use in adults around the end of 2008 and to follow on with a later filing for the higher strength once additional clinical studies had been concluded. Mundipharma recently informed the Company that as a result of discussions with the authorities it has decided to file for all three strengths in one application, and launch them together, rather than having a phased approach. This will have 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 date for filing of the Marketing Authorisation Application ("MAA") for European approval for all three strengths is the third quarter of 2009. The Directors believe that the medium term financial effect of an earlier launch of the higher dose, which is forecast to represent a substantial part of sales, should compensate for the effect of holding back the launch of the lower strengths.

The target remains for Flutiform™ to be launched in the United States and Europe in 2010.

In April 2008, the Group entered into an exclusive development, distribution and license agreement for Flutiform™ with Kyorin for Japan and has received an upfront milestone payment. Under the agreement signing, development and approval milestones are worth several millions of pounds 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. The Board has plans to pursue partnering the product in Latin America after the NDA has been filed with the US Food and Drug Administration (“FDA”).

### **Requip® Once-a-day**

The FDA approved Requip® Once-a-day (as Requip® XL™) 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. Requip® Once-a-day is currently approved in 23 countries in Europe and has been launched in France, Germany, UK, and a number of other European markets.

### **Sular®**

FDA approval was given in January 2008 for all four dosage strengths of the new formulation of Sular® as bioequivalents to the original formulations and the product was launched in March 2008. Sciele has discontinued shipping the original formulation of Sular®. As of 28 July 2008, more than 80 per cent. of new prescriptions were written for new Sular® according to IMS Health NPA data. SkyePharma will receive a low mid single digit percentage royalty on net sales. SkyePharma has also received a total of U.S.\$5.0 million (£2.5 million) in milestone payments, of which U.S.\$3.0 million (£1.5 million) was received prior to the end of 2007, and the United States approval in January 2008 triggered the final U.S.\$2.0 million (£1.0 million) milestone. SkyePharma is manufacturing the new formulation of Sular® at its plant in Lyon, France.

### **Lodotra™**

SkyePharma’s marketing partner for Lodotra™ Nitec Pharma AG filed an MAA for European approval in 2006 and the Directors expect Nitec to receive the first national European approvals in the second half of 2008. Following approval, Lodotra™ is expected to be launched in Germany by Merck KGaA towards the end of 2008. 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, an end of Phase II meeting with the FDA has taken place, and Nitec has started recruitment for a Phase III study required for the NDA which the Directors believe is scheduled to be filed in the second half of 2009. SkyePharma will receive a mid-single digit percentage royalty on net sales and is manufacturing the product at its plant in Lyon, France.

### **Paxil CR™**

Following a patent licence and settlement agreement with GlaxoSmithKline (“GSK”) relating to Paroxetine Hydrochloride (HCl) Extended-release (ER) Tablets, Mylan Pharmaceuticals Inc. launched a generic version of Paxil CR™ in May 2008.

### **Feasibility agreements**

Research and Development and out-licensing activities are continuing to increase the pipeline of both oral and inhalation products including developments with, and largely funded by, collaboration partners some of which, the Directors believe, could lead to significant products if successful. One such collaboration, announced in February 2008, is with Dr. Reddy’s Laboratories Limited (“Dr Reddy’s”), to complete feasibility work on a product that uses two of SkyePharma’s proprietary drug delivery technologies. The Group received a small upfront payment and Dr. Reddy’s is funding most of the development costs. An outlicensing partner continues to be sought to complete the development and market SKP-1032, a product for the relief of pain/inflammation.

### **Board**

As previously announced Frank Condella has indicated his intention to step down from his position as Chief Executive Officer once the convertible bonds have been renegotiated and Dr Ken Cunningham,

currently Chief Operating Officer, will step up to be Chief Executive Officer at that time. The Directors have agreed that this transition will take place on announcement of the proposals for renegotiating the bonds. Frank Condella will remain on the Board and will become a Non-Executive Director.

### **Financing**

As at 30 June 2008 SkyePharma had cash and cash equivalents, net of overdrafts, of £21.3 million (31 December 2007: £31.7 million) and total liquidity (cash and cash equivalents plus undrawn facilities) of £22.8 million (31 December 2007: £33.1 million). The decrease in cash and cash equivalents is primarily due to the expenditure on the continued development of Flutiform™.

The Directors have carried out a detailed appraisal of a number of potential approaches to renegotiate or refinance the bonds well before May 2009. Since the announcement of 8 July good progress has been made in discussions with a number of key bondholders and shareholders with a view to agreeing proposals for renegotiating the convertible bonds. The Directors expect to announce these proposals shortly.

### **Outlook**

Once the bond renegotiations are completed, the Directors remain optimistic about prospects for growth of the business. Over the next eighteen months, notwithstanding the effect of generic competition on the sales of Paxil CR™, the Directors expect to see further growth in revenues from sales of recently approved products, such as Requip® Once-a-day and Pulmicort® HFA-MDI in Europe and ZYFLO CR™, the new formulation of Sular®, and from Lodotra™ in Europe, once approved. The ongoing rate of expenditure on non-funded research and development is expected to reduce significantly with the completion this year of the core clinical programme and CMC package for the NDA filing of Flutiform™ in the United States and the Board expects costs to be further offset, in the medium term, through contributions from partners on collaborative development projects.

Once Flutiform™ is approved and launched in the United States and Europe, the Board believes that there will be exciting prospects for growth in both revenues and positive cashflow.

**Jeremy Scudamore**  
**Non-Executive Chairman**

## OPERATING AND FINANCIAL REVIEW

### Review of Products

#### INHALATION PRODUCTS

##### Flutiform™ HFA-MDI

Flutiform™ HFA-MDI is a fixed-dose combination of formoterol and fluticasone in a metered-dose inhaler (“MDI”). The product incorporates a fast onset long-acting beta-agonist (formoterol fumarate) with the most commonly prescribed inhaled steroid (fluticasone propionate) in combination with an environmentally-friendly aerosol propellant hydrofluoroalkane (“HFA”) and is being developed for asthma. Flutiform™ is aimed at the market for combination steroid and long-acting beta-agonist inhalers which is forecast to be approximately U.S.\$10 billion worldwide by 2010, when the Board expects Flutiform™ to be launched in both the United States and Europe. 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™ is licensed to Abbott Respiratory LLC (formerly Kos Life Sciences LLC) (“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 outlicense Flutiform™ for Canada and the Board plans to pursue partnering the product in Latin America after the NDA has been filed with the FDA.

The development currently comprises four main programmes of work:

- Core clinical programme, comprising one safety study and three Phase III clinical efficacy studies, supported by various Phase I/II studies which have been completed. The results of the three Phase III clinical efficacy studies were announced on 30 April 2008, 17 June 2008 and 3 July 2008 respectively and in all cases the results of a top line analysis of the level of improvement in FEV1 (forced expiratory volume in the first second), the primary endpoint measured, showed statistically significant differences in favour of Flutiform™ compared with both fluticasone and formoterol taken alone and, where applicable, showed a statistically significantly lower level of discontinuations due to asthma exacerbations when compared with placebo. The safety study results have been the subject of a scientific poster presented during the American Thoracic Society meeting in Toronto, Canada on 20 May 2008. The author of the poster, Dr. Ekkehard Beck, stated “Study results suggest that long term treatment with Flutiform™ 100/10µg and Flutiform™ 250/10µg will be a safe therapy for patients with persistent asthma.” This programme is the responsibility of the Group.
- Chemistry, manufacturing and control development, which is the responsibility of the Group.
- Additional studies for the United States to support the NDA comprising one clinical efficacy study and some additional Phase I work. Abbott has financial responsibility for this work and for filing the NDA.
- Additional clinical programme to support the MAA for Europe, which is being managed by Mundipharma.

In addition, the Group is currently responsible for the supply chain for Flutiform™, but is seeking to transfer the management and some of the risks and responsibilities of the supply chain to a third party.

Abbott is responsible for any additional marketing studies for the United States market and Mundipharma is responsible for marketing studies in Europe and certain other territories. Kyorin is responsible for any clinical studies and regulatory submissions for Japan. The Directors believe that further indications, such as paediatric use and higher dose in the United States, COPD and other potential applications may be developed by Abbott and/or Mundipharma.

The status of the major aspects of the current development programme is as follows:

	Description	Number of subjects*	Responsibility	Status
<b>Core clinical programme</b>				
Safety study (SKY2028-3-003)	Long-term 6/12 month safety study	472	SkyePharma	Results announced in November 2007 and presented in detail in a scientific poster presented during the American Thoracic Society meeting in Toronto, Canada in May 2008. Results demonstrated that the drug was well tolerated in the study patients.
Efficacy study (SKY2028-3-002)	Double-blind, 12 week, superiority to single actives in mild to moderate asthma	357	SkyePharma	Results announced in April 2008. Primary endpoints were met: the levels of improvement in FEV1 showed statistically significant differences in favour of Flutiform™ compared with both fluticasone and formoterol taken alone.
Efficacy study (SKY2028-3-004)	Double-blind, 12 week, placebo-controlled, superiority to single actives, placebo in moderate to severe asthma sufferers	557	SkyePharma	Results announced on 17 June 2008. Primary endpoints were met: the levels of improvement in FEV1 showed statistically significant differences in favour of Flutiform™ compared with both fluticasone and formoterol taken alone and showed a statistically significantly lower level of discontinuations due to asthma exacerbations when compared with placebo.

	Description	Number of subjects*	Responsibility	Status
Efficacy study (SKY2028-3-001)	Double-blind, 12 week, placebo-controlled, superiority to single actives, placebo in mild to moderate sufferers	475	SkyePharma	Results announced on 3 July 2008. Primary endpoints were met: the levels of improvement in FEV1 showed statistically significant differences in favour of Flutiform™ compared with both fluticasone and formoterol taken alone and showed a statistically significantly lower level of discontinuations due to asthma exacerbations when compared with placebo.
<b>Chemistry, manufacture and control</b>	Formulation, stability, etc.	N/A	SkyePharma	Work is at an advanced stage to support the United States and EU filings.
<b>Additional work for NDA (United States)</b>				
Efficacy study (SKY2028-3-005)	Double-blind, 12 week, superiority to single active (fluticasone)	438	Abbott	Fully recruited and study ongoing. Results expected Q4 2008.
HPA axis study (SKY2028-1-003)	Double-blind, 6 week, placebo controlled, effect of Flutiform™ (250/10 and 100/10), prednisone and placebo on the Hypothalamic-Pituitary-Adrenal Axis. With mild to moderate asthma.	171	Abbott	Fully recruited. Results expected Q4 2008
Pharmokinetic study (SKY2028-1-004)	Open-label, multiple-dose exposure study, to compare the pharmacokinetics of fluticasone and formoterol Combination (Flutiform™ 250/10) in a single inhaler (SkyePharma HFA pMDI) with the administration of fluticasone (250mg) alone in healthy male and female subjects.	36	SkyePharma	Clinical work completed



	Description	Number of subjects*	Responsibility	Status
<b>Clinical work for EMEA (EU)</b>				
Paediatric study (FLT 3502)	12 week, open label, non-inferiority to comparator (Seretide)	211	Mundipharma	Results announced on 15 April 2008. Primary endpoints were met: analysis of results showed non-inferiority to Seretide
Efficacy study (FLT 3501)	12-week, open label, non inferiority to comparator (Seretide)	182	Mundipharma	Results announced on 22 July 2008. Primary endpoints were met: analysis of results showed that there was an improvement in lung function from baseline measurement (FEV1) whilst the performance of Flutiform™ was not statistically inferior to that of Seretide
Efficacy study (FLT 3505)	12-week, open label, non inferiority, comparator to the two active components (fluticasone and formoterol) administered concurrently	196	Mundipharma	Results announced on 22 July 2008. Primary endpoints were met: analysis of results showed that Flutiform™ is not inferior compared with the concurrent administration of fluticasone and formoterol.
Higher dose strength efficacy study (FLT 3503)	8-week, double-blind, superiority to fluticasone comparator, non-inferiority to the two active components (fluticasone and formoterol) administered concurrently	Over 400	Mundipharma	Recruitment started August 2008

\* In studies for the NDA for the USA the number of subjects is the total number actually recruited or planned to be recruited. Not all subjects are expected to complete the studies. In studies for the MAA for Europe the number of subjects in completed studies is the total number of subjects which met the requirements for the per protocol analysis.

Abbott has exclusive rights to market Flutiform™, subject to FDA approval, in the United States, and a right of first negotiation for Canada. In addition to the U.S.\$25 million (£12.5 million) signing payment already received, 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 (£30 million) sales related milestones. Based on the current project plan, the milestone receivable on acceptance by the FDA of the NDA is expected to be U.S.\$2.0 million (£1.0 million) and the milestone receivable on approval is expected to be U.S.\$37.5 million (£18.8 million) or U.S.\$25.0 million (£12.5 million), depending whether approval is in the second half of 2009 or 2010. The royalty rate on sales in the United States escalates upwards from a mid teens percentage. If certain of Abbott's development costs exceed U.S.\$20.5 million the excess is recoverable out of up to 25 per cent. of any post-approval milestones and royalty payments until such time as 100 per cent. of the excess is recovered.

Mundipharma has exclusive rights to Flutiform™ in Europe and other territories outside the Americas and Japan. The licensing agreement provides for the Group to earn up to €82 million (£63.1 million) in milestones, of which €15 million (£10.1 million at that time) was paid upfront, up to €12 million (£9.5 million) is earmarked to cover specific development costs, up to €15 million (£11.9 million) is due on launch and up to €40 million (£31.6 million) is sales related. In addition, the Group is entitled to royalties as a percentage escalating upwards from 10 per cent. on net sales. As described above, clinical studies are being conducted in Europe to support regulatory approval in adults (lower and middle strengths) and paediatrics. These European clinical studies are being paid for by Mundipharma but are part reimbursable by the Group, up to a total of €12 million (£9.5 million), out of the €12 million milestone, the balance of which, now agreed at €3 million (£2.4 million), is payable to SkyePharma on the earlier of the completion of the studies or 31 December 2008. In addition development work is being carried out for Europe on a higher strength version of Flutiform™ funded by Mundipharma and partially reimbursed by the Group through reductions in royalties and sales-related milestones for a limited period of time.

As described in the Chairman's Statement Mundipharma, which is responsible for the clinical trial programme for Flutiform™ for approval in Europe, has revised its plans for filing and marketing of Flutiform™. The Directors believe this will have 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 date for filing of the MAA for European approval for all three strengths is now the third quarter of 2009.

In addition, under new EU regulations, there is a requirement to have an agreed Paediatric Investigation Plan ("PIP"). The recently formed Paediatric Committee ("PDCO") of the European Medicines Agency has reviewed the plans for Flutiform™ and, in a report, has recommended changes to the paediatric development plan. There will be further discussions with the PDCO to agree the PIP. This is likely to result in the requirement for additional work to obtain a paediatric indication in Europe and to mean that the MAA for paediatrics will be filed after the MAA for adults.

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 (as noted above) that €3 million (£2.4 million) would be paid to the Group as the agreed balance of the €12 million (£9.5 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 PDCO 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 (£2.8 million) 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 allows Mundipharma to develop at its cost and market Flutiform™ with a 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 has been 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.

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™**

Foradil® Certihaler™ is the multi-dose dry powder inhaler version of Novartis's long-acting beta-2-agonist Foradil® (formoterol fumarate). Foradil® Certihaler™ is approved in 30 countries and the modified inhaler was approved by the FDA in December 2006. Work continues on seeking a marketing and distribution partner for the approved Foradil® Certihaler™ in the United States, which is estimated to be concluded around the end of 2008. Other avenues for potential applications for the SkyeHaler™ device are also being explored.

## **ORAL AND TOPICAL PRODUCTS**

### **Paxil CR™**

Paxil CR™ is an improved formulation of the anti-depressant Paxil® and was developed by SkyePharma with GSK using SkyePharma's Geomatrix™ technology. Sales of Paxil CR™ in the first half of 2008 were £52 million, down by 33 per cent. (using constant exchange rates) compared with the first half of 2007. The majority of these sales (£42 million) were in the United States. The royalty rate on sales in the United States is 5 per cent. on net sales until significant generic competition enters the market, when it will reduce to a low single digit percentage.

As described in the Chairman's Statement Mylan Pharmaceuticals Inc. ("Mylan") launched a generic version of Paxil CR™ in May 2008. Of the three strengths launched, the Directors believe that the 37.5mg strength will be manufactured by GSK using the Company's Geomatrix™ technology and, therefore, GSK's sales to Mylan will give rise to royalty payments to the Company.

### **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 the first half of 2008, reported sales of all forms of Xatral® were €168.0 million (£130.0 million), up 6.3 per cent. (using constant exchange rates) compared with the first half of 2007. European sales have been affected by generic competition after the expiry of European patents starting in May 2006, with sales for the first half of 2008 reported as €81.0 million (£62.7 million), down 4.7 per cent. compared with the first half of 2007. This decline was offset by strong growth in the United States, where sales of Uroxatral® were €54 million (£41.8 million), up 14.9 per cent. compared with the first half of 2007. Sales in other countries were also up 26.9 per cent. to €33.0 million (£25.5 million). The term of the United States patent for the treatment of dysuria has been successfully extended to January 2011 (Geomatrix™ patent reaching to August 2017). A number of companies have filed abbreviated New Drug Applications with the FDA seeking approval to market a generic version of Uroxatral® in the United States. Sanofi-aventis has commenced patent infringement actions in response to several of these certifications. SkyePharma earns low single digit royalties on net sales of Xatral® OD (Uroxatral®).

### **Solaraze®**

Solaraze® (diclofenac) is marketed in the United States by Nycomed. Nycomed acquired Bradley, the Company's previous licensee for the United States, in February 2008. Sales in the first half of 2008 were approximately U.S.\$17 million (£8.7 million), up by approximately 19 per cent. on the first half of 2007. The Directors believe that Nycomed will leverage the combined sales and marketing capabilities to enhance both the Bradley and Nycomed product lines with responsibilities for marketing and distribution now successfully transferred to Nycomed. SkyePharma's low teens royalty rate on net sales was unaffected by the acquisition. Sales in the first half of 2008 in Europe and certain other territories by Shire were €6.1 million (£4.7 million) compared with the €5.1 million (£3.5 million) reported in the first half of 2007. In October 2007, it was announced that the distribution and marketing rights for Solaraze® were being divested by Shire to Almirall together with a portfolio of other products. This transaction has now been consummated and responsibilities for marketing and distribution are being transferred to Almirall. 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 in respect of which the Group has received a small consent fee.

### **Triglide®**

Triglide® (fenofibrate), an oral treatment for elevated blood lipid disorders, is marketed in the United States by Sciele 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. Triglide® total prescriptions in the first half of 2008 increased approximately 8 per cent. compared with the first half of 2007. At the end of the first half of 2008, Triglide® had a 1.73 per cent. market share of new prescriptions of the fibrate market and a 1.66 per cent. share of total prescriptions of the fibrate market, according to IMS Health NPA data. 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 permitting it to launch Fenoglide™ a few months earlier than the Triglide® licence agreement otherwise allowed, SkyePharma ceased making further marketing contributions in respect of Triglide® to Sciele, which has 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, or 1 per cent. once SkyePharma manufactures Fenoglide™ at its plant in Lyon, France, which the Directors believe could happen in 2010.

### **Requip® Once-a-day**

Requip® (ropinirole) is a once daily formulation for Parkinson's disease which was developed in partnership with GSK. The new Requip® once daily formulation 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 Requip® once daily formulation offers physicians and patients a simpler titration schedule compared with the recommended titration schedule for immediate-release Requip®, which is dosed three times a day. Requip® Once-a-day is currently approved in 23 countries in Europe and has been launched in France, Germany, UK and a number of other European markets.

The FDA approved Requip® Once-a-day (as Requip® XL™) 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.

SkyePharma earns low mid single digit percentage royalties on net sales of Requip® Once-a-day. GSK's worldwide sales of Requip®, the immediate release form for Parkinson's disease and restless leg syndrome, in the first half of 2008 were £152 million, down by 12 per cent. (using constant exchange rates) compared with the first half of 2007. Parkinson's disease makes up about 40 per cent. of current Requip® immediate release product sales in the United States.

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

The Group has developed an extended release formulation of the oral asthma drug zileuton for 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. Critical 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.

Net product sales of ZYFLO CR® and ZYFLO® were approximately U.S.\$7.2 million in the first half of 2008, up approximately 39 per cent. compared with net sales of ZYFLO® in the first half of 2007. Total prescriptions for ZYFLO CR® and ZYFLO® were up 66 per cent. compared with the total prescriptions for ZYFLO® in the first half of 2007.

Critical Therapeutics has advised that a number of batches of ZYFLO CR® tablets cannot be released into the commercial supply chain because they did not meet the product release specifications. The cause is being investigated by Critical Therapeutics in conjunction with its three manufacturing partners which supply the zileuton active pharmaceutical ingredient, tablet cores and coating and release. As the manufacturer of the tablet cores in semi-finished bulk form, SkyePharma is assisting with this investigation although the relevant batches passed pre-release tests in its Lyon factory. In the meantime Critical Therapeutics is meeting the demand from wholesale distributors out of existing stocks and additional production as necessary. On 1 May 2008, Critical Therapeutics and Cornerstone BioPharma Holdings, Inc., a privately-held company, announced the signing of a definitive merger agreement. Cornerstone is a specialty pharmaceutical company focused on developing and commercializing

prescription medications for respiratory disorders. According to the announcement, the stock-for-stock transaction is targeted to close in the fourth quarter of 2008.

As part of Critical Therapeutics' continued focus on conserving cash, including reduced spending on development programs and personnel, Critical Therapeutics reduced its workforce by 21 employees, or approximately 28 per cent. during the second quarter of 2008. The Directors believe that Critical Therapeutics will continue to promote ZYFLO CR™ notwithstanding these changes.

### **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. Sciele has discontinued shipping the old formulation of Sular®. As of 28 July 2008, more than 80 per cent. of new prescriptions were written for new Sular® according to IMS Health NPA data. In the second quarter of 2008 new prescriptions for new and old formulations of Sular increased 4 per cent. compared with the second quarter of 2007, but total prescriptions for both formulations decreased by 7 per cent. On 25 July 2008 the FDA approved a generic version of the old formulation of Sular®, for the 20mg, 30mg and 40mg doses. A generic version of the old formulation of Sular® in the 10mg dose has not been approved by the FDA. SkyePharma will receive a low mid single digit percentage royalty on net sales. SkyePharma has also received a total of U.S.\$5.0 million (£2.5 million) in milestone payments, of which U.S.\$3.0 million (£1.5 million) was received prior to the end of 2007, and the United States approval in January 2008 triggered the final U.S.\$2.0 million (£1.0 million) milestone. SkyePharma is manufacturing the new formulation of Sular® at its plant in Lyon, France.

### **Lodotra™**

Lodotra™, developed together with Nitec, is a novel single-pulse 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. Nitec filed an MAA for European approval in 2006 and the Directors expect Nitec to receive the first national European approvals in the second half of 2008. Following approval Lodotra™ is expected to be launched in Germany by Merck KGaA towards the end of 2008. 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, an end of Phase II meeting with the FDA has taken place, and Nitec has started recruitment for a Phase III study required for the NDA which the Directors believe is scheduled to be filed in the second half of 2009. SkyePharma will receive a mid single digit percentage royalty on net sales and is manufacturing the product at its plant in Lyon, France.

### **SKP-1041**

On 26 June 2007, SkyePharma announced that it had entered into an exclusive agreement with Somnus for the worldwide development and commercialisation of SKP-1041. SKP-1041 is a new controlled release formulation of a non-benzodiazepine chemical utilising SkyePharma's Geoclock™ technology. As part of the agreement, SkyePharma will formulate and manufacture SKP-1041 while Somnus will be responsible for the majority of the development and clinical study costs. Under the agreement, SkyePharma could receive up to U.S.\$35 million (£17.5 million) in milestone payments, of which U.S.\$4 million (£2.0 million) was received on signature, up to U.S.\$11 million (£5.5 million) is payable during the development phase, mainly on product approval, and U.S.\$20 million (£10 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.

### **OTHER PROJECTS**

In addition to the development projects described above, the Company is also working on a number of early stage and internal development projects.



## **Share of sales from Pacira**

In March 2007, the Company sold its injectable business to Blue Acquisition Corp (now Pacira Inc). The terms of the sale included up to U.S.\$62 million (£31.1 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 (£31.1 million) depend on the completion of Phase III studies and the achievement of certain launch and various substantial sales targets of DepoBupivacaine™. 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™ and, subject to a cap of 20 per cent. of the relevant royalty income, 3 per cent. of net sales worldwide of certain Biologics products. These payments continue to be due, for each relevant country, for as long as the relevant products remain subject to patent protection in that country, but may terminate earlier if, after five years from the date of Disposal, the Continuing Group commences development, manufacturing, marketing or sale of certain competing categories of products. DepoBupivacaine™ is currently in Phase II and Phase III clinical development for a number of indications with Pacira Inc.

## **MANUFACTURING**

Manufacturing operations in Europe take place at the Company's Lyon facility in France and Muttenz facility in Switzerland. The Company 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 Company manufactures one other oral product, Triglide®, based on its solubilisation technology, at its Lyon facility. The Company produces bio-batches for its internal development products and its collaborative partners in both facilities.

The FDA has inspected the Lyon facility in respect of a number of oral products and all these inspections have been passed.

The Lyon facility also has the filling line for dry powder inhaler products which was set up pursuant to a development contract with Novartis. The FDA approved the facility for the commercial filling of the Foradil® Certihaler™ in 2005. As the product is not currently being actively marketed, apart from production runs to maintain regulatory compliance, dry powder inhaler production activities are currently suspended pending the re-licensing and re-launch of Foradil® Certihaler™ or alternative uses of the SkyeHaler™ device.

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.

The Lyon facility currently has capacity to take on additional production on a sub-contract basis, and is in discussions on one such opportunity which could provide additional contribution to overheads.

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, UK. The Group is responsible for supplying the various components and ingredients to sanofi-aventis and is sourcing these from various suppliers located in Europe. Whilst the volumes of Flutiform™ are expected to be significant, the mark-up on these supplies is modest. The Group is seeking to transfer the management and some of the risks and responsibilities of the Flutiform™ supply chain to a third party.

## **FINANCIAL REVIEW**

### **Continuing Business and Discontinued Operations**

The Injectable Business, which was sold on 23 March 2007, is included as Discontinued Operations in line with 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 business. Except where otherwise stated, all commentary in the Chairman's Statement and the Operating and Financial review relates to the continuing business.

## Revenue

Revenues of £28.4 million for the first half of 2008 were 44 per cent. above the £19.7 million for the first half of 2007. At constant exchange rates, using 2007 rates, revenue would have been up 39 per cent. year on year.

Revenues recognised from signing and milestone payments total £5.3 million in 2008, compared with £5.9 million for the first half of 2007. In the current year, the Group has recognised a further £2.5 million (2007: £7.1 million) of the upfront payments received in 2006 relating to Flutiform™. These comprised recognition of a further £1.8 million of the upfront payment from Abbott (cumulatively £12.2 million from a total of £12.5 million (U.S.\$25.0 million)) and £0.7 million of the upfront payment from Mundipharma (cumulatively £5.4 million from a total of £10.2 million (€15 million)). A large part of the balance has been deferred to be released post-launch to offset a temporary royalty reduction being SkyePharma's contribution to Mundipharma's costs for developing the higher strength version. Also recognised is the remaining deferred upfront payment relating to a development agreement with Baxter. This agreement was terminated in 2008 triggering full recognition of the remaining £1.3 million deferred.

Contract research and development costs recharged increased £2.8 million to £3.4 million compared with £0.6 million for the first half of 2007, the increase primarily relating to costs of the extra Flutiform™ study required by the FDA being recharged to Abbott and work on the partnership development charged to Dr. Reddy's.

Royalty income was £11.6 million, an increase of £3.4 million on the £8.2 million in the first half of 2007 mainly due to launches of Pulmicort® HFA-MDI, Requip® Once-a-day and the new formulation of Sular®.

Manufacturing and distribution revenue increased by £3.1 million to £8.1 million, compared with £5.0 million in 2007. The increase mainly related to the production of the new formulation of Sular®. Manufacturing and distribution revenue includes a £2.9 million (H1 2007: £2.5 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.

## Deferred income

During the first half of 2008, there was a net increase in deferred income of £0.3 million. Deferred income decreases as income is recognised from upfront payments over the period of development of products in excess of payment received, mainly in respect of Flutiform™. This has been offset by payments received from Dr. Reddy's and Kyorin. The movement in deferred income was as follows:

	31 December 2007	Received	Recognised	30 June 2008
	£m	£m	£m	£m
Contract development and licensing income . . . .	13.0	4.6	(4.3)	13.3

## Cost of sales

Cost of sales comprises: expenditure on research and development conducted for third parties; costs of chemistry, manufacturing and control development and clinical work incurred on behalf of collaborative partners; the direct costs of contract manufacturing; direct costs of licensing arrangements; and royalties payable. Cost of sales increased to £11.3 million (H1 2007: £7.4 million), and gross profit increased 39 per cent. to £17.1 million (H1 2007: £12.3 million).

## Selling, marketing & distribution and administration expenses

Selling, marketing and distribution expenses, which mainly comprises selling expenses, decreased to £0.3 million for the first six months of 2008, compared with £0.4 million in 2007.

Amortisation and impairment of other intangibles included in Administration expenses totalled £1.2 million (2007: £0.3 million). The non-cash charge for the first half of 2008 includes a goodwill impairment loss of £1.0 million relating to the Insoluble Drug Delivery ("IDD®") technology business unit acquired in 2001. The remaining carrying value of the goodwill is £26.3 million supported by an assessment by the Directors of the prospects for sales of Triglide® during its remaining life and other potential applications of SkyePharma's insoluble drug delivery technologies. If other potential applications are not realised there may need to be a substantial impairment of the carrying value of the related goodwill.

Other administration expenses for the Continuing Operations of the Group were £7.2 million (2007: £6.6 million). Administration costs include exchange translation losses on foreign currency balances of £0.5m (H1 2007: gain of £0.3m) and a £0.4m increase due to the translation of costs into sterling. At constant exchange rates other administration expenses would have been down eight per cent. compared with the first half of 2007.

### **Research and development expenses**

Research and development expenses comprise the Group's internally funded expenditure on projects, feasibility studies and technology development.

Research and development expenses in the first half year decreased to £10.6 million (H1 2007: £13.8 million) and included £8.8 million (including attributable overheads) on developing Flutiform™ (H1 2007: £11.5 million). The Directors estimate that, as at 30 June 2008, further costs to be incurred by the Group in respect of development of Flutiform™ for the United States (not including the expenditure being incurred by Abbott) will total U.S.\$24.9 million (£12.5 million), comprising U.S.\$15.4 million (£7.7 million) of revenue expenditure (including attributable overheads) plus U.S.\$9.5 million (£4.8 million) of capital expenditure. It is expected that most of this expenditure will be incurred in the second half of 2008.

### **Results**

The operating loss before exceptional items was £2.2 million, compared with £8.8 million in the first half of 2007.

The finance costs of £6.7 million (H1 2007: £5.9 million) comprise £2.1 million (H1 2007: £1.2 million) interest payable on the CRC finance, £1.2 million (H1 2007: £1.4 million) interest attributable to the Paul Capital finance, £3.2 million (H1 2007: £3.1 million) interest payable on the convertible bonds and £0.2 million (H1 2007: £0.1 million) arising on other bank borrowings. The finance charge in respect of the renegotiated agreements with Paul Capital is substantially less than with the previous agreements due to the effective interest rate being 11.2 per cent. per annum (based on the interest rate in the comparable CRC finance agreement at inception of the new Paul Capital agreements) compared with the 24.5 per cent. to 29.8 per cent. per annum applicable to the original Paul Capital royalty sharing arrangements. Finance income before exceptional items totalled £4.9 million (H1 2007: £0.6 million) comprising interest income on cash balances of £0.6 million (H1 2007: £0.6 million) and translation gains on finance facilities, due to the relatively weak U.S. dollar, totalling £4.3 million (H1 2007: £0.1 million translation loss).

The Group's income tax expense was £0.4 million (H1 2007: £0.1 million), mainly relating to provisions for irrecoverable withholding taxes.

An exceptional charge of £2.4 million has been taken in the first half year for legal, taxation, accounting and other professional costs relating to work on the convertible bonds. Additional costs are being incurred in the second half of 2008.

The loss for the half year after exceptional items from Continuing and Discontinued Operations decreased by £12.8 million to £6.8 million, primarily due to the increase in gross profit and reduction in research & development expenses incurred.

### **Earnings per share**

The loss per share from Continuing Operations amounted to 0.8 pence (H1 2007: 1.8 pence). As at 30 June 2008, there were 814,988,636 ordinary 10 pence shares and 12,000,000 deferred 10 pence "B" shares in issue.

### **Cash flows**

In the first half of 2008 there was a cash outflow before taxation from operating activities of £1.1 million (H1 2007: £11.7 million). During the first half year the Group spent £2.5 million on property, plant and equipment, mainly relating to Flutiform™.

Borrowings of £1.2 million were repaid in the year, primarily comprising amortisation payments of the Paul Capital Note. In addition, the Group paid £6.5 million of interest in the first half of 2008, mainly relating to the convertible bonds, Paul Capital, CRC Finance and a property mortgage. Interest received on cash deposits amounted to £0.6 million.



## Balance sheet

As at 30 June 2008, the Group balance sheet showed total shareholders' equity of £70.4 million deficit (31 December 2007: £59.2 million deficit). The decrease in shareholders' equity has arisen mainly due to the £6.8 million loss and a £4.6 million net currency translation effect.

As set out in note 1(j) to the Financial Statements, the comparative figures for June 2007 have been restated to correct the accounting and related deferred tax treatment of the intra-group loan.

## Borrowings and liquidity

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

	30 June 2008	31 December 2007
	£m	£m
Convertible bonds at face value . . . . .	89.6	89.6
Paul Capital funding liabilities (included at amortised cost) . . . . .	20.0	21.0
CRC funding liabilities . . . . .	37.7	36.2
Property mortgage . . . . .	6.9	6.4
Bank borrowings . . . . .	1.0	0.8
Finance lease liabilities . . . . .	0.1	0.1
Bank overdraft . . . . .	0.3	0.2
<b>Total debt (including convertible debt at face value) . . . . .</b>	<b>155.6</b>	<b>154.3</b>
Less cash and cash equivalents . . . . .	(21.6)	(31.9)
<b>Net debt (including convertible debt at face value) . . . . .</b>	<b>134.0</b>	<b>122.4</b>

## 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 30 June 2008. The £69.6 million May 2024 bonds may be converted into ordinary shares at 95 pence per share, and may be called for repayment by the bond holders at par in May 2009, May 2011, May 2014 or May 2019. The £20.0 million June 2025 bonds may be converted into ordinary shares at 58 pence per share, and may be called for repayment by the bond holders at par in June 2010, June 2012, June 2015 or June 2020. As described in the Chairman's Statement, since the announcement of 8 July, good progress has been made in discussions with a number of key bondholders and shareholders with a view to agreeing proposals for renegotiating the convertible bonds. The Directors expect to announce these proposals shortly.

The convertible bonds are included in the balance sheet at amortised cost of £65.0 million (31 December 2007: £64.7 million).

## Other borrowings and cash

Bank and other borrowings amounted to £8.3 million at 30 June 2008 (31 December 2007: £7.5 million), consisting principally of a £6.9 million property mortgage secured on the assets of SkyePharma AG (31 December 2007: £6.4 million).

As at 30 June 2008, SkyePharma had net cash of £21.3 million, comprising cash and cash equivalents of £21.6 million net of a bank overdraft of £0.3 million, compared with £31.7 million net cash at 31 December 2007. As at 30 June 2008, the Group had total liquidity (cash and cash equivalents plus undrawn facilities) of £22.8 million (31 December 2007: £33.1 million).

## Going concern basis

The Directors have carried out a detailed appraisal of a number of potential approaches to renegotiate or refinance the bonds well before May 2009. Since the announcement of 8 July good progress has been made in discussions with a number of key bondholders and shareholders with a view to agreeing proposals for renegotiating the convertible bonds. The Directors expect to announce these proposals shortly. As a result the Board continues to have a reasonable expectation that the Group will have adequate resources to continue in operational existence for the foreseeable future and have, therefore, prepared the financial information contained herein on a going concern basis. As in respect of the auditors' report on the

financial statements for 2007 and the auditors' conclusion on the unaudited statements for the first half of 2007, the auditors' conclusion on the unaudited financial statements for 2008 includes an emphasis of matter paragraph to draw attention to the disclosures made in Note 1 to these financial statements indicating material uncertainties. The review conclusion is not qualified in this respect and the Directors believe that these risks can be managed to a successful outcome.

### **Principal Risks**

The Directors consider that the key risks which may have a material impact on the Group's performance in respect of the second six months of the financial year are as disclosed on pages 32-33 of the 2007 Annual Report and Accounts.

### **Foreign exchange**

Almost all of the Group's Continuing Operations are based in Continental Europe, and licence royalty payments are typically denominated in various currencies, with sales-related payments based on underlying sales in local currencies. This gives rise to direct and indirect exposures to changes in foreign exchange rates, notably the Swiss Franc, Euro and US Dollar. To minimise the impact of any fluctuations, the Group's policy has historically been to maintain natural hedges by relating the structure of borrowings to the underlying trading cash flows that generate them. Exchange differences relating to borrowing are included in finance income/costs, other exchange differences are included within administration expenses.

Where subsidiaries are funded by the Company and this is achieved by the use of long-term intercompany loans and 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 related exchange translation differences are taken to reserves. Use has been made of forward currency options during 2007 and 2008 to minimise the currency exposure on operational transactions.

### **Forward looking statements**

The Chairman's Statement and Operating and Financial Review contain certain forward looking statements. Although the Directors believe that the expectations reflected in these forward looking statements are reasonable, they 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 prospects for renegotiating the convertible bonds the timescales for regulatory timings for Flutiform™, the statements under "Outlook" including the timescales for the successful development, approval and launch of new products and the objective for moving into operating profit and the target for becoming profitable, the forecast sales of Flutiform™, the risks associated with 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 protection and enforcement of intellectual property, and risks related to SkyePharma's ability to manage growth. SkyePharma undertakes no obligation to revise or update any such forward looking statement to reflect events or circumstances after the date of these Financial Statements.

**Approved Products**  
as at 28 August 2008

Licensee/partner	Product name	Generic name of active	Primary indication
<b>Oral</b>			
GlaxoSmithKline	Paxil CR™	paroxetine	Depression
GlaxoSmithKline	Requip® Once-a-day	ropinirole	Parkinson's disease
Sanofi-Aventis	Xatral® OD/ Uroxatral®	alfuzosin	BPH (urinary symptoms)‡
Sciele Pharma	Triglide™	fenofibrate	Lipid disorders
Sciele Pharma	Sular® Geomatrix™	nisoldopine	Hypertension
Critical Therapeutics/ Dey L.P.	ZYFLO CR™	zileuton	Asthma
Roche	Madopar DR®	levodopa/benserazide	Parkinson's disease
Therabel	Coruno®	molsidomine	Angina
ratiopharm	diclofenac-ratiopharm® uno	diclofenac	Pain/inflammation
<b>Inhalation</b>			
AstraZeneca	Pulmicort® HFA-MDI	budesonide	Asthma
Novartis	Foradil® Certihaler™†	formoterol	Asthma
<b>Topical</b>			
Nycomed/Almirall	Solaraze®	diclofenac	Actinic keratosis

**Pre-clinical**

*In vitro* (laboratory) feasibility study to determine whether, under laboratory conditions, the formulation of the product candidate can be achieved.

**Phase I**

First stage of human clinical testing for toxicity in healthy human volunteers.

**Phase II**

Additional in vivo testing may be performed (also called pre-pivotal trials) involving a small patient population to evaluate the optimal clinical dose.

**Phase III**

Trials in an expanded patient population, typically at dispersed sites. Also called pivotal trials.

**Filed**

SkyePharma or its partners file for regulatory approval in the jurisdictions in which it is intended that the product will be marketed. For example, in the USA, this will require filing with the Food and Drug Administration and in the European community with the European Medicines Agency.

**Development pipeline**  
as at 28 August 2008

Licensee/partner	Product name	Generic name of active	Primary indication	Pre-clinical	Phase I	Phase II	Phase III	Filed
<b>Oral</b>								
Nitec	Lodotra™	prednisone	Rheumatoid arthritis	████████	████████	████████	████████	████
SkyePharma	SKP-1032	undisclosed	Pain/inflammation	████████	████████			
Somnus Therapeutics	SKP-1041	undisclosed	Sleep disorders	████████	████████			
<b>Inhalation</b>								
Abbott/Mundipharma	Flutiform™	formoterol/fluticasone	Asthma/COPD§	████████	████████	████████	████	
Kyorin	Flutiform™	formoterol/fluticasone	Asthma/COPD§	████████				
<b>Feasibility</b>								
SkyePharma	various	undisclosed	undisclosed	████████				
Dr. Reddy's	SKP-2045	undisclosed	undisclosed	████████				

‡ Benign prostatic hypertrophy

† Currently not marketed

§ Chronic obstructive pulmonary disease

## CONDENSED CONSOLIDATED INCOME STATEMENT

for the six months ended 30 June 2008

	Notes	Unaudited 6 months to 30 June 2008 £m	(Restated) Unaudited 6 months to 30 June 2007 £m	Audited 12 months to 31 December 2007 £m
Revenue . . . . .	2	28.4	19.7	41.6
Cost of sales . . . . .		(11.3)	(7.4)	(16.1)
<b>Gross profit</b> . . . . .		<b>17.1</b>	12.3	25.5
Selling, marketing and distribution expenses . . . . .		(0.3)	(0.4)	(0.5)
Administration expenses				
Amortisation of other intangibles . . . . .		(1.2)	(0.3)	(2.7)
Other administration expenses . . . . .		(7.2)	(6.6)	(12.8)
Exceptionals—continuing operations . . . . .	5	(2.4)	—	—
		<b>(10.8)</b>	(6.9)	(15.5)
Research and development expenses . . . . .		<b>(10.6)</b>	(13.8)	(25.2)
<b>Pre-exceptional operating loss</b> . . . . .		<b>(2.2)</b>	(8.8)	(15.7)
<b>Operating loss</b> . . . . .		<b>(4.6)</b>	(8.8)	(15.7)
Finance costs . . . . .	3	(6.7)	(5.9)	(12.4)
Finance income . . . . .	3	4.9	0.6	4.4
<b>Loss before income tax</b> . . . . .		<b>(6.4)</b>	(14.1)	(23.7)
Income tax expense . . . . .		(0.4)	(0.1)	(0.3)
<b>Pre-exceptional loss for the period from continuing operations</b> . . . . .		<b>(4.4)</b>	(14.2)	(24.0)
<b>Loss for the period from continuing operations</b> . . . . .		<b>(6.8)</b>	(14.2)	(24.0)
<b>Pre-exceptional loss for the period from discontinued operations</b> . . . . .		—	(4.4)	(4.4)
Exceptionals—discontinued operations . . . . .	6	—	(1.0)	1.4
<b>Loss for the period from discontinued operations</b> . . . . .		—	(5.4)	(3.0)
<b>Loss for the period from continuing and discontinued operations</b> . . . . .		<b>(6.8)</b>	(19.6)	(27.0)
<b>Basic and diluted earnings per share</b> . . . . .	4			
Continuing operations . . . . .		<b>(0.8)p</b>	(1.8)p	(3.1)p
Continuing and discontinued operations . . . . .		<b>(0.8)p</b>	(2.5)p	(3.5)p

See Notes to the Interim Financial Statements.

**CONDENSED CONSOLIDATED BALANCE SHEET**

as at 30 June 2008

	Notes	Unaudited 30 June 2008 £m	(Restated) Unaudited 30 June 2007 £m	Audited 31 December 2007 £m
<b>ASSETS</b>				
<b>Non-current assets</b>				
Goodwill . . . . .	7	26.3	29.2	27.3
Other intangible assets . . . . .		9.2	6.0	8.7
Property, plant and equipment . . . . .		28.8	23.7	26.1
Available-for-sale financial assets . . . . .		0.1	0.1	0.1
		<u>64.4</u>	<u>59.0</u>	<u>62.2</u>
<b>Current assets</b>				
Inventories . . . . .		1.0	0.5	0.9
Trade and other receivables . . . . .		14.8	10.4	11.7
Financial assets at fair value through profit or loss . . .		0.2	—	0.1
Cash and cash equivalents . . . . .		21.6	41.4	31.9
		<u>37.6</u>	<u>52.3</u>	<u>44.6</u>
<b>Total Assets . . . . .</b>		<u><b>102.0</b></u>	<u><b>111.3</b></u>	<u><b>106.8</b></u>
<b>LIABILITIES</b>				
<b>Current liabilities</b>				
Trade and other payables . . . . .		(25.7)	(20.8)	(21.4)
Other borrowings . . . . .	8	(7.9)	(6.5)	(6.8)
Deferred income . . . . .		(3.1)	(6.4)	(5.0)
		<u>(36.7)</u>	<u>(33.7)</u>	<u>(33.2)</u>
<b>Non-current liabilities</b>				
Convertible bonds . . . . .	8	(65.0)	(64.4)	(64.7)
Other borrowings . . . . .	8	(58.1)	(51.0)	(57.9)
Deferred income . . . . .		(10.2)	(8.5)	(8.0)
Provisions . . . . .		(2.4)	(1.8)	(2.2)
		<u>(135.7)</u>	<u>(125.7)</u>	<u>(132.8)</u>
<b>Total Liabilities . . . . .</b>		<u><b>(172.4)</b></u>	<u><b>(159.4)</b></u>	<u><b>(166.0)</b></u>
<b>Net liabilities . . . . .</b>		<u><b>(70.4)</b></u>	<u><b>(48.1)</b></u>	<u><b>(59.2)</b></u>
<b>SHAREHOLDERS' EQUITY</b>				
Share capital . . . . .	9	82.7	82.7	82.7
Share premium . . . . .		382.8	382.8	382.8
Translation reserve . . . . .		(8.8)	0.1	(4.1)
Fair value reserve . . . . .		(0.2)	(0.2)	(0.2)
Retained losses . . . . .		(536.3)	(522.9)	(529.8)
Other reserves . . . . .		9.4	9.4	9.4
<b>Total Shareholders' Equity . . . . .</b>		<u><b>(70.4)</b></u>	<u><b>(48.1)</b></u>	<u><b>(59.2)</b></u>

See Notes to the Interim Financial Statements.

**CONDENSED CONSOLIDATED STATEMENT OF RECOGNISED INCOME AND EXPENSE**

for the six months ended 30 June 2008

	<b>Unaudited 6 months to 30 June 2008</b>	<b>(Restated) Unaudited 6 months to 30 June 2007</b>	<b>Audited 12 months to 31 December 2007</b>
	<u>£m</u>	<u>£m</u>	<u>£m</u>
Net currency translation effect . . . . .	<b>(4.6)</b>	(2.4)	(7.4)
Actuarial gains on defined benefit plans . . . . .	<u>—</u>	<u>0.1</u>	<u>—</u>
Net losses recognised directly in equity . . . . .	<b>(4.6)</b>	(2.3)	(7.4)
Loss for the period from continuing operations . . . . .	<b>(6.8)</b>	(14.2)	(24.0)
Loss for the period from discontinued operations . . . . .	<u>—</u>	<u>(5.4)</u>	<u>(3.0)</u>
<b>Total recognised income and expense for the period . . . . .</b>	<b><u>(11.4)</u></b>	<b><u>(21.9)</u></b>	<b><u>(34.4)</u></b>

See Notes to the Interim Financial Statements.

## CONDENSED CONSOLIDATED CASH FLOW STATEMENT

for the six months ended 30 June 2008

	Note	Unaudited 6 months to 30 June 2008 £m	Restated Unaudited 6 months to 30 June 2007 £m	Audited 12 months to 31 December 2007 £m
<b>Operating activities</b>				
Cash used in operating activities . . . . .	(a)	(1.1)	(11.7)	(17.6)
Income tax paid . . . . .		(0.4)	(0.1)	(0.3)
<b>Net cash used in operating activities . . . . .</b>		<b>(1.5)</b>	<b>(11.8)</b>	<b>(17.9)</b>
<b>Investing activities</b>				
Purchases of property, plant and equipment . . . . .		(2.5)	(1.0)	(3.6)
Proceeds from disposal of available for sale investments . . . . .		—	1.2	1.2
Net proceeds from disposal of subsidiary . . . . .		—	4.6	4.6
Interest received . . . . .		0.6	1.2	1.6
<b>Net cash (used in)/generated by investing activities . . . . .</b>		<b>(1.9)</b>	<b>6.0</b>	<b>3.8</b>
<b>Financing activities</b>				
Proceeds from share issue . . . . .		—	14.8	14.8
Proceeds from loan drawdown . . . . .		—	28.5	35.8
Repayments of borrowings . . . . .		(1.2)	(2.2)	(3.5)
Interest paid . . . . .		(6.5)	(4.9)	(11.1)
<b>Net cash (used in)/generated from financing activities . . . . .</b>		<b>(7.7)</b>	<b>36.2</b>	<b>36.0</b>
<b>Effect of exchange rate changes . . . . .</b>	(b)	<b>0.7</b>	<b>0.3</b>	<b>(0.8)</b>
<b>Net (decrease)/increase in cash and cash equivalents . . . . .</b>		<b>(10.4)</b>	<b>30.7</b>	<b>21.1</b>
Net cash and cash equivalents including bank overdraft at beginning of the period . . . . .		31.7	10.6	10.6
Net (decrease)/increase in cash and cash equivalents including bank overdraft . . . . .		(10.4)	30.7	21.1
<b>Net cash and cash equivalents including bank overdraft at end of the period . . . . .</b>	(b)	<b>21.3</b>	<b>41.3</b>	<b>31.7</b>
<b>Analysis of net cash:</b>				
Cash and cash equivalents . . . . .		21.6	41.4	31.9
Bank overdraft . . . . .		(0.3)	(0.1)	(0.2)
<b>Net cash and cash equivalents . . . . .</b>		<b>21.3</b>	<b>41.3</b>	<b>31.7</b>

See Notes to the Interim Financial Statements.

**NOTES TO THE CONDENSED CONSOLIDATED CASH FLOW STATEMENT**

**(a) Cash flow from operating activities**

	<b>Unaudited 6 months to 30 June 2008</b>	<b>Restated Unaudited 6 months to 30 June 2007</b>	<b>Audited 12 months to 31 December 2007</b>
	£m	£m	£m
Loss for the period from continuing operations . . . . .	<b>(6.8)</b>	(14.2)	(24.0)
Loss for the period from discontinued operations . . . . .	—	(5.4)	(3.0)
Loss for the period from continuing and discontinued operations . . . . .	<b>(6.8)</b>	(19.6)	(27.0)
Adjustments for:			
Tax . . . . .	<b>0.4</b>	0.1	0.3
Depreciation . . . . .	<b>2.3</b>	2.2	4.4
Amortisation . . . . .	<b>0.2</b>	0.5	0.9
Impairments . . . . .	<b>1.0</b>	—	1.9
Finance costs . . . . .	<b>6.7</b>	6.7	13.2
Finance income . . . . .	<b>(4.9)</b>	(0.6)	(4.4)
(Gain)/Loss on disposal of subsidiary . . . . .	—	1.0	(1.4)
Share based payments charge . . . . .	<b>0.5</b>	0.6	1.2
Other non-cash changes . . . . .	<b>(4.0)</b>	—	(1.1)
<b>Operating cash flows before movements in working capital . . .</b>	<b>(4.6)</b>	(9.1)	(12.0)
<b>Changes in working capital</b>			
(Increase)/Decrease in inventories . . . . .	<b>(0.4)</b>	—	0.1
(Increase)/decrease in trade and other receivables . . . . .	<b>(3.1)</b>	3.5	(1.5)
Increase/(decrease) in trade and other payables . . . . .	<b>4.2</b>	(2.6)	1.2
Increase/(decrease) in deferred income . . . . .	<b>2.8</b>	(3.3)	(5.5)
(Decrease)/increase in provisions . . . . .	—	(0.2)	0.1
<b>Cash provided by/(used in) operations . . . . .</b>	<b>(1.1)</b>	(11.7)	(17.6)

(b) June 2007 comparatives have been restated to exclude bank borrowings from net cash & cash equivalents.



## Notes to the Condensed Consolidated Financial Statements

### 1 General information and Accounting policies

#### General information

The interim report of the Group for the six months ended 30 June 2008 (“Interim Report 2008”) was authorised for issue in accordance with a resolution of the directors on 27 August 2008. The Interim Report 2008 is unaudited but has been reviewed by the auditors as set out in their report.

SkyePharma PLC is a limited company incorporated and domiciled in England whose shares are publicly traded. The principal activities of the Group are described in note 2.

The financial information for the year ended 31 December 2007 does not constitute statutory financial statements within the meaning of section 240 of the Companies Act 1985. A copy of the audited financial statements for that year have been delivered to the Registrar of Companies. The auditors’ opinion on those financial statements in accordance with s235 of the Companies Act 1985 was unqualified, the report included an emphasis of matter paragraph in respect of going concern, and it contained no statement under section 237 (2) or section 237 (3) of the Companies Act 1985.

#### Accounting policies

The interim condensed consolidated financial statements for the six months ended 30 June 2008 have been prepared using accounting policies consistent with those adopted by the Group in its financial statements for the year ended 31 December 2007.

##### (a) Basis of preparation

The Interim Report for the six months ended 30 June 2008 has been prepared in accordance with the Disclosure and Transparency rules of the Financial Services Authority and with IAS 34, “*Interim financial reporting*” as adopted by the European Union. The Interim Report 2008 should be read in conjunction with the Group’s Annual Report for the year ended 31 December 2007, which has been prepared in accordance with IFRSs as adopted by the European Union.

##### *Going concern*

As set out in Note 8: Borrowings, the Group has in issue £69.6 million bonds which may be converted into Ordinary Shares at 95 pence per share, and £20.0 million bonds which may be converted into Ordinary Shares at 58 pence per share (collectively the “Bonds”). The bond holders may call for repayment at par on certain dates starting on 4 May 2009, in respect of the £69.6 million bonds and starting on 3 June 2010 in respect of the £20.0 million bonds. The Directors have carried out a detailed appraisal of a number of potential approaches to renegotiate or refinance the bonds well before May 2009. The Directors believe that good progress has been made in discussions with a number of key bondholders and shareholders with a view to agreeing proposals for renegotiating the convertible bonds. The Directors expect to announce these proposals shortly.

In finalising these proposals the Directors will have regard to the Group’s working capital requirements, including the cash required to service debt obligations, operate the Lyon facility, complete certain product development programs and establish the supply chain for Flutiform™. The renegotiation of the convertible bonds is underpinned by expectations of the support of bondholders and shareholders and the continued progress with the Group’s business, especially the development, approval and launch in the USA and Europe of Flutiform™, which the Directors expect will lead to significant net cash inflows. Although the application of drug delivery technologies to known molecules is lower risk than drug development, there can be no absolute certainty that Flutiform™ will successfully complete development and be launched. Nevertheless, the Directors have a reasonable expectation that these risks can be managed to a successful outcome.

The Directors have made an assessment of the general working capital requirements for the next twelve months and of the likelihood of finalising the proposals for renegotiating the bonds. Based on this assessment the Board has a reasonable expectation that the Group will have adequate resources to continue in operational existence for the foreseeable future and have, therefore, prepared the financial information contained herein on a going concern basis. The financial statements do not reflect any adjustments that would be required to be made if they were to be prepared on a basis other than a going concern basis.

## **1 General information and Accounting policies (Continued)**

### *Use of estimates*

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

### **(b) Consolidation**

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

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

### **(c) Segment reporting**

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

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

### **(d) Revenue recognition**

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

#### *License signing and milestone fees*

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

#### *Contract research and development costs recharged*

Contract research and development recharged represents amounts earned for services rendered under development contracts. Revenues are recognised in the period when they are earned.

#### *Royalty income*

Royalty income is recognised on an accruals basis and represents income earned as a percentage of product sales in accordance with the substance of the relevant agreement. The Group receives sales information from the licensee on a quarterly basis. For any period the information has not been received the Group will estimate sales, any adjustments needed once actual figures are received will be booked in the subsequent period.

#### *Manufacturing and distribution*

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

## **1 General information and Accounting policies (Continued)**

### **(e) Intangible assets**

#### *Goodwill*

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

#### *Intellectual property*

Intellectual property comprises acquired patents, trade marks, know-how and other similarly identified rights. These are recorded at their fair value at acquisition date and are amortised on a straight line basis over their estimated useful economic lives from the time they are available for use. The period over which the Group expects to derive economic benefits does not exceed 20 years.

#### *Research and development*

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

#### *Computer software*

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

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

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

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

### **(g) Assets held for sale and discontinued operations**

Assets classified as held for sale are measured at the lower of carrying value and fair value less costs to sell.

Non-current assets and disposal groups are classified as held for sale if their carrying amount will be recovered through a sale transaction rather than through continuing use. This condition is regarded as met only when the sale is highly probable and expected to be completed within one year from classification and the asset is available for immediate sale in its present condition.

## 1 General information and Accounting policies (Continued)

Disposal groups are classified as discontinued operations where they represent a major line of business or geographical area of operations. The income statement for the comparative period has been restated to show the discontinued operations separate from the continuing operations.

### (h) Cash and cash equivalents

Cash and cash equivalents are highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value. Cash and cash equivalents are carried in the balance sheet at cost. For the purposes of the cash flow statement, net cash and cash equivalents comprise cash at bank and in hand, short term deposits, marketable securities and overdrafts. Bank overdrafts are included within borrowings in current liabilities on the balance sheet.

### (i) Exceptional items

Exceptional items, which are presented on the face of the income statement, are those material items of income and expense which, because of the nature and expected infrequency of the events giving rise to them merit separate presentation to allow shareholders to understand better the elements of financial performance in the year, so as to facilitate comparison with prior periods and the assessment of trends in financial performance.

### (j) Prior period adjustments

During 2007 a detailed review was carried out of the accounting treatment on IFRS transition of the convertible bonds and related intra-group loans. This has identified an incorrect treatment of the intra-group loan between SkyePharma (Jersey) Limited and SkyePharma PLC which under IFRS, should have been separated into debt and equity components and recorded at fair value, but was incorrectly recognised at nominal value. The accounts of SkyePharma Jersey are being restated, including a prior year adjustment for 2005 to correct the incorrect treatment. The accounts for the Group are corrected by way of a prior year adjustment. As a consequence the comparative information for 30 June 2007 has been restated in the Interim Report 2008, as follows:

- Deferred tax liability decreased by £7.0 million as at 30 June 2007.
- Share Premium increased by £28.5 million as at 30 June 2007.
- Cumulative retained losses increased by £1.0 million as at 30 June 2007.
- Other reserves decreased by £20.5 million as at 30 June 2007.
- There is no impact on Earnings per Share for the six months ended 30 June 2007.

## 2 Segment information

The Group consists of one business segment—the development of pharmaceutical products. An analysis of revenue by income stream is shown below.

### Revenue by income stream:

	6 months to 30 June 2008	6 months to 30 June 2007	12 months to 31 December 2007
	£m	£m	£m
Revenue earned can be analysed as:			
Licence signing and milestone fees . . . . .	5.3	5.9	10.4
Contract research and development costs recharged . . . . .	3.4	0.6	3.2
Royalties . . . . .	11.6	8.2	17.8
Manufacturing and distribution . . . . .	8.1	5.0	10.2
Continuing operations . . . . .	28.4	19.7	41.6
Discontinued operations . . . . .	—	0.8	0.8
<b>Total revenue from continuing and discontinued operations . .</b>	<b>28.4</b>	<b>20.5</b>	<b>42.4</b>

### 3 Finance costs and income

	6 months to 30 June 2008	6 months to 30 June 2007	12 months to 31 December 2007
	£m	£m	£m
<b>Interest and similar expense:</b>			
Interest:			
Bank borrowings . . . . .	(0.2)	(0.1)	(0.4)
Paul Capital finance . . . . .	(1.2)	(1.4)	(2.6)
CRC finance . . . . .	(2.1)	(1.2)	(3.1)
Convertible bonds . . . . .	(3.2)	(3.1)	(6.3)
Total interest expense . . . . .	<u>(6.7)</u>	<u>(5.8)</u>	<u>(12.4)</u>
Translation difference on finance facilities . . . . .	—	(0.1)	—
<b>Total finance costs</b> . . . . .	<u><b>(6.7)</b></u>	<u><b>(5.9)</b></u>	<u><b>(12.4)</b></u>
<b>Finance income:</b>			
Interest income . . . . .	0.6	0.6	1.6
Translation difference on finance facilities . . . . .	4.3	—	2.8
<b>Total finance income</b> . . . . .	<u><b>4.9</b></u>	<u><b>0.6</b></u>	<u><b>4.4</b></u>

### 4 Earnings per share

	6 months to 30 June 2008	6 months to 30 June 2007	12 months to 31 December 2007
	£m	£m	£m
<b>Continuing operations</b>			
Attributable loss before exceptional items . . . . .	(4.4)	(14.2)	(24.0)
Exceptional items . . . . .	(2.4)	—	—
Basic and diluted attributable loss . . . . .	<u>(6.8)</u>	<u>(14.2)</u>	<u>(24.0)</u>
<b>Continuing and discontinued operations</b>			
Attributable loss before exceptional items . . . . .	(4.4)	(18.6)	(28.4)
Exceptional items . . . . .	(2.4)	(1.0)	1.4
Basic and diluted attributable loss . . . . .	<u>(6.8)</u>	<u>(19.6)</u>	<u>(27.0)</u>
	<b>Number</b>	<b>Number</b>	<b>Number</b>
	m	m	m
Basic and diluted weighted average number of shares in issue . . . . .	<u>812.8</u>	<u>779.4</u>	<u>769.8</u>
<b>Continuing operations</b>			
Loss per Ordinary Share before exceptional items . . . . .	(0.5)p	(1.8)p	(3.1)p
Exceptional items . . . . .	(0.3)p	—	—
Basic and diluted loss per Ordinary Share . . . . .	<u>(0.8)p</u>	<u>(1.8)p</u>	<u>(3.1)p</u>
<b>Continuing and discontinued operations</b>			
Loss per Ordinary Share before exceptional items . . . . .	(0.5)p	(2.4)p	(3.7)p
Exceptional items . . . . .	(0.3)p	(0.1)p	0.2p
Basic and diluted loss per Ordinary Share . . . . .	<u>(0.8)p</u>	<u>(2.5)p</u>	<u>(3.5)p</u>

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 have been excluded from the weighted average number of shares. The number of shares held by the EBT at 30 June 2008 totalled 2,174,702 (2007: 2,545,781 shares).

## 5 Exceptional items

	6 months to 30 June 2008	6 months to 30 June 2007	12 months to 31 December 2007
	£m	£m	£m
<b>Continuing operations</b>			
Bond related transaction costs . . . . .	(2.4)	—	—
<b>Total exceptional items</b> . . . . .	<u>(2.4)</u>	<u>—</u>	<u>—</u>

Bond related transaction costs incurred in 2008 comprise legal, taxation, accounting and other professional costs relating to work on the convertible bonds. Additional costs are being incurred in the second half of 2008.

## 6 Discontinued operations

The Injectable Business was sold to Blue Acquisition Corp, now called Pacira, Inc. (“Pacira”) on 23 March 2007. The Injectable business has changed its name to Pacira Pharmaceuticals Inc. The consideration for the disposal was as follows:

1. Cash payments by Pacira of US\$20 million to SkyePharma:
  - a) of US\$18 million (£9.2 million) at completion;
  - b) of US\$2 million (£1.0 million) into an escrow account; and
  - c) an adjustment to the payments above based upon the net asset value of the business at completion in relation to a specified target amount of the net asset value. Subsequently this has been agreed resulting in a reduction in purchase price of US\$0.5 million (£0.3 million), which has been paid from the escrow account.
2. Milestone payments, by Pacira to SkyePharma:
  - a) US\$10 million (£5.0 million) upon the first commercial sale in the US of DepoBupivacaine™;
  - b) US\$4 million (£2.0 million) upon the first commercial sale of DepoBupivacaine™ in a major country of the EU;
  - c) US\$8 million (£4.0 million) if worldwide annual net sales of DepoBupivacaine™ reach US\$100 million (£50 million);
  - d) a further US\$8 million (£4.0 million) if worldwide annual net sales of DepoBupivacaine™ reach US\$250 million (£125 million);
  - e) a further US\$32 million (£16.0 million) if worldwide annual net sales of DepoBupivacaine™ reach US\$500 million (£251 million).
3. Ongoing payments for the period of protection by existing patents, subject to certain conditions, to SkyePharma, of:
  - a) 3% of worldwide net sales of DepoBupivacaine™; and
  - b) 3% of worldwide net sales of Biologics (not to exceed 20% of the royalty income of Pacira).

In addition, Pacira Pharmaceuticals retains responsibility for making payments to Paul Capital related to sales of DepoCyt® and DepoDur™. This obligation was included as debt in the balance sheet of the Injectable Business.

## 6 Discontinued operations (Continued)

### (a) Results of discontinued operations

	Year to 31 December 2007		
	Pre- Exceptional	Exceptional (note 5)	Total
	£m	£m	£m
Revenue . . . . .	0.8	—	0.8
Cost of sales . . . . .	(1.5)	—	(1.5)
<b>Gross loss</b> . . . . .	<b>(0.7)</b>	—	<b>(0.7)</b>
Selling, marketing and distribution expenses . . . . .	(0.5)	—	(0.5)
Administration expenses			
Amortisation of other intangibles . . . . .	(0.1)	—	(0.1)
Other administration expenses . . . . .	(0.7)	—	(0.7)
	(0.8)	—	(0.8)
Research and development expenses . . . . .	(1.6)	—	(1.6)
Gain on disposal of subsidiary undertaking . . . . .	—	1.4	1.4
<b>Operating loss</b> . . . . .	<b>(3.6)</b>	1.4	<b>(2.2)</b>
Finance costs . . . . .	(0.8)	—	(0.8)
<b>Loss for the year from discontinued operations</b> . . . . .	<b>(4.4)</b>	1.4	<b>(3.0)</b>

The loss for the year relates to the period 1 January 2007 to 23 March 2007, being the date of disposal.

### (b) Exceptional items

	6 months to 30 June 2008	6 months to 30 June 2007	Year to 31 December 2007
	£m	£m	£m
<b>Discontinued operations</b>			
(Loss)/Gain on disposal of subsidiary undertaking . . . . .	—	(1.0)	1.4

The gain on disposal of the Injectable Business was £1.4 million as analysed below:

	£m
<b>Consideration:</b>	
Cash . . . . .	10.2
Purchase price adjustment . . . . .	(0.3)
Total cash consideration . . . . .	9.9
Less: Disposal costs and provisions . . . . .	(5.3)
<b>Net proceeds</b> . . . . .	<b>4.6</b>
Net assets of Injectable Business at disposal (see note below) . . . . .	(5.8)
Attributable goodwill . . . . .	(1.6)
Realisation of translation reserve . . . . .	4.2
<b>Gain on disposal</b> . . . . .	<b>1.4</b>

Note: The net assets of the Injectable Business at disposal take into account the transfer of liabilities to Paul Capital with the business and the restructuring of the Group's Paul Capital finance liabilities on 23 March 2007, as the Paul Capital finance restructuring was inextricably linked with the disposal of the Injectable business.

The residual gain on disposal was £1.4 million. The change from the previously disclosed £1.0 million loss on sale is due to a reassessment of the Injectable Business net asset value eliminated on sale.

The Directors consider that no tax provision is required on that gain.



## 7 Goodwill

	<u>Total</u> £m
<b>Cost</b>	
At 1 January 2008 .....	33.7
Impairment .....	—
<b>At 30 June 2008</b> .....	<u>33.7</u>
<b>Accumulated amortisation</b>	
At 1 January 2008 .....	6.4
Impairment .....	1.0
<b>At 30 June 2008</b> .....	<u>7.4</u>
<b>Net book value</b>	
<b>At 31 December 2007</b> .....	<u>27.3</u>
<b>At 30 June 2008</b> .....	<u>26.3</u>

At 30 June 2008, the Group incurred an impairment loss of £1.0 million (31 December 2007: £1.9m) (recorded in administration expenses) relating to the Insoluble Drug Delivery (“IDD”) technology goodwill. The remaining carrying value of goodwill is £26.3 million, supported by an assessment by the Directors of the prospects for sales of Triglide® and other potential applications of SkyePharma’s IDD technologies. If other potential applications are not realised there may need to be a substantial impairment of the carrying value of the related goodwill.

## 8 Borrowings

	<u>As at</u> <u>30 June</u> <u>2008</u> £m	<u>As at</u> <u>30 June</u> <u>2007</u> £m	<u>As at</u> <u>31 December</u> <u>2007</u> £m
<b>Current</b>			
Bank overdraft and borrowings .....	1.3	0.9	1.0
Property mortgage .....	0.3	0.3	0.3
Paul Capital finance .....	5.4	5.3	5.4
CRC finance .....	0.9	—	0.1
<b>Total current borrowings</b> .....	<u>7.9</u>	<u>6.5</u>	<u>6.8</u>
<b>Non-current</b>			
Convertible bonds due May 2024 .....	51.9	51.4	51.7
Convertible bonds due June 2025 .....	13.1	13.0	13.0
<b>Convertible bonds</b> .....	<u>65.0</u>	<u>64.4</u>	<u>64.7</u>
Property mortgage .....	6.6	5.7	6.1
Paul Capital finance .....	14.6	16.7	15.6
CRC finance .....	36.8	28.5	36.1
Finance lease liabilities .....	0.1	0.1	0.1
Other non-current borrowings .....	58.1	51.0	57.9
<b>Total non-current borrowings</b> .....	<u>123.1</u>	<u>115.4</u>	<u>122.6</u>
<b>Total borrowings</b> .....	<u>131.0</u>	<u>121.9</u>	<u>129.4</u>

### Bank overdraft and borrowings

At 30 June 2008 bank borrowings include an overdraft of £0.3 million (CHF 0.6 million) (2007: £0.2 million) and loan due of £1.0 million (CHF 2 million) with the Basellandschaftliche Kantonalbank. This loan can be terminated with six weeks notice by either party and bears interest at 6.5%. Both amounts are secured on the assets of SkyePharma AG.



## 8 Borrowings (Continued)

### Convertible bonds

The Group has £69.6 million 6% convertible bonds due May 2024 at a conversion price of 95 pence and £20 million 8% convertible bonds due June 2025 at a conversion price of 58 pence. The £69.6 million May 2024 bonds may be called for repayment by the bond holders at par in May 2009, May 2011, May 2014 or May 2019 and the £20.0 million June 2025 bonds may be called for repayment by the bond holders at par in June 2010, June 2012, June 2015 or June 2020.

The convertible bonds are included in the balance sheet partly in non-current liabilities (30 June 2008: £65.0 million, 31 December 2007: £64.7 million) and partly in share premium in shareholders' equity (30 June 2008 and 31 December 2007: £28.5 million). The total face value of the convertible bonds is £89.6 million.

### Property mortgage

At 30 June 2008, the Group had a property mortgage facility with the Basellandschaftliche Kantonalbank of £6.9 million (CHF 14.0 million) (31 December 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 annum and are fully repayable in 2011.

### Paul Capital finance

In March 2007 the Group completed a restructuring of the Paul Capital debt from a royalty sharing arrangement for a number of specified products, into a fixed amortisable note of \$92.5 million (£46.1 million). The note will be increased by up to an additional \$12.5 million (£6.2 million) if worldwide sales of DepoDur™ reach certain thresholds. The Injectable Business was sold on the basis that it retained responsibility to Paul Capital for its obligations to share royalties received in respect of DepoCyte® and DepoDur™, and, to the extent that payments are made in this respect, the Group's liability to Paul Capital under the Note will be reduced accordingly. The note is repayable in accordance with an amortisation schedule through to 2015. The restructuring of the Paul Capital debt is on substantially different terms from those applying to the royalty sharing arrangement and therefore has been treated as a new financial liability arising in 2007 on extinguishment of an original financial liability.

The carrying value of the new fixed amortisable Note is 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). At 30 June 2008, the carrying value of the Note was £20.0 million (2007: £21.0 million).

### CRC Loan

In December 2006 SkyePharma announced an agreement with a specialist lending entity domiciled in Ireland and advised by Christofferson Robb & Company LLC for a 10 year secured amortising loan facility. The facility comprises initial commitments of \$35.0 million and €26.5 million repayable over 10 years based on a minimum amortisation schedule. Interest is generally charged on a quarterly basis at the respective US and Euro three month LIBOR rates plus a 5.85% margin. From 23 March 2007, the interest rate on the first €7.5 million of the Euro facility was increased to three month EURIBOR plus 10.85%.

Half of the committed principal on each loan was drawn down in January 2007 and a further \$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. The liability carrying amount as of 30 June 2008 is £37.7million (net of £0.8 million of costs) (2007: £36.2 million).

## 9 Share Capital

Group	30 June 2008	31 December 2007	30 June 2008	31 December 2007
	Number of shares	Number of shares	£ million	£ million
<b>Authorised</b>				
Ordinary Shares of 10p each . . . . .	<b>1,188,000,000</b>	1,188,000,000	<b>118.8</b>	118.8

## 9 Share Capital (Continued)

	Ordinary Shares of 10p each	Nominal value	Deferred 'B' Shares of 10p each	Nominal value	Total nominal value
	Number	£ million	Number	£ million	£ million
<b>Issued</b>					
<b>At 1 January 2008 and 30 June</b>					
<b>2008</b> .....	<b>814,988,636</b>	<b>81.5</b>	<b>12,000,000</b>	<b>1.2</b>	<b>82.7</b>

## 10 Post Balance Sheet Events

In July 2008 the Group entered into an amendment agreement with Mundipharma to make a number of changes to its existing licence agreement. It was agreed that €3 million (£2.4 million) would be paid to the Group as the agreed balance of the €12 million (£9.5 million) milestone due from Mundipharma less the Group's reimbursement to Mundipharma to contribute to the cost of European clinical studies to support regulatory approval in adults (lower and middle strengths) and paediatrics. In the event that the PDCO requests additional work to obtain a paediatric indication, SkyePharma will reimburse Mundipharma for half the cost of this work up to \$3.5 million (£2.8 million) 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.

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

## **Directors Responsibility Statement**

The directors confirm that this condensed set of financial statements has been prepared in accordance with IAS34 “Interim Financial Reporting” as adopted by the European Union, and that the interim management report herein includes a fair review of the information required by the Disclosure and Transparency Rules of the Financial Services Authority, paragraphs DTR 4.2.7 and DTR 4.2.8.

The Directors of SkyePharma PLC are as listed on page 24 of the SkyePharma PLC Annual Report for the year ended 31 December 2007.

By order of the Board

**F Condella**

*Chief Executive Officer*

**P Grant**

*Finance Director*

## INDEPENDENT REVIEW REPORT TO SKYEPHARMA PLC

We have been engaged by the Company to review the condensed consolidated financial statements in the Interim Report for the six months ended 30 June 2008 which comprises the consolidated income statement, consolidated balance sheet, consolidated statement of recognised income and expense, consolidated cash flow statement and related notes. We have read the other information contained in the Interim Report and considered whether it contains any apparent misstatements or material inconsistencies with the financial information.

This report is made solely to the company in accordance with guidance contained in ISRE 2410 (UK and Ireland) “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Auditing Practices Board. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company, for our work, for this report, or for the conclusions we have formed.

### **Directors’ Responsibilities**

The Interim Report, including the condensed consolidated financial statements contained herein, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the Interim Report in accordance with the Disclosure and Transparency Rules of the United Kingdom’s Financial Services Authority.

As disclosed in note 1, the annual financial statements of the group are prepared in accordance with IFRSs as adopted by the European Union. The financial information included in this Interim Report has been prepared in accordance with International Accounting Standard 34, “Interim Financial Reporting”, as adopted by the European Union.

### **Our Responsibility**

Our responsibility is to express to the Company a conclusion on the condensed consolidated financial statements in the Interim Report based on our review.

### **Scope of Review**

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### **Conclusion**

Based on our review, nothing has come to our attention that causes us to believe that the condensed consolidated financial statements in the Interim Report for the six months ended 30 June 2008 are not prepared, in all material respects, in accordance with International Accounting Standard 34 as adopted by the European Union and the Disclosure and Transparency Rules of the United Kingdom’s Financial Services Authority.

### **Emphasis of matter—Going Concern**

In arriving at our review conclusion we have considered the adequacy of disclosures made in note 1 to the condensed consolidated financial statements which indicates the existence of material uncertainties in respect of the successful completion of refinancing the convertible bonds prior to May 2009 which could affect the Group’s ability to continue as a going concern. In view of the significance of this, we consider that it should be brought to your attention but our review conclusion is not qualified in this respect. The financial statements do not reflect any adjustments which would be required to be made if they were to be prepared on a basis other than the going concern basis.

Ernst & Young LLP  
London

27 August 2008