



INTERIM REPORT 2009



Making good drugs better

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## OPERATIONAL HIGHLIGHTS

- Flutiform™ accepted for review by US FDA; meeting to determine how to address potential review issues to be held shortly.
- Flutiform™ development remains on track in EU and Japan — EU filing for Flutiform™ still expected Q1 2010.
- Lodotra™ launched in Germany for treatment of rheumatoid arthritis-related stiffness
  - Mundipharma distribution agreement signed by partner Nitec for the rest of Europe
  - FDA filing planned Q2 2010.
- Significant price increases negotiated for several manufactured products.
- Restructuring of French and Swiss operations, reducing annual costs by approximately £2.0 million.



	H1 2009 £m	H1 2008 £m
Revenue	25.5	28.4
Research and development expenses	(10.3)	(16.7)
Pre-exceptional operating profit/(loss)	4.9	(1.6)
<b>Net loss after tax</b>	<b>(6.1)</b>	<b>(6.8)</b>
		31 December 2008
<b>Net debt and liquidity</b>		
Total debt less cash including convertible bonds†	112.3	115.8
Liquidity — cash and cash equivalents plus undrawn facilities	23.8	37.5

† Total debt less cash including convertible bonds includes convertible bonds at IFRS value.

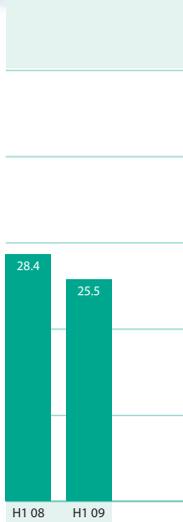
## OUR MISSION

SkyePharma's mission is to become one of the world's leading speciality drug delivery companies, powered through excellence in its oral and inhalation technologies.

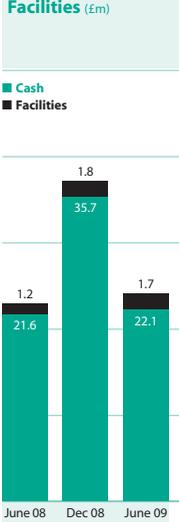
SkyePharma strives to deliver clinical benefits for patients by using its multiple delivery technologies to create enhanced versions of existing pharmaceutical products.



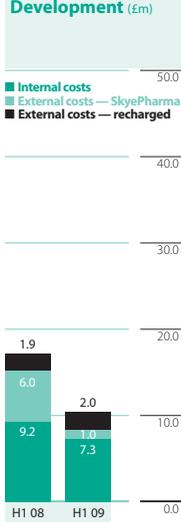
**Revenue (£m)**



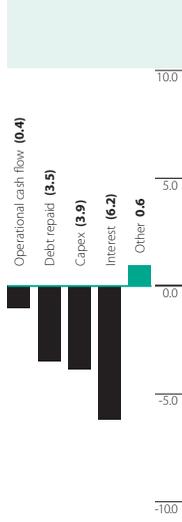
**Cash and Facilities (£m)**



**Research & Development (£m)**



**Cash Flow (£m)**





**“SkyePharma made good progress on a number of fronts during the first half of 2009, with Flutiform™ accepted for review by the FDA in the US. Although some potential review issues have been raised by the FDA we are aiming to address these as quickly as possible and we remain confident in the potential for Flutiform™ in the US and other key markets.”**

## CHAIRMAN'S STATEMENT

### JEREMY SCUDAMORE

#### Overview

Trading for the first six months of 2009 was in line with the Board's expectations. Lodotra™ was launched in Germany and partnered with Mundipharma for the rest of Europe and the New Drug Application (“NDA”) for Flutiform™ was accepted for review by the US Food and Drug Administration (“FDA”) in May 2009. As previously announced, the FDA gave preliminary notice of some potential review issues related to the NDA in June 2009 and the Company announced that additional clinical work may be required to provide more data on dosing. A meeting will be held with the FDA shortly with a view to determining how these potential issues may be addressed and what, if any, additional clinical work is required. Should additional clinical work be required it is likely to impact the time frame for the review and approval of Flutiform™ in the US although the development remains on track in Europe (target filing date is Q1 2010) and Japan. Further progress has been made with improving the Group's profitability through cost reduction measures, including headcount reductions in both France and Switzerland, and through significant price increases negotiated for some manufactured products.

#### Financial Highlights

The Group achieved revenues of £25.5 million in

the first half of 2009, a decrease of £2.9 million (10 per cent) compared with the first half of 2008, which included £2.9 million of non-recurring manufacturing revenues. Excluding this non-recurring revenue, and milestones, which, by their nature vary from period to period, revenues would have decreased by 5 per cent if exchange rates in 2009 had been the same as 2008. This is mainly due to the growth in royalty revenues for Solaraze® and Requip® only partially compensating for the reductions in revenues from Paxil CR™ and Triglide®.

The £2.9 million non-recurring manufacturing revenue related to the Foradil® Certihaler® agreement with Novartis. This agreement has now been terminated, and all items relating to this in the first half of 2009 have been recorded in exceptional items.

The pre-exceptional operating profit of £4.9 million in the first half of 2009 (H1 2008: loss of £1.6 million) is a substantial improvement on last year due to the decrease in research and development expenses, reflecting the reduction in spend on developing Flutiform™, the focus on partnered projects and cost savings.

Exceptional income of £5.0 million has arisen as a result of reaching agreements in July 2009, with Novartis and with a subcontractor, on the immediate termination of the contracts relating to Foradil® Certihaler®. These termination agreements follow the decision not to proceed

with US commercialisation of the Foradil® Certihaler® as announced in December 2008. Following the termination, SkyePharma retains exclusive rights to seek alternative uses for the SkyeHaler™ multi-dose dry powder inhaler, used in the Foradil® Certihaler®. Foradil® Certihaler® was approved in the United States in December 2006. The effect of the termination agreements has been a net cash inflow in the second half of 2009 of £5.0 million.

The exceptional charge of £4.5 million consists of a non-cash £3.0 million impairment charge related to goodwill, and £1.5 million of employee termination and other costs associated with the restructuring of the manufacturing facility in Lyon, France and the research and development facility in Muttenz, Switzerland.

The net result for the first half of 2009, after exceptional items, net finance costs and tax was a loss of £6.1 million (H1 2008: loss of £6.8 million).

### **Financial Strength**

Cash usage in the first half of 2009 was in line with the Board's expectations. The Group's cash balance at 30 June 2009 was £22.1 million and since that date an additional £5.0 million cash has been retained by the Group from the settlement with Novartis and a subcontractor in respect of the termination of the Foradil® Certihaler® contract.

Approximately £6.6 million of the 6% 2024 convertible bonds were converted into ordinary shares in the first half of 2009. These conversions both strengthen the Group's Balance Sheet and will result in an interest saving of nearly £0.4 million per annum.

Cash will continue to be controlled tightly to ensure that the cash reserves remain sufficient to bring the business to sustainable profitability.

### **Board**

Dr Thomas Werner was appointed to the Board on 16 May 2009 as a Non-Executive Director. Dr Werner is a senior level pharmaceutical executive with over 26 years' experience in the

pharmaceutical industry. Previously, he was Managing Director and Senior Vice President of GlaxoSmithKline Germany. Prior to that, he held senior positions at GlaxoWellcome Germany, Bristol-Myers Squibb Germany and Convatec Germany. Subsequently, he has been appointed to the Audit and the Nomination & Governance Committees.

Dr Jerry Karabelas stepped down from the Board on 15 May 2009, following a decision not to seek re-election at the Annual General Meeting on that date. Jerry served on the Board from 2000, and as Chairman from February 2006 to November 2007. He has been replaced as Chairman of the Remuneration Committee by Frank Condella. The Board thanks him for his services over this period.

### **Outlook**

Trading for the second half of 2009 is expected to remain in line with the Board's expectations, with overall revenues similar to those reported in the first half. The second half year will benefit from the cost reductions already implemented and the continuing effect of price increases for certain manufactured products negotiated in the first six months.

The volatility of exchange rates will continue to have a significant effect on reported amounts for revenues and costs, but due to natural hedges, the impact on cash flows is expected to be small.

The Board continues to believe that existing liquidity is sufficient to meet the needs of the business for the foreseeable future.

Notwithstanding the potential issues raised by the FDA, the Directors remain confident that, once approved and launched in its various markets, Flutiform™ will be a successful product for SkyePharma, in terms of both revenues and cash flows.

### **Jeremy Scudamore**

Non-Executive Chairman  
20 August 2009

## PRODUCTS

## Approved Products

as at 20 August 2009

Licensee/partner	Product name	Generic name of active	Primary indication
<b>Inhalation</b>			
AstraZeneca	Pulmicort® HFA-MDI	budesonide	Asthma
<b>Oral</b>			
sanofi-aventis	Xatral® OD/Uroxatral®	alfuzosin	BPH (urinary symptoms)‡
GlaxoSmithKline	Requip® Once-a-day	ropinirole	Parkinson's disease
GlaxoSmithKline	Paxil CR™	paroxetine	Depression
Sciele Pharma (Shionogi)	Triglide®	fenofibrate	Lipid disorders
Sciele Pharma (Shionogi)	Sular®	nisoldipine	Hypertension
Roche	Madopar DR®	levodopa/benserazide	Parkinson's disease
Cornerstone Therapeutics	ZYFLO CR®	zileuton	Asthma
Therabel	Coruno®	molsidomine	Angina
ratiopharm	diclofenac-ratiopharm®uno	diclofenac	Pain/inflammation
Nitec (Merck KGaA/ Mundipharma)	Lodotra™ (EU)	prednisone	Rheumatoid arthritis
<b>Topical</b>			
Nycomed/Almirall	Solaraze	diclofenac	Actinic keratosis

## Development pipeline

as at 20 August 2009

Licensee/partner	Product name	Generic name of active	Primary indication
<b>Inhalation</b>			
Abbott	Flutiform™ (US)	formoterol/fluticasone	Asthma
Mundipharma	Flutiform™ (EU)	formoterol/fluticasone	Asthma
Kyorin	Flutiform™ (Japan)	formoterol/fluticasone	Asthma
<b>Oral</b>			
Nitec	Lodotra™ (US)	prednisone	Rheumatoid arthritis
Somnus Therapeutics	SKP-1041	zaleplon	Sleep maintenance
<b>Feasibility</b>			
SkyePharma	various	undisclosed	undisclosed

‡ Benign prostatic hypertrophy



**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.

Pre-clinical	Phase I	Phase II	Phase III	Filed
				
				
				



**"In the first half of 2009, Lodotra™ was launched in Germany for the treatment of rheumatoid arthritis-related morning stiffness and subsequently approved in other major European markets. The Company also significantly reduced its cost base through the reorganisation of manufacturing operations in France, and research & development facilities in Switzerland. We also successfully negotiated some substantial price increases for manufactured products and a £5.0 million cash settlement on the termination of agreements related to the Foradil® Certihaler®. The Company is now actively seeking partners for the SkyeHaler™."**

## CHIEF EXECUTIVE OFFICER'S REVIEW

With the approval and launch of Lodotra™ in 2009, the Group now has 12 approved products which have generated royalty and manufacturing revenues of £18.9 million in the first half of 2009 (H1 2008: £19.7 million).

The most important pipeline product continues to be Flutiform™, a fixed-dose combination of fluticasone, an inhaled corticosteroid ("ICS"), and formoterol, a long-acting beta agonist ("LABA") in a Metered Dose Inhaler ("MDI"). ICS/LABA combinations account for the largest segment, by sales revenues, of the global asthma and chronic obstructive pulmonary disease ("COPD") market, which generated an estimated US\$29.2 billion globally in 2008. Also in the pipeline is SKP-1041, a novel sleep therapeutic, and the Group is working on a number of feasibility projects.

The Group continues to seek new partnerships for its proprietary technology, and is actively seeking potential applications of its SkyeHaler™ dry powder inhaler ("DPI"). This is one of only a few DPI devices which have been incorporated in products approved by the FDA, and is the only such device which is not proprietary to a major pharmaceutical company.

In order to conserve cash ahead of the anticipated approval and successful

commercialisation of Flutiform™, the Board does not intend to finance any late phase clinical studies and will, therefore, seek to out-license new developments after proof of principle and work on further development on a contract development basis.

The Group continues to focus on controlling and reducing costs where appropriate to balance income and expenses. Headcount has been reduced by over 10 per cent at the Group's research and development facility in Muttentz, Switzerland. At the manufacturing facility in Lyon, France, following consultations with the Works Council, the workforce of over 120 employees has been reduced by approximately one third. In aggregate these measures have led to an exceptional charge of £1.5 million in the first half of 2009 and will lead to annual savings of approximately £2.0 million per annum from next year.

## BUSINESS REVIEW — PRODUCTS INHALATION PRODUCTS

### Flutiform™

Flutiform™ is licensed to Abbott Respiratory LLC ("Abbott") in the United States, to Mundipharma International Corporation Limited ("Mundipharma") in the rest of the world (outside Japan and the Americas) and to Kyorin Pharmaceutical Company Ltd ("Kyorin") for Japan. Discussions are continuing with a view to commercialising Flutiform™ for Canada and Latin America.

### **Progress with Flutiform™ in the US**

Following completion of a clinical programme comprising a long-term safety study and four efficacy studies, covering nearly 2,300 patients, the NDA for Flutiform™ was filed in Q1 2009 and has been accepted for review by the FDA. In line with standard practice, the FDA issued a 74-day letter to confirm that the NDA is sufficiently complete to permit a substantive review and gave preliminary notice of some potential review issues. The FDA states that its filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during its review, and that issues may be added, deleted, expanded upon or modified as it reviews the application.

As previously announced, further clarification is required of some of the potential review issues and a meeting has been arranged with the FDA with a view to agreeing how they may be addressed. Although the requirements cannot be precisely assessed prior to discussion with the FDA, based on a preliminary assessment, it appears likely that some additional clinical work may be required to provide more data on dosing.

The regulatory review timeline for asthma treatments is typically longer than the standard 10-month Prescription Drug User Fee Act timeline. Should additional clinical work be required this is likely to impact on the timeline for the review and any potential approval. The meeting with the FDA is due to take place shortly, but it is possible that further follow-up questions will arise and additional dialogue may be needed to reach conclusions on how to address any concerns raised. Work on certain line extensions of Flutiform™ for the US has been put on hold pending the outcome of the discussions with the FDA. The Board does not expect any potential delay to the US filing to impact the progress of Flutiform™ development in Europe and Japan.

An update announcement will be made once the implications of the review issues raised by the FDA are sufficiently clear.

Abbott has exclusive rights to market Flutiform™, subject to FDA approval, in the United States. In addition to the US\$25 million

(£12.5 million) received on signing, and the US\$0.8 million (£0.5 million) received on the acceptance of the NDA by the FDA, the agreement with Abbott provides for the Group to receive time-dependent milestones on approval together with up to US\$60 million (£36.3 million) in sales related milestones. The royalty rate on sales in the United States escalates upwards from a mid teens percentage.

If Flutiform™ is approved in the US in 2010, the approval milestone would be US\$25.0 million (£15.1 million), reducing to US\$18.0 million (£10.9 million) if approval is received in 2011 or later. To the extent that certain of Abbott's development costs (including costs of any additional studies required by the FDA in support of the NDA) exceed US\$20.5 million (£12.4 million) the excess is recoverable from up to 25 per cent of any approval or post-approval milestone and royalty payments until such time as 100 per cent of the excess is recovered.

### **Progress with Flutiform™ in Europe**

In addition to the data supporting the NDA for the US, four Phase III additional clinical studies by Mundipharma will support the European Marketing Authorisation Application ("EMAA") for Flutiform™. Three of these studies have been completed comprising a 12-week open-label non-inferiority comparator study in 211 paediatric patients, a 12-week open-label non-inferiority comparator study in 182 adult and teenage patients and a 12-week open-label non-inferiority study comparing with the two active components in 196 adult and teenage patients.

The ongoing study is an 8-week double-blind higher dose strength study to demonstrate the superiority of Flutiform™ over fluticasone and comparing its non-inferiority with the two active components (fluticasone and formoterol). The study is now fully recruited, and the last patient last visit will take place early in September 2009. The target date for filing the EMAA remains Q1 2010.

Mundipharma has exclusive rights to Flutiform™ in Europe and other territories outside the Americas and Japan. The licensing agreement provides for the Group to earn up to €73 million

(£59.8 million) in milestones, of which €15 million (£10.1 million at that time) was paid upfront, €3 million (£2.9 million) was paid on 31 December 2008, up to €15 million (£12.8 million) is due on launch and up to €40 million (£34.0 million) is sales related. In addition, the Group is entitled to royalties as a percentage of net sales escalating upwards from 10 per cent. The development work being carried out for Europe on a higher strength version of Flutiform™ is being funded by Mundipharma and reimbursed by the Group through reductions in royalties and sales-related milestones for a limited period of time, and up to a cost of €15 million (£12.8 million) in total.

Mundipharma is developing at its own cost a specific new breath-actuated actuator for Flutiform™, which the Directors believe will enhance the sales of the product. Mundipharma will pay the Group royalties escalating upwards from 10 per cent on net sales of Flutiform™ whether or not such sales incorporate the new actuator.

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

#### **Progress with Flutiform™ in Japan**

In April 2008, the Group entered into an exclusive development, distribution and licence agreement for Flutiform™ with Kyorin for Japan and has received an upfront milestone payment. Development and approval milestones worth several million pounds are payable to the Group under the agreement and there is a high mid single digit percentage royalty on net sales. The development costs associated with obtaining approval for the Japanese market will largely

be met by Kyorin, which is responsible for clinical studies and regulatory submissions. Development is proceeding to plan, and is expected to take several years. Recruitment for the Phase II study commenced in December 2008, and is currently ongoing.

#### **Supply of Flutiform™**

Under the agreements with Abbott, Mundipharma and Kyorin, the Group is responsible for supplying Flutiform™ and has committed to capital expenditure totalling €9.7 million (£8.2 million), of which €6.5 million (£5.5 million) has been spent to date, on tooling at two subcontractors. In addition, the Group has committed to capital expenditure of €3.1 million (£2.6 million), which is being funded by Partners. Of this, €1.6 million (£1.3 million) has been spent to date. The Group has entered into an agreement for the product to be manufactured in a sanofi-aventis factory in Holmes Chapel, United Kingdom. The Group is responsible for supplying the various components and ingredients to sanofi-aventis and is sourcing these from various suppliers located in Europe. The Group has also made certain minimum volume commitments worth up to €6.7 million (£5.7 million) to be met by 31 December 2010. The Group continues discussions with a view to transferring the responsibility of the Flutiform™ supply chain to a third party and is seeking to recover capital expenditure incurred on setting up the supply chain in any such transfer.

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

#### **Pulmicort® HFA-MDI**

This new HFA-MDI containing AstraZeneca's inhaled corticosteroid Pulmicort® (budesonide), which was developed for territories outside the United States, has replaced the previous CFC-MDI formulation of Pulmicort® in 25 countries, being most of the markets in which the CFC-MDI formulation of Pulmicort® had previously been

sold. The Group earns a mid teens royalty on AstraZeneca's net sales of Pulmicort® HFA-MDI.

## ORAL AND TOPICAL PRODUCTS

### Xatral® OD

Xatral® OD (Uroxatral® in the United States) is a once-daily version of sanofi-aventis' Xatral® (alfuzosin hydrochloride), a treatment for the signs and symptoms of Benign Prostatic Hypertrophy ("BPH"). In the first half of 2009, reported sales of all forms of Xatral® were €153 million (£136.8 million), down 10.5 per cent (using constant exchange rates) compared with the first half of 2008. European sales continue to be affected by generic competition after the expiry of European patents in May 2006, with sales for the first six months of 2009 reported as €49 million (£43.8 million), down 33.3 per cent (using constant exchange rates) compared with the same period in 2008. In the United States, sales of Uroxatral® were €74 million (£66.1 million), up 20.4 per cent compared with 2008. Sales in other countries were also down 9.1 per cent (using constant exchange rates) to €30 million (£26.8 million).

A number of companies have filed Abbreviated New Drug Applications ("ANDA's) with the FDA seeking approval to market a generic alfuzosin hydrochloride drug product in the United States. Sanofi-aventis has taken legal action in response to most of these ANDAs, and such legal action remains pending.

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

### Solaraze®

Solaraze® (diclofenac), a topical gel treatment for actinic keratosis, is marketed in the United States by Nycomed. Net sales in the first half of 2009 were approximately US\$23.8 million (£15.9 million), up by approximately 38 per cent on 2008. The Group earns a low teens royalty rate on net sales. The distribution and marketing partner in Europe and certain other territories is Almirall. Sales in the first half of 2009 by Almirall were €10.7 million (£9.6 million) compared with €6.1 million (£4.7 million) up 76 per cent compared with the first half of 2008. Solaraze® is the market leader in Europe and Australia.

Sales were particularly strong in the key markets of Germany and the United Kingdom.

### Requip® Once-a-day

Requip® Once-a-day is a once daily formulation for Parkinson's disease which was developed in collaboration with GlaxoSmithkline ("GSK"). The new extended release Requip® uses the Group's patented Geomatrix™ technology and is designed to provide smoother blood levels of ropinirole without the peaks and troughs that multiple daily doses invariably deliver. In addition, the new once daily formulation offers physicians and patients a simple titration schedule. It also provides for a convenient, once-daily dosing schedule compared with the immediate-release ropinirole, which is dosed three times a day. Extended release Requip® is currently approved in 35 countries worldwide and has been launched in 24 European countries including France, Germany and the UK.

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

The Group earns low mid single digit percentage royalties on net sales of Requip® Once-a-day. In the first half of 2009 sales of Requip® Once-a-day were £52 million, with £13.0 million generated in the United States and £39.0 million in Europe.

### Sular®

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

Sales of Sular® continue to be affected by the sale of a generic version of the old formulation of Sular® which was launched in 2008.

In February 2009 a paragraph IV certification was filed by a generic manufacturer in respect of the 25.5mg and 34mg strengths of the new formulation of Sular® and in March 2009 a further certification was filed for the 8.5mg and 17mg strengths of the new formulation. Sciele did not file a patent infringement suit within 45 days of receiving notification of the paragraph IV certifications and, therefore, there is no automatic 30-month stay to prevent the generic manufacturer from launching a generic version once approved. The impact of any generic launch on sales of the new formulation of Sular® is dependent on a number of factors including the timing of launch, pricing strategy of the generic company and the number and timing of additional generic formulations, if any, that reach the market. If net sales of the new formulation of Sular® are significantly lower following generic entry, the Group's royalty rate would be reduced from a low mid single digit percentage to a low single digit percentage on net sales.

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

#### **Paxil CR™**

Paxil CR™ is an advanced formulation of the anti-depressant Paxil® and was developed by the Group in collaboration with GSK using the Group's Geomatrix™ technology. In the first half of 2009 sales of Paxil CR™ were £32.0 million, a decrease of 44 per cent (using constant exchange rates) on the first half of 2008. Generic erosion has been, as expected, quite rapid with approximately 80 per cent of prescriptions being written for the generic form of the product.

#### **Triglide®**

Triglide® (fenofibrate), an oral treatment for elevated blood lipid disorders, is marketed in the United States by Sciele, and is being sold alongside Fenoglide®, a fenofibrate product in-licensed from LifeCycle Pharma A/S. Triglide® was launched in 2005 and Fenoglide® was launched in February 2008. The effect of competition has continued to reduce Triglide® total prescriptions during the first half of 2009. The Group 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 the Group's plant in Lyon, France. Under an agreement with Sciele allowing the launch of Fenoglide® a few months earlier than the Triglide® licence agreement would otherwise have allowed, Sciele agreed to purchase and distribute minimum numbers of samples of Triglide® and to share revenues from Fenoglide® with the Group. The share of net sales of Fenoglide® is 4 per cent for 2009.

#### **ZYFLO CR® (zileuton) extended release tablets**

The Group developed an extended release formulation of the oral asthma drug zileuton for Cornerstone Therapeutics, Inc (formerly Critical Therapeutics Inc.). ZYFLO CR® extended-release tablets, taken twice daily, utilise the Group's proprietary Geomatrix™ technology, and the product was approved by the FDA in May 2007 for the prophylaxis and 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. The Group receives a high mid single digit percentage royalty on net sales of ZYFLO CR® and also manufactures the product.

#### **Lodotra™**

In April 2009, Lodotra™, the novel night-time release formulation of low dose prednisone, utilising SkyePharma's proprietary Geoclock™ technology and developed in collaboration with Nitec Pharma AG ("Nitec"), was launched in Germany by Merck KGaA (Nitec's licensee for Germany and Austria). This is the first launch in Europe following the final assessment report from the German BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte). The report concluded that Lodotra™ is approvable for the treatment of rheumatoid arthritis and associated morning stiffness in 15 European countries, under the European Medicines Agency's decentralised procedure. Nitec has recently concluded a distribution agreement with Mundipharma for the rest of Europe, and the product has since been approved in 10 countries including the UK.

Nitec continues to work on its programme for US registration of Lodotra™ and announced

on 27 February 2009 that it had finalised recruitment for the second pivotal Phase III trial (a 12-week, multicentre, double blind trial involving 300 patients) required for filing the NDA. Data on this trial is anticipated in Q4 2009, with a filing with the FDA planned for Q2 2010.

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

### **SKP-1041**

In December 2008 the Group and its partner, Somnus Therapeutics Inc ("Somnus"), announced the successful completion of a Phase I trial of the controlled release sleep maintenance drug SKP-1041, triggering a US\$1 million (£0.7 million) development milestone. The product is a new formulation of zaleplon, a non-benzodiazepine hypnotic agent, which utilises the Group's proprietary Geoclock™ technology for delayed release. The formulation is designed to treat people who have difficulty maintaining sleep but not with sleep onset, and is intended to prevent middle-of-the-night awakening, while avoiding daytime drowsiness.

The Investigational New Drug Application ("IND") for SKP-1041 was filed with the FDA in Q1 2009 and planning is under way to commence Phase II trials in the second half of 2009.

Under the agreement with Somnus, the Group could receive up to US\$35 million (£20.9 million) in milestone payments, of which US\$4 million (£2.0 million) was received on signature, up to US\$11 million (£6.8 million) is payable during the development phase, mainly on product approval, and US\$20 million (£12.1 million) is sales related. The Group is entitled to receive a royalty on future sales escalating upwards from a high mid single digit percentage.

### **Feasibility agreements**

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

### **Share of sales from Pacira**

The terms of the sale in 2007 of the Injectable Business included up to US\$62 million (£37.5 million) in contingent milestone payments and a percentage of sales of certain future products for a fixed period of time. These primarily relate to the launch and various substantial sales targets of DepoBupivacaine™ which is currently in Phase II and Phase III clinical development for a number of indications with Pacira Pharmaceuticals Inc. ("Pacira Pharmaceuticals"). In February 2009 Pacira Pharmaceuticals announced a setback in one of the clinical trials of DepoBupivacaine™. No further details of the setback have been publicly disclosed.

### **MANUFACTURING**

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

During 2007 and 2008, Sciele made a substantial investment in implementing a high capacity line, for the manufacture of the recently approved new formulation of Sular® in the Lyon facility. Under an agreement signed in June 2009, the Group has purchased this equipment for a nominal amount.

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



**“As at 30 June 2009, the Group had cash and cash equivalents totalling £22.1 million, together with available facilities of £1.7 million. Cash will continue to be controlled tightly to ensure that the cash reserves remain sufficient to bring the business through to sustainable profitability.”**

## FINANCIAL REVIEW

### Revenue

Revenues for the first six months of 2009 were £25.5 million, a decrease of 10 per cent from the £28.4 million achieved in the first six months of 2008. Excluding non-recurring manufacturing revenue and milestones, revenues would have decreased by 5 per cent if exchange rates in 2009 had been the same as 2008, mainly due to the growth in royalty revenues for Solaraze® and Requip® only partially compensating for the reductions in revenues from Paxil CR™ and Triglide®.

Royalty income was £12.8 million, an increase of £1.2 million from the £11.6 million earned in the first six months of 2008. The increase was primarily due to exchange rate effects. Increases in royalties due to growth in sales of Solaraze® and Requip® have been more than offset by reductions in volumes of Paxil CR™ and Triglide®, due to the effects of generic competition.

Contract research and development costs recharged to partners increased by £1.4 million to £4.8 million compared with £3.4 million in the first half of 2008. This increase primarily arose from work on Flutiform™ for the EU and Japan, the costs of which are directly recharged to partners.

Revenues recognised from signing and milestone payments are substantially lower than the first half of 2008, falling to £1.8 million from £5.3 million. This is primarily due to the Flutiform™ upfront payments received in 2006 having been largely recognised in 2008 and prior years, and one-off milestone payments in 2008 that have not been repeated in 2009.

Manufacturing and distribution revenue totalled £6.1 million for the first six months of 2009, a reduction of £2.0 million from 2008 which included a £2.9 million contribution from Novartis towards maintaining manufacturing capacity for Foradil® Certihaler®. In 2009 this contract has been terminated, and amounts receivable recorded in exceptional items. In the first six months of 2009 manufacturing and distribution revenue included the effects of some of the substantial price increases negotiated in the period, which more than offset the effects of a decrease in the volumes produced for Sular®.

### Research and development expenses

In the first half of 2009 research and development expenses decreased by £6.4 million to £10.3 million (H1 2008 restated: £16.7 million). This is primarily due to the completion of the Flutiform™ development programme ahead of filing the NDA, coupled with cost savings achieved at the Muttenz facility.

The Group's net investment in research and development (being expenses net of contract development revenues) totalled £5.5 million (H1 2008 restated: £13.3 million) a reduction of 60 per cent, reflecting the reduction in spend on developing Flutiform™, the focus on partnered development projects and cost savings.

### Exceptional items

In July 2009 the Group announced that it had reached agreement with Novartis and a subcontractor on immediate termination of the contracts related to Foradil® Certihaler®. The net effect of this agreement has resulted in exceptional income of £5.0 million in the first half of 2009 (H1 2008: Nil).

The exceptional charge for the first six months of 2009 was £4.5 million (H1 2008: £3.4 million), which included a charge of £1.5 million related to the workforce reduction at the Group's manufacturing facility in Lyon, France and research and development facility in Muttenz, Switzerland as described in the Chief Executive Officer's statement. The charge consisted of statutory redundancy and notice payments, the costs expected to be incurred under the social plan (required under French law) and professional costs incurred in finalising the plan.

Also a non-cash charge of £3.0 million has arisen on the impairment of the Insoluble Drug Delivery® ("IDD®") goodwill. The remaining value is supported by management's assessment of future sales for Triglide®.

### Finance costs and income

Finance costs — interest totalled £6.9 million (H1 2008: £6.7 million) and comprises interest payable on the CRC finance of £2.1 million (H1 2008: £2.1 million), £1.5 million (H1 2008: £1.2 million) of interest attributable to the Paul Capital finance and £3.1 million (H1 2008: £3.2 million) interest payable on the convertible bonds. The remaining charge of £0.2 million (H1 2008: £0.2 million) relates to other bank borrowings.

Finance income of £0.2 million (restated H1 2008: £0.6 million) relates to bank interest income.

Finance costs — revaluation consists of a charge of £2.0 million (H1 2008: Nil) arising in H1 2009 on the revaluation of the Paul Capital Finance liability. This reflects the Group's revised assessment of payments to be made by the former Injectable Business, now called Pacira Pharmaceuticals, on sales of DepoCyt® DepoDur™ which are paid to Paul Capital and reduce the Group's debt under the Paul Capital Finance facility.

Foreign exchange translation comprises a charge of £2.5 million (restated H1 2008: gain of £4.7 million) relating to net translation gains and losses on borrowings and cash denominated in a currency other than the entity's functional currency.

### Result

The loss for the first half of 2009 attributable to the Company's shareholders was £6.1 million (H1 2008: loss of £6.8 million). The loss for the first half of 2009 was arrived at after charging £2.5 million (H1 2008: gain of £4.7 million) relating to exchange translation effects on net debt due to the decline in value of the Swiss Franc in the first half of 2009.

The loss per share amounted to 26.7 pence (restated H1 2008: 84.0 pence).

### Cash flow

In the first half of 2009 there was a cash outflow from operating activities of £0.1 million compared with £1.1 million in the first half of 2008.

The Group spent £3.7 million (H1 2008: £2.5 million) on property, plant and equipment, mainly relating to the Flutiform™ supply chain.

Borrowings of £3.5 million (H1 2008: £1.2 million) were repaid in the first 6 months of 2009, along with £6.4 million (H1 2008: £6.5 million) of interest.

## Borrowings and liquidity

The Groups' total net debt, measured in accordance with IFRS, comprises:

	<b>30 June 2009</b>	31 December 2008
	<b>£m</b>	£m
Convertible bonds	<b>58.2</b>	62.7
Paul Capital Finance	<b>25.4</b>	28.6
CRC finance	<b>42.1</b>	49.5
Property mortgage	<b>7.4</b>	9.0
Bank overdraft & borrowings	<b>1.1</b>	1.4
Finance lease liabilities	<b>0.2</b>	0.3
<b>Total debt</b>	<b>134.4</b>	151.5
Less cash and cash equivalents	<b>(22.1)</b>	(35.7)
<b>Net debt</b>	<b>112.3</b>	115.8
<b>Net debt (including convertible debt at face value)</b>	<b>137.1</b>	142.7

Total debt has decreased by £17.1 million due to repayments totalling £3.5 million and conversion of £6.6 million of bonds. The remainder is due to currency translation effects.

During the first six months of 2009 £6.6 million of 6% 2024 convertible bonds were converted into ordinary shares at a conversion price of £3.71 per share. This has resulted in the issue of 1,775,467 ordinary shares. These conversions will reduce the Group's interest costs by approximately £0.4 million per annum and strengthen the balance sheet through the reduction in debt.

The first US\$20 million (£12.1 million) of net milestone payments received after 1 January 2009 in respect of Flutiform™ (from all territories) are to be paid in equal share to Paul Capital and CRC in accordance with the finance agreements. US\$0.7 million (£0.4 million) of finance debt was repaid in the first half of 2009, out of a development milestone received from Kyorin and an acceptance of filing milestone received from Abbott.

As at 30 June 2009, the Group had cash and cash equivalents totalling £22.1 million (31 December 2008: £35.7 million), together with available

facilities of £1.7 million (31 December 2008: £1.8 million). Cash will continue to be controlled tightly to ensure that the cash reserves remain sufficient to bring the business through to sustainable profitability.

The Directors continue to have reasonable expectations that the working capital position will be further enhanced by the transfer of the responsibility and most of the risks and rewards of the Flutiform™ supply chain to a third party which, as described in Note 12: Non-current assets held for sale, not already funded by partners, would result in a recovery of £5.5 million for assets held for sale and alleviate a further €3.2 million (£2.7 million) of capital commitments.

Having reviewed the existing contractual arrangements and potential scenarios which could arise, the Directors do not believe that the working capital available to the Group over the next 12 months is likely to be adversely impacted to a material degree should there be a requirement for additional clinical work as a result of the potential review issues raised by the FDA as described in the Chairman's Statement on page 2.

### Going Concern

The Directors have made an assessment of the working capital requirements of the Group for the next 12 months, taking into account revenue projections, operating costs, finance costs, debt repayment obligations, potential obligations in respect of the approval of Flutiform™, proposed cost reduction actions and the risks inherent in such forecasts. After making appropriate enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the interim report.

### Principal risks

The Directors consider that key risks which may have a material impact on the Group's performance in the second half of 2009 remain as disclosed on pages 41–42 of the 2008 Annual Report and Accounts.

### Foreign exchange

Almost all of the Group's operations are based overseas in Continental Europe and licence royalty payments are typically denominated in various currencies, with sales-related payments based on underlying sales in local currencies. This gives rise to direct and indirect exposure 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 borrowing to the underlying trading cash flows which generate them. Exchange translation gains and losses relating to funding (cash and debt) are included in translation gain on net debt, other realised exchange gains and losses and currency translation gains and losses are included within the revenue and expense line to which they most closely relate. Where subsidiaries are funded centrally, this is achieved by the use of long-term intercompany loans. Where settlement of these loans is neither planned nor likely to occur in the foreseeable future, they are treated as part of the net investment and exchange differences are taken to reserves. No

use was made of currency options and forward currency contracts during the first half of 2009.

### Forward looking statements

The foregoing discussions contain certain forward looking statements. Although SkyePharma believes that the expectations reflected in these forward looking statements are reasonable, it can give no assurance that these expectations will materialise. Because the expectations are subject to risks and uncertainties, actual results may vary significantly from those expressed or implied by the forward looking statements based on a number of factors. Such forward looking statements include, but are not limited to, the timescales for regulatory timings for Flutiform™, the statements under "Outlook" including the timescales for the approval and launch of new products and the target for becoming cash flow positive, the forecast sales of Flutiform™, the development of new products, risks relating to obtaining and maintaining regulatory approval for existing, new or expanded indications of existing and new products, risks related to SkyePharma's ability to manufacture products on a large scale or at all, risks related to SkyePharma's and its marketing partners' ability to market products on a large scale to maintain or expand market share in the face of changes in customer requirements, competition and technological change, risks related to regulatory compliance, the risk of product liability claims, risks related to the ownership and use of intellectual property, and risks related to SkyePharma's ability to manage growth. SkyePharma undertakes no obligation to revise or update any such forward looking statement to reflect events or circumstances after the date of these interim financial statements.

## RESPONSIBILITY STATEMENT

The Directors of SkyePharma, as listed on page 31 of the 2008 Annual Report and Accounts, with the exception of Dr Jerry Karabelas, who stepped down on 15 May 2009, and the addition of Dr Thomas Werner who was appointed on 16 May 2009, confirm that to the best of their knowledge:

1. The condensed set of financial statements has been prepared in accordance with IAS 34 "Interim Financial Reporting";
2. The interim management report includes a fair review of the information required by the Disclosure and Transparency Rules ("DTR") 4.2.7 — an indication of important events that have occurred during the first six months of the year, and a description of the principal risks and uncertainties for the remaining six months of the year;
3. The interim management report includes a fair review of the information required by DTR 4.2.8 — the disclosure of related party transactions occurring during the first six months of the year, and any changes in related party transactions disclosed in the 2008 Annual Report and Accounts.

By Order of the Board

**K Cunningham**

Chief Executive Officer

**P Grant**

Chief Financial Officer

20 August 2009

## CONDENSED CONSOLIDATED INCOME STATEMENT FOR THE SIX MONTHS ENDED 30 JUNE 2009

		Unaudited 6 months ended 30 June 2009 £m	(Restated) Unaudited 6 months ended 30 June 2008 £m	(Restated) Audited Year ended 31 December 2008 £m
	Notes			
Revenue	4	25.5	28.4	62.2
Cost of sales	5	(7.0)	(9.6)	(19.6)
<b>Gross profit</b>		<b>18.5</b>	18.8	42.6
Selling, marketing and distribution expenses		(1.1)	(0.7)	(1.5)
Research and development expenses	6	(10.3)	(16.7)	(25.1)
Corporate costs		(1.5)	(2.3)	(3.5)
Amortisation of intangible assets		(0.3)	(0.2)	(0.7)
Share-based payment charge		(0.4)	(0.5)	(0.8)
Other expense		—	—	(0.1)
<b>Pre-exceptional operating profit/(loss)</b>		<b>4.9</b>	(1.6)	10.9
Exceptional income	7	5.0	—	—
Exceptional expense	7	(4.5)	(3.4)	(28.5)
<b>Operating profit/(loss)</b>		<b>5.4</b>	(5.0)	(17.6)
Finance cost — interest	8	(6.9)	(6.7)	(14.1)
Finance income	8	0.2	0.6	0.9
Finance cost — revaluation	2, 8	(2.0)	—	(3.0)
Foreign exchange (loss)/gain on net debt	2, 9	(2.5)	4.7	5.7
<b>Loss before tax</b>		<b>(5.8)</b>	(6.4)	(28.1)
Taxation		(0.3)	(0.4)	(0.6)
<b>Loss for the period attributable to the owners of the parent</b>		<b>(6.1)</b>	(6.8)	(28.7)
<b>Basic and diluted earnings per share</b>	10	<b>(26.7)p</b>	(84.0)p	(247.4)p

See Notes to the Interim Financial Statements.

## CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED 30 JUNE 2009

	<b>Unaudited 6 months ended 30 June 2009 £m</b>	Unaudited 6 months ended 30 June 2008 £m	Audited Year ended 31 December 2008 £m
<b>Loss for the period</b>	<b>(6.1)</b>	(6.8)	(28.7)
Exchange differences on translation of foreign operations	<b>9.2</b>	(4.7)	(20.7)
Available-for-sale financial assets			
Fair value movement taken to equity	—	—	(0.1)
Actuarial losses on defined benefit plans	—	—	(0.1)
<b>Other comprehensive income/(loss)</b>	<b>9.2</b>	(4.7)	(20.9)
<b>Total comprehensive income/(loss) attributable to the owners of the parent</b>	<b>3.1</b>	(11.5)	(49.6)

See Notes to the Interim Financial Statements.

## CONDENSED CONSOLIDATED BALANCE SHEET

### AS AT 30 JUNE 2009

	Notes	Unaudited 30 June 2009 £m	Unaudited 30 June 2008 £m	Audited 31 December 2008 £m
<b>ASSETS</b>				
<b>Non-current assets</b>				
Goodwill	11	4.8	26.3	7.8
Intangible assets		9.1	9.2	10.8
Property, plant and equipment		21.4	28.8	26.3
Available-for-sale financial assets		—	0.1	—
		<b>35.3</b>	64.4	44.9
<b>Current assets</b>				
Inventories		2.2	1.0	1.5
Trade and other receivables		24.2	14.8	19.4
Financial assets at fair value through profit or loss		—	0.2	—
Cash and cash equivalents		22.1	21.6	35.7
		<b>48.5</b>	37.6	56.6
Non-current assets classified as held for sale	12	6.8	—	3.9
<b>Total assets</b>		<b>90.6</b>	102.0	105.4
<b>LIABILITIES</b>				
<b>Current liabilities</b>				
Trade and other payables		(23.6)	(25.7)	(26.0)
Borrowings	13	(19.2)	(7.9)	(12.8)
Deferred income		(1.0)	(3.1)	(1.6)
		<b>(43.8)</b>	(36.7)	(40.4)
<b>Non-current liabilities</b>				
Convertible bonds	13	(58.2)	(65.0)	(62.7)
Other borrowings	13	(57.0)	(58.1)	(76.0)
Deferred income		(10.2)	(10.2)	(12.4)
Provisions	14	(2.9)	(2.4)	(3.7)
		<b>(128.3)</b>	(135.7)	(154.8)
<b>Total liabilities</b>		<b>(172.1)</b>	(172.4)	(195.2)
<b>Net liabilities</b>		<b>(81.5)</b>	(70.4)	(89.8)
<b>SHAREHOLDERS' EQUITY</b>				
Share capital	15	98.5	82.7	96.7
Share premium		390.2	382.8	387.2
Translation reserve		(15.6)	(8.8)	(24.8)
Fair value reserve		(0.3)	(0.2)	(0.3)
Treasury share reserve		(0.2)	—	(0.2)
Retained losses		(563.5)	(536.3)	(557.8)
Other reserves		9.4	9.4	9.4
<b>Total shareholders' equity</b>		<b>(81.5)</b>	(70.4)	(89.8)

See Notes to the Interim Financial Statements.

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE SIX MONTHS ENDED 30 JUNE 2009

	Attributable to owners of the parent							Total shareholders' equity £m
	Share capital £m	Share premium £m	Translation reserve £m	Treasury Fair value reserve £m	share reserve £m	Retained losses £m	Other reserves £m	
As at 1 January 2009	96.7	387.2	(24.8)	(0.3)	(0.2)	(557.8)	9.4	(89.8)
Loss for the period	—	—	—	—	—	(6.1)	—	(6.1)
Other comprehensive loss	—	—	9.2	—	—	—	—	9.2
<b>Total comprehensive loss for the period</b>	—	—	9.2	—	—	(6.1)	—	3.1
Issue of share capital	1.8	3.0	—	—	—	—	—	4.8
Share-based payment charge	—	—	—	—	—	0.4	—	0.4
<b>At 30 June 2009</b>	<b>98.5</b>	<b>390.2</b>	<b>(15.6)</b>	<b>(0.3)</b>	<b>(0.2)</b>	<b>(563.5)</b>	<b>9.4</b>	<b>(81.5)</b>

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 31 DECEMBER 2008

	Attributable to owners of the parent							Total shareholders' equity £m
	Share capital £m	Share premium £m	Translation reserve £m	Treasury Fair value reserve £m	share reserve £m	Retained losses £m	Other reserves £m	
As at 1 January 2008	82.7	382.8	(4.1)	(0.2)	—	(529.8)	9.4	(59.2)
Loss for the period	—	—	—	—	—	(28.7)	—	(28.7)
Other comprehensive loss	—	—	(20.7)	—	—	—	—	(20.7)
<b>Total comprehensive loss for the period</b>	—	—	(20.7)	—	—	(28.7)	—	(49.4)
Issue of share capital	14.0	4.4	—	—	—	—	—	18.4
Own shares acquired during the period	—	—	—	—	(0.2)	—	—	(0.2)
Impairment	—	—	—	(0.1)	—	—	—	(0.1)
Share-based payment charge	—	—	—	—	—	0.8	—	0.8
Pension actuarial losses	—	—	—	—	—	(0.1)	—	(0.1)
<b>At 31 December 2008</b>	<b>96.7</b>	<b>387.2</b>	<b>(24.8)</b>	<b>(0.3)</b>	<b>(0.2)</b>	<b>(557.8)</b>	<b>9.4</b>	<b>(89.8)</b>

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE SIX MONTHS ENDED 30 JUNE 2008

	Attributable to owners of the parent							Total shareholders' equity £m
	Share capital £m	Share premium £m	Translation reserve £m	Fair value reserve £m	Retained losses £m	Other reserves £m		
As at 1 January 2008	82.7	382.8	(4.1)	(0.2)	(529.8)	9.4	(59.2)	
Loss for the period	—	—	—	—	(6.8)	—	(6.8)	
Other comprehensive loss	—	—	(4.7)	—	—	—	(4.7)	
<b>Total comprehensive loss for the period</b>	—	—	(4.7)	—	(6.8)	—	(11.5)	
Share-based payment charge	—	—	—	—	0.5	—	0.5	
Other	—	—	—	—	(0.2)	—	(0.2)	
<b>At 30 June 2008</b>	<b>82.7</b>	<b>382.8</b>	<b>(8.8)</b>	<b>(0.2)</b>	<b>(536.3)</b>	<b>9.4</b>	<b>(70.4)</b>	

See Notes to the Interim Financial Statements.

## CONDENSED CONSOLIDATED CASH FLOW STATEMENT

### FOR THE PERIOD ENDED 30 JUNE 2009

		<b>Unaudited</b> <b>6 months ended</b>	Unaudited 6 months ended	Audited Year ended
	Notes	<b>30 June</b> <b>2009</b> <b>£m</b>	30 June 2008 £m	31 December 2008 £m
<b>Cash flow from operating activities</b>				
Cash (used in)/generated by operations	(a)	<b>(0.1)</b>	(1.1)	5.1
Income tax paid		<b>(0.3)</b>	(0.4)	(0.6)
<b>Net cash generated by/(used in) operating activities</b>		<b>(0.4)</b>	(1.5)	4.5
<b>Cash flows from investing activities</b>				
Purchases of property, plant and equipment		<b>(3.7)</b>	(2.5)	(4.2)
Purchases of intangible assets		<b>(0.2)</b>	—	(0.1)
Interest received		<b>0.2</b>	0.6	0.9
<b>Net cash used in investing activities</b>		<b>(3.7)</b>	(1.9)	(3.4)
<b>Cash flows from financing activities</b>				
Repayments of borrowings		<b>(3.5)</b>	(1.2)	(3.0)
Interest paid		<b>(6.4)</b>	(6.5)	(13.2)
Net proceeds from issue of ordinary share capital		<b>—</b>	—	18.4
Bond modification cost		<b>—</b>	—	(4.3)
<b>Net cash used in by financing activities</b>		<b>(9.9)</b>	(7.7)	(2.1)
<b>Effect of exchange rate changes</b>		<b>0.6</b>	0.7	4.8
Net (decrease)/increase in net cash and cash equivalents		<b>(13.4)</b>	(10.4)	3.8
Net cash and cash equivalents at beginning of the year		<b>35.5</b>	31.7	31.7
Net (decrease)/increase in cash and cash equivalents		<b>(13.4)</b>	(10.4)	3.8
<b>Net cash and cash equivalents at end of the year</b>		<b>22.1</b>	21.3	35.5
<b>Analysis of net cash and cash equivalents:</b>				
Cash and cash equivalents		<b>22.1</b>	21.6	35.7
Bank overdraft		<b>—</b>	(0.3)	(0.2)
<b>Net cash and cash equivalents</b>		<b>22.1</b>	21.3	35.5

See Notes to the Interim Financial Statements.

## NOTES TO THE CONDENSED CONSOLIDATED CASH FLOW STATEMENT

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

	6 months ended 30 June 2009 £m	6 months ended 30 June 2008 £m	Year ended 31 December 2008 £m
Loss for the period	(6.1)	(6.8)	(28.7)
Adjustments for:			
Tax	0.3	0.4	0.6
Depreciation	1.5	2.3	4.7
Amortisation	0.3	0.2	0.7
Impairments	3.0	1.0	25.7
Finance costs	6.9	6.7	17.1
Finance income	(0.2)	(4.9)	(0.9)
Aborted transaction costs	—	—	1.5
Share-based payments charge	0.4	0.5	0.8
Exchange gains/(losses) on translation	2.2	—	(5.3)
Other non-cash charges	0.4	(4.0)	(1.5)
<b>Operating cash flows before movements in working capital</b>	<b>8.7</b>	<b>(4.6)</b>	<b>14.7</b>
<b>Changes in working capital</b>			
Increase in inventories	(1.2)	(0.4)	(0.1)
Increase in trade and other receivables	(7.6)	(3.1)	(2.3)
(Decrease)/increase in trade and other payables	0.7	4.2	(3.2)
(Decrease)/increase in deferred income	(0.7)	2.8	(4.0)
<b>Cash (used in)/generated by operations</b>	<b>(0.1)</b>	<b>(1.1)</b>	<b>5.1</b>

## NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

### 1 General information

The interim report of the Group for the six months ended 30 June 2009 ("Interim Report 2009") was authorised for issue in accordance with a resolution of the Directors on 20 August 2009. The Interim Report 2009 is unaudited but has been reviewed by the Auditors as set out in their report.

SkyePharma PLC (the "Company") and its subsidiaries (together the "Group") is a speciality pharmaceutical Group which uses its multiple drug delivery technologies to create enhanced versions of existing pharmaceutical products.

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

The financial information for the year ended 31 December 2008 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 has been delivered to the Registrar of Companies. The Auditors' opinion on those financial statements was unqualified, did not draw attention to any matters by way of an emphasis of matter paragraph, and it contained no statement under section 237 (2) or section 237 (3) of the Companies Act 1985.

### 2 Accounting policies (a) Basis of preparation

The interim report for the six months ended 30 June 2009 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 2009 should be read in conjunction with the Group's Annual Report for the year ended 31 December 2008, which has been prepared in accordance with IFRSs as adopted by the European Union.

#### *Going concern*

The Directors have made an assessment of the working capital requirements of the Group for the next twelve months, taking into account revenue projections, operating costs, finance costs, debt repayment obligations, potential obligations in respect of the approval of Flutiform™, proposed cost reduction actions and the risks inherent in such forecasts. After making appropriate enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the Interim Report.

#### *Significant accounting policies*

The same accounting policies, presentation and methods of computation are as those applied in the Group's 2008 annual report and accounts, except as described below:

#### ■ IFRS 8 — Segment reporting

IFRS 8 requires the disclosure of operating segments to be based on information used internally by management to assess the performance of, and allocate resources to the business. Previously primary (business) and secondary (geographical) segments were identified using a risks and returns approach.

## NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

### 2 Accounting policies continued

As a result the Group has identified that it has one operating segment, the development and manufacture of pharmaceutical products, consistent with the business segment identified under IAS 14 in the 2008 Annual Report. No changes to disclosure requirements for the Interim Report arose on adoption of IFRS 8.

#### ■ IAS 1 — Revised Presentation of Financial Statements

IAS 1 (revised) requires the presentation of a Statement of Changes in Equity (SOCIE) as a primary statement in the Group's accounts. In addition, the statement of comprehensive income is introduced, presented either within the consolidated income statement or as a separate primary statement. The Group has elected to present it as a separate statement.

#### ■ Other amendments to IFRS

Other amendments to IFRS, applicable to periods commencing from 1 January 2009 have had no effect on the results or disclosures of the Group.

#### ■ Reclassification of June 2008 income statement

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

- Cost of sales has decreased by £1.7 million to £9.6 million
- Selling, marketing and distribution has increased by £0.4 million to £0.7 million
- Research and development expenses have increased by £6.1 million to £16.7 million
- Corporate expenses (formerly called Administration expenses) have decreased by £4.9 million to £2.3 million
- Share-based payment charge of £0.5 million has been disclosed separately
- Finance income has decreased by £4.3 million to £0.6 million
- Foreign exchange gain on net debt of £4.7 million has been disclosed separately

The goodwill impairment charge of £1.0 million from the first half of 2008 has been reclassified from amortisation and impairment of intangibles to exceptional items to be consistent with the treatment at 31 December 2008.

#### ■ Reclassification of December 2008 income statement

Revaluation of the Paul Capital and CRC liabilities due to changes in payment timing estimates have been reclassified from finance costs to finance costs — revaluation, shown on the face of the consolidated income statement. The effect of this has been as follows:

- Finance costs — interest have decreased by £3.0 million to £14.1 million
- Finance costs — revaluation of £3.0 million has been disclosed separately

### 3 Segment information

For management reporting purposes, the Group is treated as one segment — the development and manufacture of pharmaceutical products.

### 4 Analysis of revenue

	Unaudited 6 months ended 30 June 2009 £m	Unaudited 6 months ended 30 June 2008 £m	Audited Year ended 31 December 2008 £m
Revenue earned is analysed as follows:			
Signing and milestone payments	1.8	5.3	12.4
Contract research and development costs recharged	4.8	3.4	8.0
Royalties	12.8	11.6	22.4
Manufacturing and distribution	6.1	8.1	19.4
<b>Total revenue</b>	<b>25.5</b>	<b>28.4</b>	<b>62.2</b>

### 5 Cost of sales

	Unaudited 6 months ended 30 June 2009 £m	(Restated) Unaudited 6 months ended 30 June 2008 £m	Audited Year ended 31 December 2008 £m
Manufacturing and distribution	6.6	9.3	19.0
Other cost of sales	0.4	0.3	0.6
<b>Total cost of sales</b>	<b>7.0</b>	<b>9.6</b>	<b>19.6</b>

### 6 Research & development expense

	Unaudited 6 months ended 30 June 2009 £m	(Restated) Unaudited 6 months ended 30 June 2008 £m	Audited Year ended 31 December 2008 £m
Clinical trials, supplies and other external costs directly recharged to development partners	2.0	1.5	3.3
Other external clinical trial and supply costs	1.0	6.0	7.0
Other research and development costs	7.3	9.2	14.8
<b>Total research and development expense</b>	<b>10.3</b>	<b>16.7</b>	<b>25.1</b>

## NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## 7 Exceptional items

	Unaudited 6 months ended 30 June 2009 £m	(Restated) Unaudited 6 months ended 30 June 2008 £m	Audited Year ended 31 December 2008 £m
<b>Exceptional income</b>			
Foradil® Certihaler® termination	5.0	—	—
<b>Total exceptional income</b>	<b>5.0</b>	<b>—</b>	<b>—</b>
<b>Exceptional expense</b>			
Foradil® Certihaler® termination	—	—	(5.9)
Restructuring charges	(1.5)	—	(0.8)
Goodwill impairment	(3.0)	(1.0)	(19.5)
Aborted transaction costs	—	(2.4)	(1.5)
Impairment on assets held for sale	—	—	(0.8)
<b>Total exceptional expense</b>	<b>(4.5)</b>	<b>(3.4)</b>	<b>(28.5)</b>

The exceptional income of £5.0 million on the termination of the Foradil® Certihaler® contracts consists of an amount receivable from Novartis, net of an amount payable to a subcontractor and costs related to the termination as described in Note 17: Post-balance sheet events. The amounts receivable and payable on termination were settled in July 2009. In the year ended 31 December 2008 a non-cash exceptional charge of £5.9 million arose, relating to the impairment of assets related to the Foradil® Certihaler®.

At 30 June 2009 the Group incurred a non-cash impairment charge of £3.0 million (31 December 2008: £19.5 million), on the IDD® goodwill. The charge has arisen due to exchange translation effects and the anticipated end of life of Triglide® now being six months nearer than at 31 December 2008.

The exceptional charge of £1.5 million for the first half of 2009 primarily consists of employee termination costs and professional fees related to the previously announced restructuring of the manufacturing facility in Lyon, France and the research and development facility in Muttenz, Switzerland.

## 8 Finance costs and income

	Unaudited 6 months ended 30 June 2009 £m	(Restated) Unaudited 6 months ended 30 June 2008 £m	(Restated) Audited Year ended 31 December 2008 £m
<b>Finance cost — interest:</b>			
Interest:			
Bank borrowings	(0.2)	(0.2)	(0.4)
Paul Capital finance	(1.5)	(1.2)	(2.7)
CRC finance	(2.1)	(2.1)	(4.5)
Convertible bonds	(3.1)	(3.2)	(6.5)
<b>Total finance cost — interest</b>	<b>(6.9)</b>	<b>(6.7)</b>	<b>(14.1)</b>
<b>Finance cost — revaluation:</b>			
Loss on revaluation of liabilities due to Paul Capital and CRC	(2.0)	—	(3.0)
<b>Total finance cost — revaluation</b>	<b>(2.0)</b>	<b>—</b>	<b>(3.0)</b>

The loss on revaluation of the Paul Capital finance of £2.0 million in 2009 (H1 2008: Nil) reflects revised estimates of the payments expected to be made by Pacira as detailed in Note 13: Borrowings.

	Unaudited 6 months ended 30 June 2009 £m	(Restated) Unaudited 6 months ended 30 June 2008 £m	(Restated) Audited Year ended 31 December 2008 £m
<b>Finance income:</b>			
Interest income	0.2	0.6	0.9
<b>Total finance income</b>	<b>0.2</b>	<b>0.6</b>	<b>0.9</b>

## 9 Foreign exchange on net debt

	Unaudited 6 months ended 30 June 2009 £m	(Restated) Unaudited 6 months ended 30 June 2008 £m	(Restated) Audited Year ended 31 December 2008 £m
Foreign exchange gain/(loss) on net debt:			
Paul Capital finance	(0.9)	2.1	1.6
CRC finance	(1.3)	2.2	3.7
Foreign denominated cash balances	(0.3)	0.4	0.4
<b>Total foreign exchange gain/(loss) on net debt</b>	<b>(2.5)</b>	<b>4.7</b>	<b>5.7</b>

## NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

### 10 Earnings per share

Earnings per share is calculated based on the following information:

	6 months ended	(Restated) 6 months ended	Year ended
	30 June	30 June	31 December
	2009	2008	2008
	£m	£m	£m
Attributable loss before exceptional items	(6.6)	(3.4)	(0.2)
Exceptional items	0.5	(3.4)	(28.5)
Basic and diluted attributable loss	(6.1)	(6.8)	(28.7)

	Number	(Restated) Number	Number
	m	m	m
Basic and diluted weighted average number of shares in issue	22.8	8.1	11.6
Loss per Ordinary Share before exceptional items	(28.9)p	(42.0)p	(1.7)p
Exceptional items	2.2p	(42.0)p	(245.7)p
Basic and diluted loss per Ordinary Share	(26.7)p	(84.0)p	(247.4)p

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.

Deferred 'B' shares and deferred 'C' shares have been excluded from the weighted average number of shares.

### 11 Goodwill

Group	Total £m
<b>Cost</b>	
At 1 January 2009	33.7
At 1 January 2009 and 30 June 2009	33.7
<b>Accumulated amortisation</b>	
At 1 January 2009	25.9
Impairment	3.0
<b>At 30 June 2009</b>	28.9
<b>Net book value</b>	
<b>At 31 December 2008</b>	7.8
<b>At 30 June 2009</b>	4.8

For the six months to 30 June 2009 the Group incurred a non-cash impairment charge of £3.0 million (Year ended 31 December 2008: £19.5 million), on the IDD® goodwill, as disclosed in Note 7: Exceptional items.

No changes have been made to the assumptions supporting the value in use calculation. The impairment charge has arisen due to exchange translation effects and the anticipated end of life of Triglide® now being 6 months nearer than at 31 December 2008.

## 12 Non-current assets classified as held for sale

The Group continues to be in discussions with a view to transferring the responsibility and most of the risks of the Flutiform™ supply chain to a third party.

As at 30 June 2009 the Group had capitalised assets held at their net realisable value of £6.8 million (31 December 2008: £3.9 million) related to the supply chain, of which £1.3 million has been funded and reimbursed to our partners.

For the year ended 31 December 2008 the Group had incurred an impairment of £0.8 million for foreign exchange losses expected to be incurred on the sale, and other associated costs. The charge was included within exceptional items in the 2008 Income Statement. No such charge arose in the first half of 2009.

## 13 Borrowings

	As at 30 June 2009 £m	As at 30 June 2008 £m	As at 31 December 2008 £m
<b>Current</b>			
Bank overdraft & borrowings	1.1	1.3	1.4
Property mortgage	0.3	0.3	0.4
Paul Capital finance	8.5	5.4	7.4
CRC finance	9.2	0.9	3.5
Finance lease liabilities	0.1	—	0.1
<b>Total current borrowings</b>	<b>19.2</b>	<b>7.9</b>	<b>12.8</b>
<b>Non-current</b>			
Convertible bonds due May 2024	45.9	51.9	50.5
Convertible bonds due June 2025	12.3	13.1	12.2
<b>Convertible bonds</b>	<b>58.2</b>	<b>65.0</b>	<b>62.7</b>
Property mortgage	7.1	6.6	8.6
Paul Capital finance	16.9	14.6	21.2
CRC finance	32.9	36.8	46.0
Finance lease liabilities	0.1	0.1	0.2
<b>Other non-current borrowings</b>	<b>57.0</b>	<b>58.1</b>	<b>76.0</b>
<b>Total non-current borrowings</b>	<b>115.2</b>	<b>123.1</b>	<b>138.7</b>
<b>Total borrowings</b>	<b>134.4</b>	<b>131.0</b>	<b>151.5</b>

### Convertible bonds

In the six months ended 30 June 2009 a total of 6,587 6 per cent 2024 convertible bonds with a principal value of £6.6 million were converted into ordinary shares at the conversion price of £3.71 per share. This resulted in the issue of 1,775,467 ordinary shares.

The remaining bonds are included partly in non-current liabilities (30 June 2009: £58.2 million, 31 December 2008: £62.7 million) and partly in share premium (30 June 2009 and 31 December 2008: £28.5 million). The total face value of the outstanding convertible bonds as at 30 June 2009 was £83.0 million (31 December 2008: £89.6 million).

### Paul Capital

The loss on revaluation of the Paul Capital Finance of £2.0 million in 2009 (H1 2008: Nil) reflects revised estimates of the payments expected to be made by Pacira (on sales of Depocyt® and DepoDur™) to Paul Capital. This results in higher residual amounts to be funded by the Group.

## NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

### 13 Borrowings continued CRC

A total of £5.4 million has been classified as current liabilities, although this amount is only payable in the next twelve months to CRC to the extent that the Flutiform™ US approval milestone is received in that timescale.

### 14 Provisions

	As at 30 June 2009 £m	As at 30 June 2008 £m	As at 31 December 2008 £m
<b>Group</b>			
At 1 January 2009	3.7	2.2	2.2
Exchange	(0.5)	0.2	1.0
Actuarial losses	—	—	0.1
Charge for the period	0.1	—	0.4
Released	(0.4)	—	—
<b>At 30 June 2009</b>	<b>2.9</b>	<b>2.4</b>	<b>3.7</b>

The provision primarily relates to the Group's retirement commitments under its pension scheme in respect of its employees in Switzerland and the Group's leaving indemnity commitments in respect of its employees in France.

### 15 Share capital

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

Issued and fully paid	Ordinary Shares Nominal value		Deferred 'B' shares Nominal value		Deferred 'C' shares Nominal value		Total £m
	Number	£m	Number	£m	Number	£m	
At 1 January 2009	22,167,695	22.2	12,000,000	1.2	7,334,899,200	73.3	96.7
Shares issued	1,775,467	1.8	—	—	—	—	1.8
At 30 June 2009	23,943,162	24.0	12,000,000	1.2	7,334,899,200	73.3	98.5

#### Issue of shares

In 2009 issued ordinary share capital was increased by 1,775,467 as a result of the conversion of certain convertible bonds.

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

## **16 Contingencies and commitments**

At 31 December 2008 the Group disclosed a contingency associated with the termination of the collaboration, manufacturing and supply agreements for the Foradil® Certihaler™. As disclosed in Note 17: Post-balance sheet events, this contingency has been resolved.

The Group has further capital commitments due within the next 12 months, not contractually funded by Partners, totalling €3.2 million (£2.7 million) relating to the Flutiform™ supply chain. As indicated in Note 12: Non-current assets held for sale, these are expected to be sold at cost as part of the negotiations to transfer the responsibility and most of the risks of the Flutiform™ supply chain to a third party. However, a small exchange loss may be incurred as a result of currency fluctuations.

## **17 Post-balance sheet events**

On 17 July 2009 the Group announced that it had reached agreement with Novartis Pharma AG and a subcontractor on immediate termination of the contracts relating to Foradil® Certihaler®. The net effect of the termination has resulted in an exceptional gain of approximately £5.0 million included in the results to June 2009, as disclosed in Note 7: Exceptional items.

## INDEPENDENT REVIEW REPORT TO SKYEPHARMA PLC

### Introduction

We have been engaged by the Company to review the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2009 which comprises condensed consolidated income statement, condensed consolidated statement of comprehensive income, condensed consolidated balance sheet, condensed consolidated statement of changes in equity, condensed consolidated cash flow statement and related explanatory notes that have been reviewed. We have read the other information contained in the half yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial statements.

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 half-yearly financial report is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the half-yearly financial report in accordance with the Disclosure and Transparency Rules of the United Kingdom's Financial Services Authority.

As disclosed in Note 2: Accounting policies, the annual financial statements of the Group are prepared in accordance with IFRSs as adopted by the European Union. The condensed set of financial statements included in this half-yearly financial 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 set of financial statements in the half-yearly financial 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 set of financial statements in the half-yearly financial report for the six months ended 30 June 2009 is 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.

### Ernst & Young LLP

Reading  
20 August 2009



# SkyePharma PLC

## Making good drugs better

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