

## Shire's new product portfolio delivers strong quarterly performance

October 29, 2008 – Shire plc (LSE: SHP, NASDAQ: SHPGY) the global specialty biopharmaceutical company announces results for the three months to September 30, 2008.

### Q3 2008 Financial Highlights

- Product sales up 31% to \$713 million
- Product sales excluding ADDERALL XR<sup>®</sup> up 51% to \$444 million
- New product sales<sup>(1)</sup> \$276 million, 39% of product sales (2007: 22%)
- Total revenues up 28% to \$779 million
- Non GAAP earnings<sup>(2)</sup> per ADS up 88% to \$1.17 (2007: \$0.62)
- US GAAP earnings<sup>(2)</sup> per ADS down 62% to \$0.07 (2007: \$0.19)

(1) New product sales comprise DAYTRANA<sup>®</sup>, ELAPRASE<sup>®</sup>, FIRAZYR<sup>®</sup>, FOSRENOL<sup>®</sup>, LIALDA<sup>®</sup> / MEZAVANT<sup>®</sup> and VYVANSE<sup>®</sup>

(2) Earnings from continuing operations

### Angus Russell, Chief Executive Officer, commented:

"Shire had another very strong quarter across its business. Product sales were up 31% and Non GAAP earnings per ADS rose 88%, compared with the same period last year.

"Our new products continued to underpin this growth, generating revenues of \$276 million, representing 39% of our total product sales and exceeding ADDERALL XR sales for the first time. The performance of ELAPRASE, VYVANSE, LIALDA and FOSRENOL ROW were particularly strong. This quarter FIRAZYR was made available in Germany and the UK. We remain confident that these products will continue to deliver strong growth, driven in part by our geographical expansion into the important emerging markets.

"Shire remains highly cash generative, supporting the investment we continue to make in developing our substantial pipeline of products and in expanding the reach of our existing portfolio. We have a robust balance sheet, good liquidity, and strong cash flow, with \$279 million of cash flows from operating activities in the third quarter alone.

"We are in a strong position as we look ahead to the end of 2008 and beyond, with an excellent portfolio and pipeline for future growth, developed around our focused specialty biopharmaceutical strategy."

## Q3 2008 Unaudited Results

	Q3 2008			Q3 2007		
	US GAAP	Adjustments	Non GAAP <sup>(1)</sup>	US GAAP	Adjustments	Non GAAP <sup>(1)</sup>
	\$M	\$M	\$M	\$M	\$M	\$M
<b>Revenues</b>	<b>778.6</b>	<b>-</b>	<b>778.6</b>	608.7	-	608.7
<b>Operating income</b>	<b>122.9</b>	<b>155.7</b>	<b>278.6</b>	22.6	126.0	148.6
<b>Net income</b>	<b>11.8</b>	<b>204.2</b>	<b>216.0</b>	34.7	83.7	118.4
<b>Diluted earnings per:</b>						
<b>Ordinary share</b>	<b>2.2c</b>	<b>36.9c</b>	<b>39.1c</b>	6.3c	14.5c	20.8c
<b>ADS</b>	<b>6.6c</b>	<b>110.7c</b>	<b>117.3c</b>	18.9c	43.5c	62.4c

Note: Average exchange rates for Q3 2008 and Q3 2007 were \$1.89: £1.00 and \$2.02: £1.00, respectively.

- (1) Non GAAP operating income, Non GAAP net income, Non GAAP diluted earnings per ordinary share and Non GAAP diluted earnings per ADS exclude intangible asset amortization charges and other items as described on page 5. For an explanation of why Shire's management believes that these Non GAAP financial measures are useful to investors, see page 5. For a reconciliation of these Non GAAP financial measures to the most directly comparable financial measures prepared in accordance with US GAAP, see pages 24-28.

## 2008 Updated Financial Outlook

Based on the continued positive sales trends in the third quarter we are able to reiterate the **2008** revenue growth of at least 20% and we also reaffirm the cost guidance given as part of the second quarter 2008 results.

- Guidance, published with our second quarter results, for net sales of VYVANSE for 2008 was the lower end of a range of \$350 to \$400 million. We have highlighted a number of variables that would impact the sales growth of VYVANSE during the second half of the year and beyond. We are pleased with the consistent market share gains that VYVANSE has achieved in the third quarter and during the start of the fourth quarter. Based on current sales trends we now believe that 2008 VYVANSE net sales will be in the range of current published analyst estimates of \$310m to \$330m.

We are encouraged that VYVANSE has now achieved a market share of 10.2% in the week ending October 17th, which represents an annual net sales run rate of over \$370m. Based on the current US ADHD market gross sales value of \$4bn, each 1% increase in VYVANSE's market share currently represents an additional \$36m of annual net sales.

- The costs associated with the launch of FIRAZYR in the EU and continued development of FIRAZYR in the US are now included within our previous guidance ranges. Previous guidance excluded all Jerini AG ("Jerini") related costs.

## 2009 Financial Outlook

Anticipation of generic competition to ADDERALL XR during 2009 has led to a wide range of external earnings estimates for **2009**. To address this, we are providing one time high level confirmation of our expectations for 2009.

Our plans for 2009, based on 2008 year to date actual foreign exchange rates (€1:\$1.52, £1:\$1.95) support a Non GAAP diluted earnings per ADS for 2009 in the range of \$3.00 to \$3.40. This is in line with many market estimates. In recent weeks we have seen significant movements in foreign exchange rates. Each 10c movement in the Euro:\$ and £:\$ exchange rates impacts Shire's Non GAAP diluted earnings per ADS by \$0.10 and \$0.01 respectively. If rates in 2009 were to average €1:\$1.35 and £1:\$1.70, Non GAAP diluted earnings per ADS would be in the range of \$2.80 to \$3.20.

Shire's management expects that the new product portfolio will continue to deliver strong, high margin growth throughout 2009 and 2010 and provide the platform for future revenue and earnings growth. There are a number of variables that can impact the exact rate of erosion of ADDERALL XR's sales and we have

contingency plans in place to cover these different outcomes. While we will continue to invest in the future growth drivers of the business, our discretionary cost base will be tightly managed to deliver expected earnings.

The following items are excluded from net income/(loss) from continuing operations in calculating both 2008 and 2009 Non GAAP diluted earnings:

- Intangible asset amortization and impairment charges;
- Gains and losses on the sale of non-core assets;
- Upfront payments and milestones in respect of in-licensed and acquired products (including the 2008 payment to Zymenex A/S (“Zymenex”) for METAZYM of \$135 million);
- Termination costs (including the 2008 intangible asset impairment charges, write downs and exit costs of \$150m associated with DYNEPO®);
- Costs associated with the introduction of the new holding company;
- Costs associated with the acquisition and integration of companies, and acquired in-process research and development charges (including Jerini in Q3 2008);
- Other than temporary impairment of investments (including \$54 million impairment in Q3 2008); and
- Taxes associated with these items.

Depreciation, which is included in cost of product sales, R&D costs and selling, general and administrative costs in our GAAP results, has been separately disclosed for the presentation of 2008 Non GAAP earnings (see pages 24 to 28).

## Product Highlights

New Product Launches - subject to obtaining the relevant regulatory/governmental approvals, product launches planned over the next two years include:

- MEZAVANT® (mesalazine) for use in the treatment of ulcerative colitis in certain European Union (“EU”) countries during 2008 and 2009;
- FIRAZYR® (icatibant) which was launched in Germany and the UK in Q3, following the receipt of marketing authorization from the European Commission. Launches will continue across Europe as reimbursement negotiations proceed. FIRAZYR has orphan designation and is the first hereditary angiodema (“HAE”) product to receive approval throughout the European Union;
- INTUNIV™ (guanfacine) for use in children and adolescents in the US in 2009;
- FOSRENOL® (lanthanum carbonate) in the pre-dialysis Chronic Kidney Disease (“CKD”) market in the US in 2009 subject to ongoing discussions with the FDA regarding regulatory pathway for approval;
- DAYTRANA® (methylphenidate transdermal system) for use in children in the EU in 2009 and adolescents in the US in 2010; and
- Velaglycerase alfa for the treatment of Gaucher disease in the US and the EU in 2010.

## Update on Current Portfolio

VYVANSE® (lisdexamfetamine dimesylate) – Attention Deficit and Hyperactivity Disorder (“ADHD”)

- The launch of VYVANSE for adult ADHD in June 2008 has helped to make VYVANSE the third highest prescribed ADHD product in the US. For the nine months to September 30, 2008 VYVANSE net sales totaled \$215.6 million.
- On July 2, 2008 Shire shipped to wholesalers stocks of three additional dosage strengths (20mg, 40mg and 60mg) for VYVANSE representing product sales of approximately \$24 million. These net product sales have been recognized into revenue in Q3 2008.

FOSRENOL® Hyperphosphatemia

- FOSRENOL was approved in Japan in October 2008. Shire’s out-licensee, Bayer Yakuin Limited, is now progressing pricing and reimbursement negotiations in that market.

## Pipeline Highlights

### FIRAZYR - HAE

- Jerini received a not approvable letter for FIRAZYR for use in the US from the US Food and Drug Administration (“FDA”) in April 2008, and plans to provide a complete response by the end of the year.

### JUVISTA® - Improvement of scar appearance

- Renovo Limited (“Renovo”) intends to initiate its first pivotal European Phase 3 trial in scar revision in the fourth quarter of 2008 in support of Renovo’s filing of a European regulatory dossier. If the outcome from Renovo’s multi centre, EU Phase 3 study is suitably positive, the data will be used to inform the strategy and design of Shire’s US development plan and to strengthen the chances of regulatory and commercial success in the US.

### METAZYM (HGT-1111) - Metachromatic Leukodystrophy (“MLD”)

- Shire has an ongoing enzyme replacement therapy program for the treatment of MLD, which is a lysosomal storage disorder that results from a deficiency in the enzyme arylsulfatase-A (“ASA”). METAZYM, a clinical candidate ASA acquired from Zymenex in the second quarter of 2008, has completed a Phase 1b clinical trial in 12 MLD patients in Europe and an extension to this study is ongoing. The product has been granted orphan drug designation in the US and in the EU. The current plan is to initiate a Phase 2/3 clinical trial as soon as possible following discussions with regulatory authorities in Q4 2008.

## Business Highlights

### Acquisition of Jerini

- During Q3 2008 Shire acquired a majority voting interest in Jerini and published an Offer Document in respect of acquiring the remaining shares in Jerini that it did not already own. By September 30, 2008 Shire had acquired over 90% of the shares in Jerini and now owns approximately 93% of the shares. The acquisition has added Jerini’s HAE product, FIRAZYR, to the portfolio.

### Sale of non-core assets

- Following the transfer of the relevant marketing consents Shire recognised previously deferred gains of \$4 million arising from the divestment of non-core products to Laboratorios Almirall S.A (“Almirall”) in 2007.

### HGT analyst day

Shire is holding an analyst day on November 18, 2008 in Lexington, Massachusetts

Please visit [www.shire.com](http://www.shire.com) for registration and additional information

### For further information please contact:

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Dial in details for the live conference call for investors 14:00 GMT/10:00 EDT on October 29, 2008:

UK and International dial in: 44 (0)20 7806 1951

US dial in: +1 718 354 1385

Password/Conf ID: 4688205

Live Webcast: <http://www.shire.com/shire/InvestorRelations/presentations.jsp?tn=2&m1=21>

## Notes to editors

### SHIRE PLC

Shire's strategic goal is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit hyperactivity disorder (ADHD), human genetic therapies (HGT) and gastrointestinal (GI) diseases as well as opportunities in other therapeutic areas to the extent they arise through acquisitions. Shire's in-licensing, merger and acquisition efforts are focused on products in specialist markets with strong intellectual property protection and global rights. Shire believes that a carefully selected and balanced portfolio of products with strategically aligned and relatively small-scale sales forces will deliver strong results.

For further information on Shire, please visit the Company's website: [www.shire.com](http://www.shire.com)

### THE "SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Statements included herein that are not historical facts are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, the Company's results could be materially affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of pharmaceutical research, product development, manufacturing and commercialization including, but not limited to, the establishment in the market of VYVANSE<sup>®</sup> (lisdexamfetamine dimesylate) (Attention Deficit and Hyperactivity Disorder ("ADHD")); the impact of competitive products, including, but not limited to, the impact of those on the Company's ADHD franchise; patents, including but not limited to, legal challenges relating to the Company's ADHD franchise; government regulation and approval, including but not limited to the expected product approval date of INTUNIV<sup>™</sup> (guanfacine extended release) (ADHD); the Company's ability to secure new products for commercialization and/or development; the Company's ability to successfully integrate its stake in Jerini AG, as well as realize the anticipated benefits of the acquisition; and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K for the year ended December 31, 2007.

### Non GAAP Measures

This press release contains financial measures not prepared in accordance with US GAAP. These measures are referred to as "Non GAAP" measures and include: *Non GAAP operating income; Non GAAP net income; Non GAAP diluted earnings per ordinary share; Non GAAP diluted earnings per ADS; effective tax rate on Non GAAP income; Non GAAP Cost of Product Sales; Non GAAP Research and Development; and Non GAAP Selling, general and administrative.* These Non GAAP measures exclude the effect of certain cash and non-cash items, both recurring and non-recurring, that Shire's management believes are not related to the core performance of Shire's business.

These Non GAAP financial measures are used by Shire's management to make operating decisions because they facilitate internal comparisons of the Company's performance to historical results and to competitors' results. These measures are also considered by Shire's Remuneration Committee in assessing the performance and compensation of employees, including its executive directors.

The Non GAAP measures are presented in this press release as the Company's management believe that they will provide investors with a means of evaluating, and an understanding of how Shire's management evaluates, the Company's performance and results on a comparable basis that is not otherwise apparent on a US GAAP basis, since many one-time, infrequent or non-cash items that the Company's management believe are not indicative of the core performance of the business may not be excluded when preparing financial measures under US GAAP.

These Non GAAP measures should not be considered in isolation from, as substitutes for, or superior to financial measures prepared in accordance with US GAAP.

The following are trademarks either owned or licensed by Shire plc or companies within the Shire group which are the subject of trademark registrations in certain territories, or which are owned by third parties as indicated and referred to in this press release:

<b>Product</b>	<b>Active ingredient</b>
ADDERALL <sup>®</sup> XR	(mixed salts of a single-entity amphetamine)
AMIGAL <sup>™</sup>	(migalastat hydrochloride) (trademark of Amicus Therapeutics (“Amicus”))
CALCICHEW <sup>®</sup> range	(calcium carbonate with or without Vitamin D <sub>3</sub> )
CARBATROL <sup>®</sup>	(carbamazepine - extended-release capsules)
COMBIVIR <sup>®</sup>	(lamivudine) (trademark of GlaxoSmithKline (“GSK”))
DAYTRANA <sup>®</sup>	(methylphenidate transdermal system)
DYNEPO <sup>®</sup>	(epoetin delta) (trademark of Sanofi-Aventis)
ELAPRASE <sup>®</sup>	(idursulfase)
EPIVIR <sup>®</sup>	(lamivudine) (trademark of GSK)
EPZICOM <sup>®</sup> /KIVEXA (EPZICOM)	(lamivudine) (trademark of GSK)
FIRAZYR <sup>®</sup>	(icatibant)
FOSRENOL <sup>®</sup>	(lanthanum carbonate)
INTUNIV <sup>™</sup>	(guanfacine – extended release)
JUVISTA <sup>®</sup>	(human TGFβ <sub>3</sub> ) (trademark of Renovo)
LIALDA <sup>®</sup>	(mesalamine)
MEZAVANT <sup>®</sup>	(mesalazine)
PENTASA <sup>®</sup>	(mesalamine) (trademark of Ferring)
PLICERA <sup>™</sup>	(isofagomine tartrate) (trademark of Amicus)
RAZADYNE <sup>®</sup>	(galantamine) (trademark of Johnson & Johnson (“J&J”))
RAZADYNE <sup>®</sup> ER	(galantamine) (trademark of J&J)
REMINYL <sup>®</sup>	(galantamine hydrobromide) (UK and Republic of Ireland)
REMINYL <sup>®</sup>	(galantamine) (trademark of J&J, excluding UK and Republic of Ireland)
REMINYL XL <sup>™</sup>	(galantamine hydrobromide) (UK and Republic of Ireland)
REMINYL XL <sup>™</sup>	(galantamine) (trademark of J&J, excluding UK and Republic of Ireland)
REPLAGAL <sup>®</sup>	(agalsidase alfa)
VYVANSE <sup>®</sup>	(lisdexamfetamine dimesylate)
XAGRID <sup>™</sup>	(anagrelide hydrochloride)
ZEFFIX <sup>®</sup>	(lamivudine) (trademark of GSK)
3TC <sup>®</sup>	(lamivudine) (trademark of GSK)

## OVERVIEW OF US GAAP FINANCIAL RESULTS

### 1. Introduction

#### Summary of Q3 2008

Revenues from continuing operations for the three months to September 30, 2008 increased by 28% to \$778.6 million (2007: \$608.7 million).

Operating income from continuing operations for the three months to September 30, 2008 was \$122.9 million, an increase of \$100.3 million over 2007 (2007: \$22.6 million). The increase in operating income was due to higher revenues and improved operating cost ratios in 2008 over the same period in 2007.

Cash inflow from operating activities for the three months to September 30, 2008 increased by 126% to \$279.4 million (2007: \$123.7 million) due to strong cash generation from operations. Excluding the up-front payment of \$75.0 million made to Renovo in respect of JUVISTA in Q3 2007, cash inflow from operating activities increased by \$80.7 million.

Cash, cash equivalents and restricted cash at September 30, 2008 totaled \$505.1 million (December 31, 2007: \$802.0 million). Cash, cash equivalents and restricted cash decreased by \$296.9 million during the nine months to September 30, 2008 as the strong cash inflow from operating activities was offset by the cash cost of acquiring a majority voting interest in Jerini (\$462.5 million, net of cash acquired), investment in the new HGT manufacturing plant in Lexington, Massachusetts, the final milestone payment to Noven Pharmaceuticals Inc. ("Noven") for DAYTRANA, dividend payments and payments to acquire shares by the Employee Share Ownership Trust ("ESOT").

### 2. Product sales

For the three months to September 30, 2008 product sales increased by 31% to \$712.5 million (2007: \$543.1 million) and represented 92% of total revenues (2007: 89%).

#### Product Highlights

Product	Sales \$M	Sales Growth <sup>(2)</sup>	US Rx Growth <sup>(1) (2)</sup>	US Average Quarterly Market Share <sup>(1)</sup>
<b>Specialty Pharmaceuticals</b>				
ADDERALL XR	268.7	8%	-5%	22.3%
VYVANSE	96.0	806%	n/a	9.0%
DAYTRANA	18.1	93%	-14%	1.6%
LIALDA / MEZAVANT	40.4	148%	+143%	12.7%
PENTASA	49.2	13%	0%	16.6%
FOSRENOL	43.0	50%	-1%	8.1%
XAGRID	19.4	15%		
<b>Human Genetic Therapies</b>				
ELAPRASE	78.2	42%		
REPLAGAL	44.6	10%		
FIRAZYR	0.2	n/a		

(1) Product specific prescription data is provided by IMS Health ("IMS"), a leading global provider of business intelligence for the pharmaceutical and healthcare industries. All other US market share data stated in the text below is also provided by IMS.

(2) Compared to Q3 2007.

#### Specialty Pharmaceuticals

##### US ADHD market share

Shire's average quarterly market share of the US ADHD market rose to 32.9% in the three months to September 30, 2008 (2007: 29.7%), driven by the continued growth in market share of VYVANSE. The overall US ADHD market grew by 8% in the same period. Shire has the leading portfolio of products in the US ADHD market.

##### ADDERALL XR – ADHD

As a result of the launch of VYVANSE in July 2007, ADDERALL XR's average quarterly market share of the US ADHD market for Q3 2008 fell to 22.3% (2007: 25.2%), a decrease of 12% compared to the same period in 2007. US prescriptions for ADDERALL XR in the three months to September 30, 2008

decreased by 5% compared to the same period in 2007 due to the 12% decrease in the average market share offset by 8% growth in the US ADHD market.

Sales of ADDERALL XR for the three months to September 30, 2008 were \$268.7 million, an increase of 8% compared to the same period in 2007 (2007: \$249.0 million). Product sales grew despite the decline in US prescriptions primarily due to price increases.

Litigation proceedings concerning Shire's ADDERALL XR patents are ongoing. Further information on this litigation can be found in our filings with the US Securities and Exchange Commission ("SEC") including our Annual Report on Form 10-K for the year to December 31, 2007.

## **VYVANSE – ADHD**

VYVANSE was launched in the US market in July 2007. Product sales for the three months to September 30, 2008 were \$96.0 million (2007: \$10.6 million) representing a 47% increase compared to sales of \$65.2 million in Q2 2008.

Product sales growth was driven by a 19% increase in prescription demand compared to Q2 2008, a price increase and the stocking impact of the new dosage strengths. For the three months to September 30, 2008 VYVANSE's average quarterly market share was 9.0% (2007: 2.4%) of the US ADHD market.

By October 17, 2008 VYVANSE had achieved a US ADHD average weekly market share of 10.2%, based on weekly prescription volumes.

## **DAYTRANA – ADHD**

Product sales for the three months to September 30, 2008 were \$18.1 million (2007: \$9.4 million). Prescriptions declined by 14% from the same period last year due to a reduction in DAYTRANA's average quarterly market share of the US ADHD market to 1.6% (2007: 2.1%).

Despite the decrease in prescriptions compared to 2007, sales of DAYTRANA grew 93% compared to the same period last year due to lower sales deductions in 2008 over 2007, when a provision was made for returns following the voluntary market withdrawal of a limited number of DAYTRANA patches.

On August 19, 2008 Shire announced a voluntary recall of two lots of DAYTRANA patches because these patches did not meet their release liner removal specifications which may have resulted in some patients and caregivers having difficulties removing the liners. The voluntary recall was not due to safety issues. Shire and Noven (the manufacturer of DAYTRANA) continue to pursue enhancements to the product and to work closely with the FDA to implement changes that may improve the usability of DAYTRANA. No interruption in the production of DAYTRANA is anticipated. Shire and Noven may take additional corrective action.

## ***US oral mesalamine market share***

Shire's average quarterly market share of the US oral mesalamine market rose to 29.3% in the three months to September 30, 2008 (2007: 22.5%), driven by the growth of LIALDA since its launch in March 2007. The overall US oral mesalamine market grew by 2.4% in the same period.

## **LIALDA/MEZAVANT – Ulcerative colitis**

Shire launched LIALDA in the US oral mesalamine market in March 2007, and during the three months to September 30, 2008 LIALDA had reached an average quarterly market share of 12.7% (2007: 5.4%). Product sales of LIALDA in the US for the three months to September 30, 2008 were \$38.6 million (2007: \$16.3 million).

Sales of MEZAVANT outside the US for the three months ended September 30, 2008 were \$1.8 million (2007: \$nil). As of September 30, 2008 LIALDA/MEZAVANT was available in five EU countries. Launches are planned in other countries during 2008 and 2009, subject to the successful conclusion of pricing and reimbursement negotiations.



## **PENTASA – Ulcerative colitis**

Sales of PENTASA in the US for the three months to September 30, 2008 were \$49.2 million, an increase of 13% compared to the same period in 2007 (2007: \$43.7 million). During the three months to September 30, 2008 Pentasa had an average market share of 16.6% (2007: 17.1%). Sales grew despite flat prescriptions due to the impact of price increases.

## **FOSRENOL – Hyperphosphatemia**

FOSRENOL is now available in 29 countries and global sales totaled \$43.0 million for the three months to September 30, 2008 (2007: \$28.7 million). US sales of FOSRENOL for the three months to September 30, 2008 were up 50% to \$24.5 million compared to the same period in 2007 (2007: \$16.3 million). Sales of FOSRENOL outside the US for the same period were up 49% to \$18.5 million (2007: \$12.4 million) with favourable exchange rate movements against the US dollar accounting for 8%.

FOSRENOL's average quarterly prescription share of the US phosphate binder retail market decreased to 8.1% for the three months to September 30, 2008 (2007: 8.5%). Product sales increased despite the decrease in prescriptions due to price increases and an increase in FOSRENOL's share of the non retail market (increased to 16% in August 2008 compared to 12% in August 2007) as a consequence of focusing on specialist physicians in clinics and dialysis centers.

## **XAGRID – Thrombocytopenia**

Sales for the three months to September 30, 2008 were \$19.4 million, an increase of 15% compared to the same period in 2007 (2007: \$16.8 million). Expressed in transaction currencies (XAGRID is primarily sold in Euros and Pounds Sterling), sales increased by 11% due to growth in many of Shire's existing markets, with exchange rate movements against the US dollar accounting for the remaining 4% increase.

## ***Human Genetic Therapies***

### **ELAPRASE – Hunter syndrome**

Sales for the three months to September 30, 2008 were \$78.2 million, an increase of 42% compared to the same period in 2007 (2007: \$55.1 million). The sales growth was primarily driven by increased unit sales in North America, EU, Latin America, and the Asia Pacific. The product is now approved for marketing and commercial distribution in 42 countries. Exchange rate movements against the US dollar contributed 5% to the growth compared to the prior year.

### **REPLAGAL – Fabry disease**

Sales for the three months to September 30, 2008 were \$44.6 million, an increase of 10% compared to the same period in 2007 (2007: \$40.7 million). The sales growth was primarily driven by increased unit sales in the EU and Asia Pacific. The product is now approved for marketing and commercial distribution in 43 countries. Exchange rate movements against the US dollar contributed 5% to the growth compared to the prior year.

### **FIRAZYR – HAE**

In September 2008, FIRAZYR was launched in Germany and the UK, recognizing sales of \$0.2 million (2007: \$nil). Launches will continue across Europe as reimbursement negotiations proceed.

### 3. Royalties

Royalty revenue decreased by 2% to \$60.8 million for the three months to September 30, 2008 (2007: \$61.9 million). The following table provides an analysis of Shire's royalty income:

#### Royalty Highlights

Product	Royalties to Shire \$M	Royalty Growth <sup>(1)</sup> %
3TC	35.9	-2%
ZEFFIX	8.6	-16%
Other	16.3	9%
Total	60.8	-2%

(1) Compared with Q3 2007.

#### 3TC – HIV infection and AIDS

Shire receives royalties from GSK on worldwide 3TC sales. Royalties from sales of 3TC for the three months to September 30, 2008 were \$35.9 million, (2007: \$36.7 million). Excluding unfavorable foreign exchange movements of 6%, there has been growth of 4% compared to the same period in 2007. The growth of 4% (excluding foreign exchange movements) primarily relates to the phasing of royalty income over Q2 and Q3 2008 and is not representative of trends in the overall 3TC market. While the nucleoside analogue market for HIV has continued to grow, competitive pressures from new products and entrants to the market have increased and are expected to lead to an overall decline in 3TC sales.

#### ZEFFIX – Chronic hepatitis B infection

Shire receives royalties from GSK on worldwide ZEFFIX sales. Royalties from sales of ZEFFIX for the three months to September 30, 2008 were \$8.6 million, a decrease of 16% (2007: \$10.2 million). The impact of foreign exchange movements has contributed 10% to the reported decline; excluding unfavorable foreign exchange movements there has been a decrease of 6% compared to the same period in 2007.

#### OTHER

Other royalties are primarily in respect of REMINYL and REMINYL XL (known as RAZADYNE and RAZADYNE ER in the US), a product marketed worldwide (excluding the UK and the Republic of Ireland) by Janssen Pharmaceutical N.V. ("Janssen"), an affiliate of Johnson & Johnson. Shire has exclusive marketing rights in the UK and the Republic of Ireland.

In the US, patent infringement litigation brought by Synaptech and Janssen against several ANDA filers culminated in a trial in Delaware in 2007. Following a decision on August 28, 2008 which rendered the relevant patent invalid, generic versions of RAZADYNE were permitted to enter the US market.

Sales of the REMINYL/RAZADYNE range, for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer's type, continue to grow in most countries however the entry of generics into the US market has severely decreased sales in that region. This decline was expected and is included in our forecasts.

Litigation proceedings relating to RAZADYNE, RAZADYNE ER, REMINYL and REMINYL XL are ongoing. Further information on these litigations can be found in our filings with the SEC, including our Annual Report on Form 10-K for the year to December 31, 2007.

#### 4. Financial details

##### Cost of product sales

	2008 \$m	% of product sales	2007 \$m	% of product sales
Cost of product sales (US GAAP)	84.2	12%	83.4	15%
Depreciation	(3.2)		(3.1)	
Cost of product sales (Non GAAP)	81.0	11%	80.3	15%

The cost of product sales increased to \$84.2 million for the three months to September 30, 2008 (12% of product sales), from \$83.4 million in the corresponding period in 2007 (15% of product sales). Cost of product sales as a percentage of product sales in the three months to September 30, 2008 compared to the same period in 2007 decreased by 3% points due to favourable changes in product mix.

##### Research and development ("R&D")

	2008 \$m	% of product sales	2007 \$m	% of product sales
R&D (US GAAP)	127.1	18%	181.4	33%
Payment for in-licensed product	-		(75.0)	
Depreciation	(3.4)		(2.9)	
R&D (Non GAAP)	123.7	17%	103.5	19%

R&D expenditure decreased to \$127.1 million for the three months to September 30, 2008 (18% of product sales), from \$181.4 million in the corresponding period in 2007 (33% of product sales). After excluding depreciation and the up-front payment of \$75.0 million to Renovo in respect of JUVISTA made in Q3 2007, R&D expenditure increased by \$20.2 million over the same period in 2007, decreasing as a percentage of product sales to 17% (2007: 19% of product sales). Contributing to the increased R&D expenditure in the third quarter of 2008 over 2007 were costs associated with projects in-licensed and acquired since the second half of 2007 including PLICERA, SPD550, AMIGAL, FIRAZYR and METAZYM together with Phase 3(b) and Phase 4 studies to support new product launches.

##### Selling, general and administrative ("SG&A")

	2008 \$m	% of product sales	2007 \$m	% of product sales
SG&A (US GAAP)	320.4	45%	328.4	60%
Costs associated with the introduction of a new holding company	(2.0)		-	
Amortization	(29.7)		(31.1)	
Legal settlement provision	-		(27.0)	
Depreciation	(12.0)		(10.5)	
SG&A (Non GAAP)	276.7	39%	259.8	48%

SG&A expenses decreased by \$8.0 million to \$320.4 million for the three months to September 30, 2008 compared to \$328.4 million in the corresponding period in 2007. After the exclusion of certain costs as outlined in the table above, SG&A decreased as a percentage of product sales to 39% (2007: 48% of product sales). This reduction of Non GAAP SG&A as a percentage of product sales reflects the sales impact in the three months to September 30, 2008 of the successful launches of VYVANSE, LIALDA/MEZAVANT and ELAPRASE.

### **Integration costs**

During the three months to September 30, 2008 the Company recorded integration costs of \$7.5 million (2007: \$nil) in respect of Jerini, primarily being acquisition related costs incurred by Jerini.

### **Gain on sale of product rights**

For the three months to September 30, 2008 Shire recognized gains of \$4.0 million arising from the sale of non-core products to Laboratorios Almirall S.A. in 2007. These gains were deferred at December 31, 2007 pending the transfer of the relevant consents.

In the three months to September 30, 2007 Shire recognized gains of \$7.1 million on the disposal of EQUETRO to Validus Pharmaceuticals Inc.

### **In process R&D charge**

During the three months to September 30, 2008 the Company recorded an in-process R&D charge of \$120.5 million (2007: \$nil) in respect of FIRAZYR in markets outside of the EU which, at the acquisition date, had not been approved by the relevant regulatory authorities.

### **Interest income**

For the three months to September 30, 2008 Shire received interest income of \$3.8 million (2007: \$8.0 million). Interest income primarily relates to interest received on cash and cash equivalents. Interest income for the three months to September 30, 2008 is lower than the same period in 2007 due to lower average cash and cash equivalent balances and lower average US Dollar interest rates.

### **Interest expense**

For the three months to September 30, 2008 the Company incurred interest expense of \$19.9 million (2007: \$18.0 million).

In both three month periods to September 30, 2008 and 2007 interest expense includes a provision for interest which may be awarded by the Court in respect of amounts due to those ex-Transkaryotic Therapies, Inc. ("TKT") shareholders who have requested appraisal of the acquisition consideration payable for their TKT shares. A trial date of December 10, 2008 has been set. Further information on this litigation can be found in our filings with the SEC, including our Annual Report on Form 10-K for the year to December 31, 2007.

### **Other (expenses)/income, net**

Other (expenses)/income for three months to September 30, 2008 includes impairment charges in respect of the Company's available for sale securities totalling \$54.1 million (2007 : \$nil), including \$43.7 million relating to the Company's investment in Renovo.

The decline in the market value of the Company's investment in Renovo initially arose from the results of clinical trials for JUVISTA announced by Renovo over 2007 and 2008. In considering whether the decline in value is temporary or "other than temporary" under US GAAP, the Company had to consider the following factors: the severity of the decline from historical cost (87%) and its duration (eleven months); market analysts' targets of Renovo's share price for the next 18-24 months; and the revised expected filing date for JUVISTA due to the adoption of a sequential rather than parallel Phase 3 development plan.

These factors, together with the significant decline in global equity markets during the third quarter of 2008 mean that the Company is unable to reasonably estimate the period over which a full recovery in the value of its investment in Renovo could occur. As such, the Company had to conclude that for US GAAP purposes the decline in value is "other than temporary".

In such circumstances US GAAP requires the full difference between the book value of the investment and the fair (market) value be recognized as an other than temporary impairment, even when there is an intention to continue to hold the investment. Accordingly the Company has recognized an impairment charge of \$43.7 million through the Statement of Operations in the three months to September 30, 2008. If in the future JUVISTA's Phase 3 trials report positively and Renovo's other products progress through development, Renovo's share price could react favorably and the Company may recover some or all of this impairment loss. Any future potential increases in the value of Renovo will be recognized through other comprehensive income.

## **Taxation**

The effective rate of tax for the three months to September 30, 2008 was 82% (2007: -211%). Excluding the tax effect of items excluded from Non GAAP income as outlined on page 24, principally the IPR&D charge in respect of FIRAZYR in non EU markets which is not deductible for tax, the effective rate of tax on Non GAAP income is 20% (2007: 14%). The effective rate of tax on Non GAAP income has increased as a result of higher profits and lower levels of tax deductible expenditure in higher tax territories (principally the US) in 2008 compared to 2007, and reductions to specific tax liabilities in 2007 following tax filings made in Q3 2007.

### **Equity in earnings of equity method investees**

Earnings of equity method investees of \$1.6 million were recorded for the three months to September 30, 2008 (2007: \$0.5 million). This comprised earnings of \$1.6 million from the 50% share of the anti-viral commercialization partnership with GSK in Canada (2007: \$1.7 million).

## FINANCIAL INFORMATION

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**Unaudited US GAAP results for the three months to September 30, 2008**  
**Consolidated Balance Sheets**

	<b>September 30, 2008 \$M</b>	December 31, 2007 \$M
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	473.3	762.5
Restricted cash	31.8	39.5
Accounts receivable, net	489.8	441.5
Inventories, net	149.6	174.1
Assets held for sale	40.0	10.6
Deferred tax asset	87.0	143.3
Prepaid expenses and other current assets	127.6	125.3
Total current assets	1,399.1	1,696.8
Non current assets:		
Investments	52.9	110.2
Property, plant and equipment, net	496.5	368.6
Goodwill	335.5	219.4
Other intangible assets, net	1,842.7	1,764.5
Deferred tax asset	124.1	143.7
Other non-current assets	76.7	26.9
Total assets	4,327.5	4,330.1
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	703.1	674.2
Deferred tax liability	4.2	11.3
Liability to dissenting shareholders	494.5	480.2
Other current liabilities	64.0	96.5
Total current liabilities	1,265.8	1,262.2
Non-current liabilities:		
Convertible bonds	1,100.0	1,100.0
Other long term debt	32.2	32.9
Deferred tax liability	339.6	332.4
Other non-current liabilities	397.2	375.6
Total non-current liabilities	1,869.0	1,840.9
Total liabilities	3,134.8	3,103.1

**Unaudited US GAAP results for the three months to September 30, 2008**  
**Consolidated Balance Sheets (continued)**

	<b>September 30, 2008 \$M</b>	December 31, 2007 \$M
Minority interest	2.4	-
Shareholders' equity:		
Common stock of 5p par value; 1,000 million shares authorized; and 560.0 million shares issued and outstanding (2007: 750 million shares authorized; and 556.8 million shares issued and outstanding)	55.5	55.2
Exchangeable shares: nil shares issued and outstanding (2007: 0.7 million)	-	33.6
Treasury stock (21.0 million shares (2007: 10.3 million shares))	(410.9)	(280.8)
Additional paid-in capital	2,575.2	2,503.4
Accumulated other comprehensive income	85.6	55.7
Accumulated deficit	(1,115.1)	(1,140.1)
Total shareholders' equity	1,190.3	1,227.0
Total liabilities and shareholders' equity	4,327.5	4,330.1



**Unaudited US GAAP results for the three and nine months to September 30, 2008**  
**Consolidated Statements of Operations**

	<b>3 months to September 30, 2008 \$M</b>	<b>3 months to September 30, 2007<sup>(1)</sup> \$M</b>	<b>9 months to September 30, 2008 \$M</b>	<b>9 months to September 30, 2007<sup>(1)</sup> \$M</b>
Continuing operations				
Revenues:				
Product sales	<b>712.5</b>	543.1	<b>2,049.9</b>	1,508.8
Royalties	<b>60.8</b>	61.9	<b>190.7</b>	185.4
Other revenues	<b>5.3</b>	3.7	<b>15.8</b>	17.6
<b>Total revenues</b>	<b>778.6</b>	608.7	<b>2,256.4</b>	1,711.8
Costs and expenses:				
Cost of product sales <sup>(1) (2) (3)</sup>	<b>84.2</b>	83.4	<b>317.4</b>	224.7
Research and development <sup>(1) (3)</sup>	<b>127.1</b>	181.4	<b>394.4</b>	365.7
Selling, general and administrative <sup>(1) (2)</sup>	<b>320.4</b>	328.4	<b>1,083.7</b>	847.5
Integration costs	<b>7.5</b>	-	<b>7.5</b>	1.3
Gain on sale of product rights	<b>(4.0)</b>	(7.1)	<b>(20.7)</b>	(12.1)
In-process R&D charge	<b>120.5</b>	-	<b>255.5</b>	1,896.0
<b>Total operating expenses</b>	<b>655.7</b>	586.1	<b>2,037.8</b>	3,323.1
<b>Operating income/(loss)</b>	<b>122.9</b>	22.6	<b>218.6</b>	(1,611.3)
Interest income	<b>3.8</b>	8.0	<b>23.0</b>	42.7
Interest expense	<b>(19.9)</b>	(18.0)	<b>(54.0)</b>	(53.8)
Other (expenses)/income, net	<b>(52.0)</b>	(1.6)	<b>(38.6)</b>	0.7
<b>Total other (expenses)/income, net</b>	<b>(68.1)</b>	(11.6)	<b>(69.6)</b>	(10.4)
Income/(loss) from continuing operations before income taxes, minority interests and equity in earnings of equity method investees	<b>54.8</b>	11.0	<b>149.0</b>	(1,621.7)
Income taxes	<b>(45.0)</b>	23.2	<b>(89.3)</b>	(43.9)
Minority interest	<b>1.3</b>	-	<b>1.3</b>	-
Equity in earnings of equity method investees, net of taxes	<b>1.6</b>	0.5	<b>1.3</b>	1.7
<b>Income/(loss) from continuing operations</b>	<b>12.7</b>	34.7	<b>62.3</b>	(1,663.9)
Loss from discontinued operations	<b>(0.9)</b>	-	<b>(0.9)</b>	-
<b>Net income/(loss)</b>	<b>11.8</b>	34.7	<b>61.4</b>	(1,663.9)

<sup>(1)</sup> For the three months to September 30, 2007 \$4.6 million of depreciation was reclassified from Selling, general and administrative (SG&A) costs to Cost of product sales (\$2.1 million) and Research and development costs (\$2.5 million). For the nine months to September 30, 2007 \$13.4 million of depreciation was reclassified from SG&A costs to Cost of product sales (\$6.0 million) and Research and development costs (\$7.4 million).

<sup>(2)</sup> Cost of product sales includes amortization of intangible assets relating to favorable manufacturing contracts of \$0.4 million for the three months to September 30, 2008 (2007: \$0.5 million) and \$1.3 million for the nine months to September 30, 2008 (2007: \$0.5 million). Selling, general and administrative costs include amortization and impairment charges of intangible assets relating to intellectual property rights acquired of \$30.1 million for the three months to September 30, 2008 (2007: \$31.1 million) and \$182.4 million for the nine months to September 30, 2008 (2007: \$64.0 million).

<sup>(3)</sup> Costs, predominantly relating to manufacturing set-up costs for new products, of \$1.8 million and \$5.4 million for the three months and nine months to September 30, 2007, have been reclassified from Research and development costs to Cost of product sales.

**Unaudited US GAAP results for the three months and nine months to September 30, 2008  
Consolidated Statements of Operations (continued)**

	<b>3 months to September 30, 2008</b>	3 months to September 30, 2007	<b>9 months to September 30, 2008</b>	9 months to September 30, 2007
<b>Earnings per ordinary share - basic</b>				
Earnings/(loss) from continuing operations	<b>2.4c</b>	6.4c	<b>11.5c</b>	(308.8c)
Loss from discontinued operations	<b>(0.2c)</b>	-	<b>(0.2c)</b>	-
Earnings/(loss) per ordinary share - basic	<b>2.2c</b>	6.4c	<b>11.3c</b>	(308.8c)
<b>Earnings per ordinary share – diluted</b>				
Earnings/(loss) from continuing operations	<b>2.4c</b>	6.3c	<b>11.5c</b>	(308.8c)
Loss from discontinued operations	<b>(0.2c)</b>	-	<b>(0.2c)</b>	-
Earnings/(loss) per ordinary share - diluted	<b>2.2c</b>	6.3c	<b>11.3c</b>	(308.8c)
Earnings/(loss) per ADS - diluted	<b>6.6c</b>	18.9c	<b>33.9c</b>	(926.4c)
<b>Weighted average number of shares:</b>				
Basic	<b>540.3</b>	546.4	<b>542.6</b>	538.9
Diluted	<b>541.5</b>	554.7	<b>545.3</b>	538.9

**Unaudited US GAAP results for the three months and nine months to September 30, 2008**  
**Consolidated Statements of Cash Flows**

	<b>3 months to September 30, 2008 \$M</b>	3 months to September 30, 2007 \$M	<b>9 months to September 30, 2008 \$M</b>	9 months to September 30, 2007 \$M
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>				
Net income/(loss)	<b>11.8</b>	34.7	<b>61.4</b>	(1,663.9)
Adjustments to reconcile net income/(loss) to net cash provided by operating activities:				
Loss from discontinued operations	<b>0.9</b>	-	<b>0.9</b>	-
Depreciation and amortization	<b>49.1</b>	48.1	<b>145.4</b>	111.8
Amortization of deferred financing charges	<b>1.3</b>	1.4	<b>3.8</b>	10.6
Interest on building financing obligation	<b>0.7</b>	-	<b>2.6</b>	-
Impairment of intangible assets	-	-	<b>90.4</b>	-
Impairment of available of sale securities	<b>54.1</b>	-	<b>54.1</b>	-
Share based compensation	<b>16.2</b>	11.7	<b>52.0</b>	34.1
In-process R&D charge	<b>120.5</b>	-	<b>120.5</b>	1,896.0
Gain on sale of product rights	<b>(4.0)</b>	(7.1)	<b>(20.7)</b>	(12.1)
Gain on sale of long-term assets	<b>0.4</b>	-	<b>(9.4)</b>	-
Movement in deferred taxes	<b>6.8</b>	(49.6)	<b>24.2</b>	(35.8)
Equity in earnings of equity method investees	<b>(1.6)</b>	(0.5)	<b>(1.3)</b>	(1.7)
Minority Interest	<b>(1.3)</b>	-	<b>(1.3)</b>	-
Changes in operating assets and liabilities, net of acquisitions:				
(Increase)/decrease in accounts receivable	<b>(12.3)</b>	38.8	<b>(40.7)</b>	(64.2)
Increase in sales deduction accrual	<b>1.4</b>	0.4	<b>36.9</b>	19.3
Decrease/(increase) in inventory	<b>29.2</b>	(6.2)	<b>39.6</b>	(46.2)
(Increase)/decrease in prepayments and other current assets	<b>(8.4)</b>	(8.6)	<b>15.8</b>	2.7
(Increase)/decrease in other assets	<b>(51.1)</b>	0.6	<b>(53.5)</b>	1.3
Increase/(decrease) in accounts and notes payable and other liabilities	<b>56.7</b>	96.1	<b>(9.7)</b>	103.8
Increase/(decrease) in deferred revenue	<b>1.9</b>	(42.9)	<b>7.4</b>	45.6
Return on investment on joint ventures	<b>7.1</b>	6.8	<b>7.1</b>	6.8
Net cash provided by operating activities <sup>(A)</sup>	<b>279.4</b>	123.7	<b>525.5</b>	408.1

**Unaudited US GAAP results for the three months and nine months to September 30, 2008  
Consolidated Statements of Cash Flows**

	<b>3 months to September 30, 2008 \$M</b>	3 months to September 30, 2007 \$M	<b>9 months to September 30, 2008 \$M</b>	9 months to September 30, 2007 \$M
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>				
Movements in short-term investments	-	-	-	55.8
Movements in restricted cash	<b>2.5</b>	(2.4)	<b>7.7</b>	(12.0)
Purchases of subsidiary undertakings, net of cash acquired	<b>(462.5)</b>	-	<b>(462.5)</b>	(2,458.6)
Expenses related to the New River acquisition	-	-	-	(60.4)
Purchases of long-term investments	<b>(0.2)</b>	(50.9)	<b>(1.3)</b>	(56.7)
Purchases of property, plant and equipment	<b>(77.1)</b>	(28.5)	<b>(166.5)</b>	(62.1)
Purchases of intangible assets	<b>(25.0)</b>	(26.4)	<b>(25.0)</b>	(58.2)
Proceeds from disposal of long-term assets	-	-	<b>10.3</b>	-
Proceeds/deposits received for sale of product rights	-	7.5	<b>5.0</b>	24.3
Proceeds from disposal of property, plant and equipment	<b>1.0</b>	-	<b>1.8</b>	-
Returns from equity investments	-	-	<b>0.4</b>	2.2
Net cash used in investing activities <sup>(B)</sup>	<b>(561.3)</b>	(100.7)	<b>(630.1)</b>	(2,625.7)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>				
Proceeds from drawings under bank facility	-	-	-	1,300.0
Repayment of drawings under bank facility	-	-	-	(1,300.0)
Proceeds from issue of 2.75% convertible bonds due 2014	-	-	-	1,100.0
Redemption of New River convertible notes	-	-	-	(279.4)
Proceeds from exercise of New River purchased call option	-	-	-	141.8
Payment of debt arrangement and issuance costs	-	(0.1)	-	(32.8)
Payment under building financing obligation	<b>(0.9)</b>	-	<b>(1.2)</b>	-
Proceeds from exercise of options	<b>0.7</b>	1.5	<b>1.7</b>	25.6
(Costs)/proceeds from issue of common stock, net	<b>(0.1)</b>	-	<b>(3.0)</b>	877.3
Proceeds from exercise of warrants	-	6.0	-	13.0
Payment of dividend	-	-	<b>(36.4)</b>	(29.4)
Payments to acquire shares by ESOT	<b>(36.2)</b>	(68.6)	<b>(140.2)</b>	(168.5)
Net cash (used in)/provided by financing activities <sup>(C)</sup>	<b>(36.5)</b>	(61.2)	<b>(179.1)</b>	1,647.6
Effect of foreign exchange rate changes on cash and cash equivalents <sup>(D)</sup>	<b>(9.5)</b>	2.6	<b>(5.5)</b>	6.0
Net decrease in cash and cash equivalents <sup>(A) +(B) +(C) +(D)</sup>	<b>(327.9)</b>	(35.6)	<b>(289.2)</b>	(564.0)
Cash and cash equivalents at beginning of period	<b>801.2</b>	598.5	<b>762.5</b>	1,126.9
Cash and cash equivalents at end of period	<b>473.3</b>	562.9	<b>473.3</b>	562.9

**Unaudited US GAAP results for the three and nine months to September 30, 2008**

**Selected Notes to the US GAAP Financial Statements**

**(1) Earnings per share**

	<b>3 months to September 30, 2008 \$M</b>	3 months to September 30, 2007 \$M	<b>9 months to September 30, 2008 \$M</b>	9 months to September 30, 2007 \$M
Income/(loss) from continuing operations	12.7	34.7	62.3	(1,663.9)
Loss from discontinued operations	<b>(0.9)</b>	-	<b>(0.9)</b>	-
Numerator for basic and diluted EPS	<b>11.8</b>	34.7	<b>61.4</b>	(1,663.9)
	<b>No. of shares Millions</b>	No. of shares Millions	<b>No. of shares Millions</b>	No. of shares Millions
Weighted average number of shares:				
Basic <sup>(1)</sup>	<b>540.3</b>	546.4	<b>542.6</b>	538.9
Effect of dilutive shares:				
Stock options <sup>(2)</sup>	<b>1.2</b>	8.2	<b>2.7</b>	-
Warrants <sup>(2)</sup>	-	0.1	-	-
Diluted	<b>541.5</b>	554.7	<b>545.3</b>	538.9

<sup>(1)</sup> Excludes shares purchased by the ESOT and presented by the Company as treasury stock.

<sup>(2)</sup> Calculated using the treasury stock method.

The share equivalents not included in the above calculation of the diluted weighted average number of shares are shown below:

	<b>3 months to September 30, 2008 No. of shares Millions<sup>(1)(3)</sup></b>	3 months to September 30, 2007 No. of shares Millions <sup>(1)(3)</sup>	<b>9 months to September 30, 2008 No. of shares Millions<sup>(1)(3)</sup></b>	9 months to September 30, 2007 No. of shares Millions <sup>(2)</sup>
Stock options out of the money	<b>17.0</b>	1.0	<b>17.0</b>	2.0
Stock options in the money	-	-	-	7.8
Warrants	-	-	-	0.4
Convertible bonds 2.75% due 2014	<b>32.7</b>	32.7	<b>32.7</b>	17.3

<sup>(1)</sup> For the three and nine months ended September 30, 2008 and three months ended September 30, 2007, certain stock options have been excluded from the calculation of diluted EPS because their exercise prices exceeded Shire plc's average share price during the calculation period.

<sup>(2)</sup> For the nine months ended September 30, 2007 no share options, warrants or ordinary shares underlying the convertible bonds have been included in the calculation of the diluted weighted average number of shares, because the Company made a net loss during the calculation period and the inclusion of these items would be anti-dilutive.

<sup>(3)</sup> For the three and nine months ended September 30, 2008 and the three months ended September 30, 2007, the convertible bonds were not included in the calculation of the diluted weighted average number of shares, because their effect would be anti-dilutive in the period.

Unaudited US GAAP results for the three months to September 30, 2008  
 Selected Notes to the US GAAP Financial Statements (continued)

(2) Analysis of revenues

three months to September 30,	2008	2007	2008 %	2008 % of total revenue
	\$M	\$M	change	
<b>Net product sales:</b>				
<i>Specialty Pharmaceuticals ("Specialty")</i>				
<u>ADHD</u>				
ADDERALL XR	268.7	249.0	8%	35%
VYVANSE	96.0	10.6	806%	12%
DAYTRANA	18.1	9.4	93%	2%
	<b>382.8</b>	269.0	<b>42%</b>	<b>49%</b>
<u>GI</u>				
PENTASA	49.2	43.7	13%	6%
LIALDA / MEZAVANT	40.4	16.3	148%	5%
	<b>89.6</b>	60.0	<b>49%</b>	<b>11%</b>
<u>General products</u>				
FOSRENOL	43.0	28.7	50%	6%
DYNEPO	5.2	4.4	18%	1%
CALCICHEW	13.3	13.5	-1%	2%
CARBATROL	21.6	19.3	12%	3%
REMINYL/REMINYL XL	9.6	8.2	17%	1%
XAGRID	19.4	16.8	15%	2%
	<b>112.1</b>	90.9	<b>23%</b>	<b>15%</b>
Other product sales	5.0	27.4	-82%	1%
Total Specialty product sales	<b>589.5</b>	447.3	<b>32%</b>	<b>76%</b>
<i>Human Genetic Therapies ("HGT")</i>				
ELAPRASE	78.2	55.1	42%	10%
REPLAGAL	44.6	40.7	10%	6%
FIRAZYR	0.2	-	n/a	-
Total HGT product sales	<b>123.0</b>	95.8	<b>28%</b>	<b>16%</b>
Total product sales	<b>712.5</b>	543.1	<b>31%</b>	<b>92%</b>
<b>Royalty income:</b>				
3TC	35.9	36.7	-2%	5%
ZEFFIX	8.6	10.2	-16%	1%
Other	16.3	15.0	9%	2%
Total	<b>60.8</b>	61.9	<b>-2%</b>	<b>8%</b>
Other revenues	5.3	3.7	43%	-
Total Revenue	<b>778.6</b>	608.7	<b>28%</b>	<b>100%</b>

Unaudited US GAAP results for the nine months to September 30, 2008  
Selected Notes to the US GAAP Financial Statements (continued)

(2) Analysis of revenues

nine months to September 30,	2008	2007	2008 %	2008 % of total revenue
	\$M	\$M	change	
<b>Net product sales:</b>				
<i>Specialty Pharmaceuticals ("Specialty")</i>				
<u>ADHD</u>				
ADDERALL XR	826.6	753.2	10%	37%
VYVANSE	215.6	10.6	n/a	10%
DAYTRANA	61.0	41.2	48%	3%
	<u>1,103.2</u>	<u>805.0</u>	<u>37%</u>	<u>50%</u>
<u>GI</u>				
PENTASA	138.2	127.7	8%	6%
LIALDA / MEZAVANT	99.6	21.3	-	4%
	<u>237.8</u>	<u>149.0</u>	<u>60%</u>	<u>10%</u>
<u>General products</u>				
FOSRENOL	121.6	76.0	60%	5%
DYNEPO	18.9	6.3	-	1%
CALCICHEW	40.8	39.1	4%	2%
CARBATROL	55.7	52.7	6%	2%
REMINYL/REMINYL XL	26.6	22.8	17%	1%
XAGRID	58.7	48.4	21%	3%
	<u>322.3</u>	<u>245.3</u>	<u>31%</u>	<u>14%</u>
Other product sales	24.1	80.0	-70%	1%
Total Specialty product sales	<u>1,687.4</u>	<u>1,279.3</u>	<u>32%</u>	<u>75%</u>
<i>Human Genetic Therapies ("HGT")</i>				
ELAPRASE	230.5	124.4	85%	10%
REPLAGAL	131.8	105.1	25%	6%
FIRAZYR	0.2	-	n/a	-
Total HGT product sales	<u>362.5</u>	<u>229.5</u>	<u>58%</u>	<u>16%</u>
Total product sales	<u>2,049.9</u>	<u>1,508.8</u>	<u>36%</u>	<u>91%</u>
<b>Royalty income:</b>				
3TC	108.8	111.2	-2%	5%
ZEFFIX	29.8	29.6	1%	1%
Other	52.1	44.6	17%	2%
Total	<u>190.7</u>	<u>185.4</u>	<u>3%</u>	<u>8%</u>
Other revenues	15.8	17.6	-10%	1%
Total Revenue	<u>2,256.4</u>	<u>1,711.8</u>	<u>32%</u>	<u>100%</u>

**Unaudited results for the three months to September 30, 2008**  
**Non GAAP reconciliation**

	US GAAP 3 months to September 30, 2008	Adjustments	Reclassify depreciation	Non GAAP 3 months to September 30, 2008
	\$M	\$M	\$M	\$M
<b>Total revenues</b>	<b>778.6</b>	-	-	<b>778.6</b>
<b>Costs and expenses:</b>				
Cost of product sales	84.2	-	(3.2) <sup>(h)</sup>	81.0
Research and development	127.1	-	(3.4) <sup>(h)</sup>	123.7
Selling, general and administrative	320.4	(31.7) <sup>(a)</sup>	(12.0) <sup>(h)</sup>	276.7
Integration costs	7.5	(7.5) <sup>(b)</sup>	-	-
Gain on sale of product rights	(4.0)	4.0 <sup>(c)</sup>	-	-
In-process R&D charge	120.5	(120.5) <sup>(d)</sup>	-	-
Depreciation	-	-	18.6 <sup>(h)</sup>	18.6
Total operating expenses	655.7	(155.7)	-	500.0
<b>Operating income</b>	<b>122.9</b>	<b>155.7</b>	-	<b>278.6</b>
Interest income	3.8	-	-	3.8
Interest expense	(19.9)	-	-	(19.9)
Other income, net	(52.0)	54.1 <sup>(e)</sup>	-	2.1
Total other (expenses)/income, net	(68.1)	54.1	-	(14.0)
Income from continuing operations before income taxes, minority interests and equity in earnings of equity method investees	54.8	209.8	-	264.6
Income taxes	(45.0)	(6.5) <sup>(f)</sup>	-	(51.5)
Minority interest	1.3	-	-	1.3
Equity in earnings of equity method investees, net of tax	1.6	-	-	1.6
<b>Income from continuing operations</b>	<b>12.7</b>	<b>203.3</b>	-	<b>216.0</b>
Loss from discontinued operations	(0.9)	0.9 <sup>(g)</sup>	-	-
<b>Net Income</b>	<b>11.8</b>	<b>204.2</b>	-	<b>216.0</b>
Impact of convertible debt, net of tax	-	8.6 <sup>(1)</sup>	-	8.6
<b>Numerator for diluted EPS</b>	<b>11.8</b>	<b>212.8</b>	-	<b>224.6</b>
Weighted average number of shares (millions) - diluted	541.5	32.7 <sup>(1)</sup>		574.2
Diluted earnings per ordinary share	2.2c	36.9c		39.1c
Diluted earnings per ADS	<b>6.6c</b>	<b>110.7c</b>		<b>117.3c</b>

<sup>(1)</sup> Under US GAAP the convertible bonds were not included in the calculation of the diluted weighted average number of shares nor was the after tax income statement effect of the bonds added to the numerator as the impact was anti-dilutive. On a Non-GAAP basis the after tax impact of the convertible bond has been added to the numerator and the number of shares underlying the convertible bonds are now included in the calculation of the diluted weighted average number of shares as they have a dilutive effect

The following adjustments and reclassifications are included above:

- Amortization of intangible assets relating to intellectual property rights acquired (\$29.7 million) and costs associated with the new holding company (\$2.0 million);
- Integration and transaction related costs in respect of the acquisition of Jerini (\$7.5 million);
- Gains on the disposal of non-core product rights (\$4.0 million);
- In-process R&D in respect of the acquisition of Jerini (\$120.5 million);
- Other than temporary impairment of available for sale securities (\$54.1 million)
- Tax effect of adjustments outlined in (a) to (e);
- Discontinued operations in respect of Jerini businesses held for sale (\$0.9 million); and
- Depreciation of \$18.6 million included in cost of product sales, R&D costs and SG&A costs for US GAAP now separately disclosed for the presentation of Non GAAP earnings.



## Unaudited results for the three months to September 30, 2007

### Non GAAP reconciliation

	US GAAP 3 months to September 30, 2007 \$M	Adjustments \$M	Reclassify depreciation \$M	Non GAAP <sup>(1)</sup> 3 months to September 30, 2007 \$M
<b>Total revenues</b>	608.7	-	-	608.7
<b>Costs and expenses:</b>				
Cost of product sales	83.4	-	(3.1)	80.3
Research and development	181.4	(75.0)	(2.9)	103.5
Selling, general and administrative	328.4	(58.1)	(10.5)	259.8
Gain on sale of product rights	(7.1)	7.1	-	-
Depreciation	-	-	16.5	16.5
Total operating expenses	586.1	(126.0)	-	460.1
<b>Operating income</b>	<b>22.6</b>	<b>126.0</b>	<b>-</b>	<b>148.6</b>
Interest income	8.0	-	-	8.0
Interest expense	(18.0)	-	-	(18.0)
Other income, net	(1.6)	-	-	(1.6)
Total other (expenses)/income, net	(11.6)	-	-	(11.6)
Income before income taxes and equity in earnings of equity method investees	11.0	126.0	-	137.0
Income taxes	23.2	(42.3)	-	(19.1)
Equity in earnings of equity method investees, net of tax	0.5	-	-	0.5
<b>Net income</b>	<b>34.7</b>	<b>83.7</b>	<b>-</b>	<b>118.4</b>
Impact of convertible debt, net of tax	-	3.8	-	3.8
<b>Numerator for diluted EPS</b>	<b>34.7</b>	<b>87.5</b>	<b>-</b>	<b>122.2</b>
Weighted average number of shares (millions) - diluted	554.7	32.7	-	587.4
Diluted earnings per ordinary share	6.3c	14.5c	-	20.8c
Diluted earnings per ADS	<b>18.9c</b>	<b>43.5c</b>	<b>-</b>	<b>62.4c</b>

(1) Non GAAP earnings for 2007 have been recalculated to include the impact of the share based compensation charge which had previously been excluded. The impact, net of tax, is a decrease in non GAAP net income of \$7.8 million.

(2) Under US GAAP the convertible bonds were not included in the calculation of the diluted weighted average number of shares nor was the after tax income statement effect of the bonds added to the numerator as the impact was anti-dilutive. On a Non-GAAP basis the after tax impact of the convertible bond has been added to the numerator and the number of shares underlying the convertible bonds are now included in the calculation of the diluted weighted average number of shares as they have a dilutive effect.

The following adjustments and reclassifications are included above:

- a) Upfront payment in respect of the in-license of JUVISTA from Renovo (\$75.0 million);
- b) Amortisation of intangible assets relating to intellectual property rights acquired (\$31.1 million) and legal settlement provision for the REPLAGAL Class Action Suit (\$27.0 million);
- c) Gain on disposal of non-core product rights (\$7.1 million);
- d) Tax effect of adjustments outlined in (a) to (c); and
- e) Depreciation of \$16.5 million included in cost of product sales, R&D costs and SG&A costs for US GAAP now separately disclosed for the presentation of non GAAP earnings.

## Unaudited results for the nine months to September 30, 2008

### Non GAAP reconciliation

	US GAAP 9 months to September 30, 2008 \$M	Adjustments \$M	Reclassify depreciation \$M	Non GAAP 9 months to September 30, 2008 \$M
<b>Total revenues</b>	2,256.4	-	-	2,256.4
<b>Costs and expenses:</b>				
Cost of product sales	317.4	(53.4) <sup>(a)</sup>	(8.8) <sup>(i)</sup>	255.2
Research and development	394.4	(6.5) <sup>(b)</sup>	(9.4) <sup>(i)</sup>	378.5
Selling, general and administrative	1,083.7	(196.1) <sup>(c)</sup>	(34.0) <sup>(i)</sup>	853.6
Integration costs	7.5	(7.5) <sup>(d)</sup>	-	-
Gain on sale of product rights	(20.7)	20.7 <sup>(e)</sup>	-	-
In-process R&D charge	255.5	(255.5) <sup>(f)</sup>	-	-
Depreciation	-	-	52.2 <sup>(i)</sup>	52.2
Total operating expenses	2,037.8	(498.3)	-	1,539.5
<b>Operating income</b>	<b>218.6</b>	<b>498.3</b>	-	<b>716.9</b>
Interest income	23.0	-	-	23.0
Interest expense	(54.0)	-	-	(54.0)
Other income, net	(38.6)	44.7 <sup>(g)</sup>	-	6.1
Total other (expenses)/ income, net	(69.6)	44.7	-	(24.9)
Income from continuing operations before income taxes, minority interests and equity in earnings of equity method investees	149.0	543.0	-	692.0
Income taxes	(89.3)	(61.6) <sup>(h)</sup>	-	(150.9)
Minority interest	1.3	-	-	1.3
Equity in earnings of equity method investees, net of tax	1.3	-	-	1.3
Income from continuing operations	62.3	481.4	-	543.7
Loss from discontinued operations	(0.9)	0.9 <sup>(i)</sup>	-	-
<b>Net income</b>	<b>61.4</b>	<b>482.3</b>	-	<b>543.7</b>
Impact of convertible debt, net of tax	-	6.2 <sup>(1)</sup>	-	6.2
<b>Numerator for diluted EPS</b>	<b>61.4</b>	<b>488.5</b>	-	<b>549.9</b>
Weighted average number of shares (millions) - diluted	545.3	32.7 <sup>(1)</sup>		578.0
Diluted earnings per ordinary share	11.3c	83.8c		95.1c
Diluted earnings per ADS	<b>33.9c</b>	<b>251.4c</b>		<b>285.3c</b>

<sup>(1)</sup> Under US GAAP the convertible bonds were not included in the calculation of the diluted weighted average number of shares nor was the after tax income statement effect of the bonds added to the numerator as the impact was anti-dilutive. On a Non-GAAP basis the after tax impact of the convertible bond has been added to the numerator and the number of shares underlying the convertible bonds are now included in the calculation of the diluted weighted average number of shares as they have a dilutive effect.

The following adjustments and reclassifications are included above:

- a) Write down of inventory and exit costs in respect of DYNEPO (\$53.4 million);
- b) R&D commitment in respect of DYNEPO (\$6.5 million);
- c) Amortization of intangible assets relating to intellectual property rights acquired (\$91.5 million), impairment charge in respect of DYNEPO intangible asset (\$90.4 million), and costs associated with the new holding company (\$14.2 million);
- d) Integration and transaction related costs in respect of the acquisition of Jerini (\$7.5 million);
- e) Gains on the disposal of non-core product rights (\$20.7 million);
- f) In-process R&D in respect of the Jerini acquisition (\$120.5 million) and METAZYM acquired from Zymenex (\$135.0 million);
- g) Gain on the disposal of a minority equity investment (\$9.4 million) offset by the other than temporary impairment of available for sale securities (\$54.1 million);
- h) Tax effect of adjustments outlined in (a) to (g);
- i) Discontinued operations in respect of Jerini businesses held for sale (\$0.9 million); and
- j) Depreciation of \$52.2 million included in cost of product sales, R&D costs and SG&A costs for US GAAP now separately disclosed for the presentation of Non GAAP earnings.

**Unaudited results for the nine months to September 30, 2007**  
**Non GAAP reconciliation**

	US GAAP 9 months to September 30, 2007 \$M	Adjustments \$M	Reclassify depreciation \$M	Non GAAP <sup>(1)</sup> 9 months to September 30, 2007 \$M
<b>Total revenues</b>	1,711.8	-	-	1,711.8
<b>Costs and expenses:</b>				
Cost of product sales	224.7	-	(9.0)	215.7
Research and development	365.7	(80.9)	(8.4)	276.4
Selling, general and administrative	847.5	(91.0)	(29.9)	726.6
Integration costs	1.3	(1.3)	-	-
Gain on sale of product rights	(12.1)	12.1	-	-
In-process R&D charge	1,896.0	(1,896.0)	-	-
Depreciation	-	-	47.3	47.3
Total operating expenses	3,323.1	(2,057.1)	-	1,266.0
<b>Operating (loss)/income</b>	<b>(1,611.3)</b>	<b>2,057.1</b>	<b>-</b>	<b>445.8</b>
Interest income	42.7	-	-	42.7
Interest expense	(53.8)	7.9	-	(45.9)
Other income, net	0.7	-	-	0.7
Total other income, net	(10.4)	7.9	-	(2.5)
(Loss)/income before income taxes and equity in earnings of equity method investees	(1,621.7)	2,065.0	-	443.3
Income taxes	(43.9)	(46.5)	-	(90.4)
Equity in earnings of equity method investees, net of tax	1.7	-	-	1.7
<b>Net (loss)/income</b>	<b>(1,663.9)</b>	<b>2,018.5</b>		<b>354.6</b>
Impact of convertible debt, net of tax	-	5.5		5.5
<b>Numerator for diluted EPS</b>	<b>(1,663.9)</b>	<b>2,024.0</b>		<b>360.1</b>
Weighted average number of shares (millions) - diluted	538.9	25.5		564.4
Diluted (loss)/earnings per ordinary share	(308.8c)	372.6c		63.8c
Diluted (loss)/earnings per ADS	<b>(926.4c)</b>	<b>1,117.8c</b>		<b>191.4c</b>

<sup>(1)</sup> Non GAAP earnings for 2007 have been recalculated to include the impact of the share based compensation charge which had previously been excluded. The impact, net of tax, is a decrease in Non GAAP net income of \$17.1 million.

<sup>(2)</sup> After the above adjustments the Company made Non GAAP net income during the calculation period. As a result (i) the after tax impact of the convertible bond has been added to the numerator and (ii) in-the-money share options, warrants and convertible bonds are now included in the calculation of the diluted weighted average number of shares as they have a dilutive effect.

The following adjustments and reclassifications are included above:

- Upfront and milestone payments in respect of in-licensing technology from Noven (\$5.9 million) and Renovo (\$75.0 million);
- Amortisation of intangible assets relating to intellectual property rights acquired (\$64.0 million) and legal settlement provision for the REPLAGAL Class Action Suit (\$27.0 million);
- Integration costs in respect of the acquisition of New River Pharmaceuticals Inc ("New River") (\$1.3 million);
- Gain on the disposal of non-core product rights (\$12.1 million);
- Write-off of in-process research and development acquired as part of the acquisition of New River (\$1,896.0 million);
- Write-off of deferred financing costs on repayment of term loans drawn down to partly fund the New River acquisition;
- Tax effect of adjustments outlined in (a) to (f); and
- Depreciation of \$47.3 million included in cost of product sales, R&D costs and SG&A costs for US GAAP now separately disclosed for the presentation of Non GAAP earnings.