# Press Release

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# Shire's replenished portfolio drives excellent quarterly performance

**April 29, 2010** – Shire plc (LSE: SHP, NASDAQ: SHPGY) the global specialty biopharmaceutical company, announces results for the three months to March 31, 2010.

## Financial Highlights

| | Q1 2010[1] | |
|---|---|---|
| Product sales | $718 million | -5% |
| Product sales from core products[2] | $626 million | +36% |
| Total revenues | $816 million | - |
| Non GAAP operating income | $265 million | -19% |
| US GAAP operating income | $218 million | -4% |
| Non GAAP diluted earnings per ADS | $1.01 | -21% |
| US GAAP diluted earnings per ADS | $0.89 | -23% |

(1) Percentages compare to equivalent 2009 period.
(2) Core products represent Shire's products excluding ADDERALL XR.

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

"This was an excellent first quarter performance with our core product sales up 36% and cash generation increasing 19% to $278 million. Despite the impact of authorised generic ADDERALL XR, total reported revenues in the quarter were at 2009 levels, reflecting our success in replenishing our portfolio with products providing strong growth and robust intellectual property. Across the business we saw significant developments: VYVANSE now has approximately a 14% share of the US ADHD market, our two recently launched products VPRIV and INTUNIV are performing well and in the EU REPLAGAL is now the leading Fabry treatment, with an estimated 60% market share.

We are investing in our growing international presence and building on our recent product launches. We are also progressing our pipeline and we expect to deliver further newsflow on our early projects later this year. Our core products are leveraging our existing infrastructure and we will continue to expand our operating margins.

Our performance in the first quarter reinforces our confidence in growing both revenue and earnings in the full year 2010 compared to 2009, and we re-iterate our aspirational target of mid-teens revenue growth on average between 2009 and 2015."

## FINANCIAL SUMMARY

## First Quarter 2010 Unaudited Results

| | Q1 2010 | | | Q1 2009 | | |
|---|---|---|---|---|---|---|
| | **US GAAP** | **Adjustments** | **Non GAAP** | US GAAP | Adjustments | Non GAAP |
| | **$M** | **$M** | **$M** | $M | $M | $M |
| **Revenues** | **816** | **-** | **816** | 818 | - | 818 |
| **Operating income** | **218** | **47** | **265** | 226 | 101 | 327 |
| **Diluted earnings per ADS** | **$0.89** | **$0.12** | **$1.01** | $1.16 | $0.12 | $1.28 |

The Non GAAP financial measures included within this release are explained on pages 19 and 20, and are reconciled to the most directly comparable financial measures prepared in accordance with US GAAP on pages 17 and 18.

- Product sales from core products were up 36% to $626 million (2009: $460 million). On a constant exchange rate ("CER") basis, which is a Non GAAP measure, core product sales were up 33%. Growth in core product sales was achieved by strong performance throughout the portfolio including:
    - VYVANSE® (up 32% to $154 million, CER: up 32%);
    - ELAPRASE® (up 22% to $101 million, CER: up 17%);
    - REPLAGAL® (up 69% to $68 million, CER: up 60%);
    - LIALDA/MEZAVANT® (up 29% to $64 million, CER: up 28%); and
    - Recently launched INTUNIV® ($35 million) and VPRIV® ($6 million).

- Product sales including ADDERALL XR® were down 5% to $718 million (CER: down 7%), as the decline in ADDERALL XR sales compared to Q1 2009 (down 69% to $92 million) offset the strong core product sales growth. The decline in ADDERALL XR product sales was expected, as Q1 2009 was the last quarter of ADDERALL XR exclusivity prior to the launch of authorized generic versions by Teva Pharmaceuticals USA Inc. ("Teva") in April 2009 and Impax Laboratories Inc. ("Impax") in October 2009.

- Total revenues of $816 million remained at 2009 levels (CER: down 2%; 2009: $818 million) as higher royalty income (primarily received on Impax's sales of authorized generic ADDERALL XR) offset lower product sales.

- Non GAAP operating income decreased by 19% to $265 million (2009: $327 million) as a result of increased investment in research and development ("R&D") and higher selling, general and administrative ("SG&A") costs in support of recent product launches. On a US GAAP basis, operating income decreased by 4% to $218 million (2009: $226 million). US GAAP operating income in Q1 2009 included costs of $65 million on termination of the Women's Health development agreement with Duramed Pharmaceuticals Inc. ("Duramed").

- Cash generation, which is a Non GAAP measure, continues to be strong and increased by 19% to $278 million in Q1 2010 (2009: $234 million). The increase in cash generation in 2010 resulted from higher cash receipts from gross product sales and royalties, partially offset by higher cash payments on the increased investment in R&D and SG&A. Cash balances (including cash equivalents and restricted cash) at March 31, 2010 were $684 million (December 31, 2009: $532 million).

## 2010 OUTLOOK

The first quarter's performance has increased our confidence in growing both revenues and earnings for the full year 2010 compared to 2009, including the effect of US Healthcare Reform.

Whilst our core portfolio will continue to deliver strong year on year growth, revenues from ADDERALL XR product sales and from total royalties are anticipated to be lower in the last three quarters of 2010 compared to their very strong performance in the first quarter. Given our confidence in our outlook, we have decided to make some targeted increases in investment in our international infrastructure, our recent product launches and in progressing our pipeline to support longer-term growth. As a result, we anticipate that R&D and SG&A spending in 2010 will be at the top end of our previously stated guidance of 5-10% growth year on year.

With the expected growth in 2010 we reiterate our aspirational target of mid-teens revenue growth on average between 2009 and 2015.

## PRODUCT LAUNCHES

Subject to obtaining the relevant regulatory/governmental approvals, future product launches in the next 12 months will include:

- VPRIV™ for the treatment of Type 1 Gaucher disease in the EU;
- REPLAGAL for the treatment of Fabry disease in the US;
- MEZAVANT for the treatment of ulcerative colitis in certain EU and RoW countries;
- FIRAZYR® for the symptomatic treatment of acute attacks of hereditary angiodema ("HAE") in certain European and Latin American countries; and
- EQUASYM® for the treatment of ADHD in certain EU countries.

## FIRST QUARTER 2010 AND RECENT PRODUCT AND PIPELINE DEVELOPMENTS

### Products

VPRIV – for the treatment of Type 1 Gaucher disease in the US

- On February 26, 2010 the U.S. Food and Drug Administration ("FDA") granted marketing approval for VPRIV, a human cell line derived enzyme replacement therapy ("ERT") for the long-term treatment of Type 1 Gaucher disease in pediatric and adult patients. The FDA designated VPRIV for Priority Review and granted marketing approval in just six months. VPRIV offers patients and their physicians a new treatment option at a critical time, as the supply of a previously approved ERT for Gaucher disease is uncertain and remains disrupted.

VYVANSE – for the treatment of ADHD

- On February 1, 2010 Shire announced the Canadian availability of VYVANSE, the first and only prodrug therapy approved for ADHD treatment in Canada. This is the first launch of VYVANSE outside the US.
- On March 4, 2010 the United States District Court for the District of Columbia (the "District Court") upheld the FDA's decision that VYVANSE is entitled to five year market exclusivity in the US. The five-year exclusivity period for VYVANSE expires on February 23, 2012 and precludes generic manufacturers from submitting an Abbreviated New Drug Application ("ANDA") to the FDA until that time, or until February 23, 2011 should a generic applicant challenge the US patents covering VYVANSE, which remain in effect until June 29, 2023. Actavis Elizabeth LLC ("Actavis") has appealed the District Court's ruling to the US Court of Appeals for the DC Circuit. No hearing date has been set.

INTUNIV – for the treatment of ADHD

- On March 16, April 5, and April 26, 2010 Shire received Paragraph IV Notice Letters from Teva, Actavis and Anchen Pharmaceuticals, Inc. ("Anchen") respectively, advising of the filing of ANDAs for generic versions of 1mg, 2mg, 3mg, and 4mg guanfacine hydrochloride extended release tablets, INTUNIV. INTUNIV is protected by three FDA Orange Book listed patents. The three patents expire in 2015, 2020 and 2022, respectively. Teva's Paragraph IV Notice Letter was only directed to the patents expiring in 2020 and 2022. On April 22, Shire filed a lawsuit against Teva in the US District Court for the District of Delaware for the infringement of these patents. Actavis's and Anchen's Paragraph IV Notice Letters were directed to all three Orange Book listed patents. Shire is currently reviewing the details of Actavis's and Anchen's Paragraph IV Notice Letters.

REPLAGAL – for the treatment of Fabry disease

- On April 14, 2010 Mt. Sinai School of Medicine of New York University sought to initiate lawsuits in Sweden and Germany alleging that REPLAGAL infringes Mt. Sinai's European Patent No. 1 942 189, granted April 14, 2010. Mt. Sinai is seeking an injunction against the use of REPLAGAL in these jurisdictions until expiration of the patent on November 30, 2013. Shire will defend its right to commercialize REPLAGAL in these countries and will vigorously oppose the validity of this patent.

**Pipeline**

REPLAGAL – for the treatment of Fabry disease in the US

- On February 24, 2010 Shire announced its receipt of Fast Track designation from the FDA for REPLAGAL, an ERT for Fabry disease. Shire filed a Biologics License Application ("BLA") for REPLAGAL in December 2009, and in Q1 2010 the FDA requested additional pharmacokinetic comparability data. As a result of this request, Shire withdrew its December BLA filing, and, at the suggestion of the FDA, requested and received Fast Track designation. Shire immediately initiated the rolling submission of the REPLAGAL BLA, and expects to submit the requested pharmacokinetic data around mid-year. REPLAGAL is currently approved for the treatment of Fabry disease in 45 countries and has been available to US patients since December 2009 under an FDA-approved treatment protocol filed at the request of FDA. The Company is also supporting emergency Investigational New Drug requests in the US. The REPLAGAL early access program was put in place as a result of the supply disruption of the only currently marketed treatment for Fabry disease in the US.

HGT-2310 – for the treatment of Hunter syndrome with central nervous system symptoms, idursulfase-IT (intrathecal delivery)

- HGT 2310 is in development as an ERT delivered intrathecally for Hunter syndrome patients with central nervous system symptoms. The Company initiated a Phase I/II clinical trial in the first quarter of 2010. This product has been granted orphan designation in the US.

LIALDA/MEZAVANT – for the treatment of diverticulitis

- LIALDA/MEZAVANT is being investigated as a treatment to prevent recurrent attacks of diverticulitis. Phase 3 worldwide clinical trials investigating the use of the product for the treatment of diverticulitis were initiated in 2007 and are ongoing. Enrollment in these trials has completed and data is estimated to be available in 2012.

## OTHER FIRST QUARTER AND RECENT DEVELOPMENTS

US Healthcare Reform

- During the quarter, President Obama signed into law Healthcare Reform, with the goal of expanding healthcare access to millions of Americans currently without health insurance and lowering the overall costs of healthcare. Healthcare Reform will affect Shire in a number of ways, including a limited impact coming from the changes to the calculation of Medicaid rebates effective from this quarter, and from Shire's share of the industry wide excise tax starting in 2011. We are pleased with the expansion of healthcare coverage to previously uninsured patients and believe this should provide a positive benefit for Shire. Furthermore, we are also pleased with Healthcare Reform providing certainty regarding regulatory exclusivity for biologics. Healthcare Reform did not materially impact Shire's results in the first quarter of 2010, and we believe Shire is well placed to manage the changes Healthcare Reform will bring in future periods.

## BOARD CHANGES

- On March 15, 2010 Bill Burns was appointed to the Board as a Non Executive Director with immediate effect. Mr Burns has also been appointed a member of Shire's Remuneration Committee.

## ADDITIONAL INFORMATION

The following additional information is included in this press release:



**For further information please contact:**


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Dial in details for the **live conference call** for investors 14:30 BST/9:30 EDT on April 29, 2010:

| | |
|---|---|
| UK dial in: | 0844 800 3850 or 01296 311 600 |
| US dial in: | 1 866 8048688 or 1 718 3541175 |
| International dial in: | +44 (0) 1296 311 600 |
| Password/Conf ID: | 327562 |
| Live Webcast: | http://www.shire.com/shireplc/en/investors |

## OVERVIEW OF Q1 2010 FINANCIAL RESULTS

### 1. Product sales

For the three months to March 31, 2010 product sales decreased by 5% to $718.2 million (2009: $756.0 million) and represented 88% of total revenues (2009: 92%). On a CER basis product sales decreased 7% compared to 2009.

Sales of core products increased by 36% to $626.4 million (2009: $460.2 million), up 33% on a CER basis.

### Product Highlights

| Product | Sales $M | Growth | | US Rx[1] | Exit Market Share[1] |
|---|---|---|---|---|---|
| | | Sales | CER | | |
| VYVANSE | 154.4 | +32% | +32% | +32% | 14% |
| ELAPRASE | 100.8 | +22% | +17% | n/a[2] | n/a[2] |
| REPLAGAL | 68.0 | +69% | +60% | n/a[3] | n/a[3] |
| LIALDA / MEZAVANT | 63.6 | +29% | +28% | +23% | 19% |
| PENTASA® | 58.2 | +14% | +14% | -6% | 15% |
| FOSRENOL® | 47.1 | +18% | +14% | -12% | 7% |
| INTUNIV | 34.5 | n/a | n/a | n/a | 2% |
| VPRIV | 5.8 | n/a | n/a | n/a | n/a |
| FIRAZYR | 2.2 | +340% | +313% | n/a[3] | n/a[3] |
| OTHER | 91.8 | +15% | +11% | n/a | n/a |
| **Core product sales** | **626.4** | **36%** | **33%** | | |
| ADDERALL XR | 91.8 | -69% | -70% | -60% | 8% |
| **Total product sales** | **718.2** | **-5%** | **-7%** | | |

(1) Data provided by IMS Health National Prescription Audit ("IMS NPA"). Exit market share represents the US market share in the week ending March 26, 2010.
(2) IMS NPA Data not available.
(3) Not sold in the US in Q1 2010, or awaiting approval in the US.

### VYVANSE - ADHD

The increase in VYVANSE product sales was driven by increased US prescription demand compared to Q1 2009, 10% growth in the US ADHD market and price increases.

### ELAPRASE - Hunter syndrome

The growth in sales of ELAPRASE was driven by increased volumes across all regions where ELAPRASE is sold. On a CER basis sales grew by 17% (79% of ELAPRASE sales are made outside of the US).

### REPLAGAL - Fabry disease

The growth in REPLAGAL product sales in Q1 2010 over 2009 was driven by an increase in demand due to significant switching of patients to REPLAGAL in the EU, attributable in part to supply shortages of a competitor product. Sales increased 60% on a CER basis (REPLAGAL is sold primarily in Euros and Pounds sterling).

### LIALDA/MEZAVANT – Ulcerative colitis

Strong product sales of LIALDA/MEZAVANT continued in Q1 2010 driven by increased US prescription demand compared to Q1 2009 and price increases. The US oral mesalamine market was flat year on year.

### PENTASA - Ulcerative colitis

Product sales of PENTASA increased in Q1 2010 compared to Q1 2009 primarily due to price increases.

### FOSRENOL - Hyperphosphatemia

Product sales increased as FOSRENOL grew its share of existing markets outside the US. Product sales also grew in the US due to price increases and growth in non-retail demand which offset the decline in US retail prescription demand.

### INTUNIV – ADHD

In line with Shire's revenue recognition policy for launch shipments, initial stocking shipments in November 2009 were deferred and are being recognised into revenue in line with end-user prescription demand. At March 31, 2010 deferred revenues on the balance sheet represented gross sales of $18.8 million.

### VPRIV – Gaucher disease

Product sales were primarily generated on a pre-approval basis via patient early access programs in the EU throughout Q1 2010 and in the US after February 26, 2010 when approval was received from the FDA.

### FIRAZYR – HAE

Product sales of FIRAZYR increased as volumes grew across European markets. FIRAZYR is the first new product for HAE in Europe in 30 years and has orphan exclusivity for acute attacks of HAE in adults in the EU until 2018.

### ADDERALL XR – ADHD

ADDERALL XR product sales decreased in 2010 compared to 2009 as Q1 2009 represented the final quarter of exclusivity prior to the launch of authorized generic versions by Teva and Impax in April and October 2009, respectively. The launch of authorized generic versions resulted in a lower prescription demand in 2010 compared to 2009 resulting in a corresponding reduction in ADDERALL XR's share of the US ADHD market (8% for Q1 2010 compared to 21% in Q1 2009).

Despite price increases taken since Q1 2009, product sales in 2010 declined at a faster rate than US prescription demand due to increased sales deductions as a percentage of branded ADDERALL XR gross sales, representing 61% of gross revenues in Q1 2010 (2009: 37%). Sales deductions in Q1 2010 included the effect of a change in estimate of inventory in the wholesaler pipeline, which decreased sales deductions as a percentage of gross sales by 8 percentage points.

## 2. Royalties

| Product | Royalties to Shire $M | Year on year growth | |
|---|---|---|---|
| | | Royalties | CER |
| 3TC® and Zeffix® | 36.6 | -6% | -7% |
| ADDERALL XR | 40.8 | n/a | n/a |
| Other | 17.9 | 52% | 47% |
| Total | 95.3 | 88% | 86% |

Royalty income increased by 88% in Q1 2010 compared to 2009 due to royalties received on sales of Impax's authorized generic version of ADDERALL XR, which commenced in October 2009. This increase more than offset the decline in royalties received from GlaxoSmithKline ("GSK") on 3TC, down 9%, due to competition from other treatments. Royalties received from GSK on ZEFFIX were slightly increased over 2009. Other royalties increased by 52%, principally due to higher royalties on sales of FOSRENOL in Japan.

## 3. Financial details

### Cost of product sales

| | Q1 2010 $M | % of product sales | Q1 2009 $M | % of product sales |
|---|---|---|---|---|
| Cost of product sales (US GAAP) | **101.9** | **14%** | 83.6 | 11% |
| Costs associated with the transfer of manufacturing from Owings Mills | **(7.2)** | | - | |
| Depreciation | **(2.5)** | | (3.6) | |
| Cost of product sales (Non GAAP) | **92.2** | **13%** | 80.0 | 11% |

Non GAAP cost of product sales as a percentage of product sales increased in Q1 2010 compared to the same period in 2009 due to changes to the product mix following the launch of authorized generic versions of ADDERALL XR by Teva and Impax in April and October 2009, and the inclusion of lower margin sales of the authorized generic to Teva and Impax which depressed gross margins for ADDERALL XR.

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

| | Q1 2010 $M | % of product sales | Q1 2009 $M | % of product sales |
|---|---|---|---|---|
| R&D (US GAAP) | **131.0** | **18%** | 185.9 | 25% |
| Women's Health exit costs | **-** | | (65.0) | |
| Depreciation | **(3.7)** | | (4.0) | |
| R&D (Non GAAP) | **127.3** | **18%** | 116.9 | 15% |

Non GAAP R&D increased in absolute terms by $10.4 million in 2010 over 2009 due to continued increased investment in R&D programs, in part as a result of acceleration of the REPLAGAL and VPRIV programs. As a percentage of core product sales, Non GAAP R&D decreased by 5 percentage points to 20% (2009: 25%).

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

| | Q1 2010 $M | % of product sales | Q1 2009 $M | % of product sales |
|---|---|---|---|---|
| SG&A (US GAAP) | **359.9** | **50%** | 318.9 | 42% |
| Intangible asset amortization | **(34.6)** | | (32.5) | |
| Depreciation | **(16.3)** | | (14.8) | |
| SG&A (Non GAAP) | **309.0** | **43%** | 271.6 | 36% |

Non GAAP SG&A increased in 2010 compared to 2009 due in part to increased selling and marketing costs incurred in support of recently launched products. As a percentage of core product sales, Non GAAP SG&A decreased by 10 percentage points to 49% (2009: 59%).

### Reorganization costs

For the three months to March 31, 2010 Shire recorded reorganization costs of $5.0 million (2009: $2.2 million) principally relating to the transfer of manufacturing from its Owings Mills facility.

### Interest expense

For the three months to March 31, 2010 the Company incurred interest expense of $9.0 million (2009: $11.0 million). Interest expense principally relates to the coupon and deferred issue costs on Shire's $1,100 million 2.75% convertible bonds due 2014.

**Other income/(expense), net**

| | **Q1 2010 $M** | Q1 2009 $M |
|---|---|---|
| Other income, net (US GAAP) | **10.8** | 50.3 |
| Gain on sale of investments | **(11.1)** | (55.2) |
| Other expense, net (Non GAAP) | **(0.3)** | (4.9) |

Non GAAP other expense, net in 2010 was lower than the same period in 2009 due to foreign exchange losses in 2009 that were not repeated in 2010.

In the first quarter of 2010 Shire recognised a gain of $11.1 million (2009: $55.2 million) relating to the disposal of its investment in Virochem Pharma Inc. ("Virochem") in March 2009. At the time of the disposal, an element of the consideration was held in escrow for twelve months pending any warranty claims and breaches of representations made by Virochem and by all selling shareholders, including Shire. The remaining consideration was released from escrow in March 2010, resulting in a gain of $11.1 million being recognized in Q1 2010.

**Taxation**

The effective rate of tax for the three months to March 31, 2010 was 24% (2009: 19%), and the effective tax rate on Non GAAP income was 26% (2009: 24%).

The Non-GAAP effective tax rate in 2010 is higher than the same period in 2009 due to unfavourable changes in profit mix and the recording of valuation allowances in 2010 in relation to loss carry forward amounts which were not recorded in Q1 2009.

**FINANCIAL INFORMATION**

**TABLE OF CONTENTS**

**Unaudited US GAAP results for the three months to March 31, 2010**
**Consolidated Balance Sheets**

| | **March 31, 2010 $M** | December 31, 2009 $M |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | **657.5** | 498.9 |
| Restricted cash | **26.8** | 33.1 |
| Accounts receivable, net | **620.7** | 597.5 |
| Inventories | **215.6** | 189.7 |
| Deferred tax asset | **114.1** | 135.8 |
| Prepaid expenses and other current assets | **131.0** | 115.2 |
| Total current assets | **1,765.7** | 1,570.2 |
| Non-current assets: | | |
| Investments | **109.6** | 105.7 |
| Property, plant and equipment, net | **668.5** | 676.8 |
| Goodwill | **373.2** | 384.7 |
| Other intangible assets, net | **1,729.6** | 1,790.7 |
| Deferred tax asset | **80.9** | 79.0 |
| Other non-current assets | **11.2** | 10.4 |
| Total assets | **4,738.7** | 4,617.5 |
| LIABILITIES AND EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | **929.2** | 929.1 |
| Deferred tax liability | **3.3** | 2.9 |
| Other current liabilities | **36.5** | 88.0 |
| Total current liabilities | **969.0** | 1,020.0 |
| Non-current liabilities: | | |
| Convertible bonds | **1,100.0** | 1,100.0 |
| Other long-term debt | **43.7** | 43.6 |
| Deferred tax liability | **321.3** | 294.3 |
| Other non-current liabilities | **247.7** | 247.1 |
| Total liabilities | **2,681.7** | 2,705.0 |
| Shareholders' equity: | | |
| Common stock of 5p par value; 1,000 million shares authorized; and 562.1 million shares issued and outstanding (2009: 1,000 million shares authorized; and 561.5 million shares issued and outstanding) | **55.6** | 55.6 |
| Additional paid-in capital | **2,697.9** | 2,677.6 |
| Treasury stock: 15.7 million shares (2009: 17.8 million) | **(311.8)** | (347.4) |
| Accumulated other comprehensive income | **107.3** | 149.1 |
| Accumulated deficit | **(492.0)** | (622.4) |
| Total shareholders' equity | **2,057.0** | 1,912.5 |
| Total liabilities and equity | **4,738.7** | 4,617.5 |

## Unaudited US GAAP results for the three months to March 31, 2010
## Consolidated Statements of Operations

| 3 months to March 31, | 2010 $M | 2009 $M |
|---|---|---|
| Revenues: | | |
| Product sales | **718.2** | 756.0 |
| Royalties | **95.3** | 50.6 |
| Other revenues | **2.7** | 11.2 |
| Total revenues | **816.2** | 817.8 |
| | | |
| Costs and expenses: | | |
| Cost of product sales[(1)] | **101.9** | 83.6 |
| Research and development | **131.0** | 185.9 |
| Selling, general and administrative[(1)] | **359.9** | 318.9 |
| Reorganization costs | **5.0** | 2.2 |
| Integration and acquisition costs | **0.6** | 1.4 |
| Total operating expenses | **598.4** | 592.0 |
| | | |
| Operating income | **217.8** | 225.8 |
| | | |
| Interest income | **0.4** | 0.6 |
| Interest expense | **(9.0)** | (11.0) |
| Other income, net | **10.8** | 50.3 |
| Total other income, net | **2.2** | 39.9 |
| | | |
| Income from continuing operations before income taxes and equity in losses of equity method investees | **220.0** | 265.7 |
| Income taxes | **(53.6)** | (49.5) |
| Equity in losses of equity method investees, net of taxes | **(0.5)** | (0.1) |
| Income from continuing operations, net of tax | **165.9** | 216.1 |
| | | |
| Loss from discontinued operations (net of income tax expense of $nil and $nil respectively) | **-** | (2.6) |
| Net income | **165.9** | 213.5 |
| | | |
| Add: Net loss attributable to noncontrolling interest in subsidiaries | **-** | 0.1 |
| Net income attributable to Shire plc | **165.9** | 213.6 |

[(1)] Cost of product sales includes amortization of intangible assets relating to favorable manufacturing contracts of $0.4 million for the three months to March 31, 2010 (2009: $0.4 million). Selling, general and administrative costs include amortization of intangible assets relating to intellectual property rights acquired of $34.6 million for the three months to March 31, 2010 (2009: $32.5 million).

## Unaudited US GAAP results for the three months to March 31, 2010
## Consolidated Statements of Operations (continued)

| 3 months to March 31, | 2010 | 2009 |
|---|---|---|
| **Earnings per ordinary share – basic** | | |
| Earnings from continuing operations | **30.5c** | 40.1c |
| Loss from discontinued operations | **-** | (0.5c) |
| Earnings per ordinary share – basic | **30.5c** | 39.6c |
| Earnings per ADS – basic | **91.5c** | 118.8c |
| **Earnings per ordinary share – diluted** | | |
| Earnings from continuing operations | **29.7c** | 38.9c |
| Loss from discontinued operations | **-** | (0.4c) |
| Earnings per ordinary share – diluted | **29.7c** | 38.5c |
| Earnings per ADS – diluted | **89.1c** | 115.5c |
| **Weighted average number of shares:** | | |
| | **Millions** | Millions |
| Basic | **543.9** | 539.2 |
| Diluted | **586.1** | 577.2 |

**Unaudited US GAAP results for the three months to March 31, 2010**
**Consolidated Statements of Cash Flows**

| **3 months to March 31,** | **2010** | 2009 |
|---|---|---|
| | **$M** | $M |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income | **165.9** | 213.5 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Loss from discontinued operations | **-** | 2.6 |
| Depreciation and amortization | **64.3** | 55.3 |
| Share based compensation | **14.1** | 15.8 |
| Gain on sale of non-current investments | **(11.1)** | (55.2) |
| Other | **5.2** | 3.3 |
| Movement in deferred taxes | **52.2** | 33.7 |
| Equity in losses of equity method investees | **0.5** | 0.1 |
| | | |
| Changes in operating assets and liabilities: | | |
| Increase in accounts receivable | **(10.8)** | (151.0) |
| Increase in sales deduction accrual | **64.9** | 121.9 |
| Increase in inventory | **(24.2)** | (9.5) |
| Increase in prepayments and other current assets | **(18.1)** | (12.3) |
| (Increase)/decrease in other assets | **(0.6)** | 3.4 |
| Decrease in accounts and notes payable and other liabilities | **(116.1)** | (39.8) |
| Returns on investment from joint venture | **-** | 4.9 |
| Cash flows used in discontinued operations | **-** | (2.6) |
| Net cash provided by operating activities[(A)] | **186.2** | 184.1 |
| | | |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Movements in restricted cash | **6.3** | (6.9) |
| Purchases of subsidiary undertakings and businesses, net of cash acquired | **-** | (74.1) |
| Purchases of property, plant and equipment | **(43.6)** | (42.0) |
| Purchases of intangible assets | **-** | (6.0) |
| Proceeds from disposal of long-term investments | **2.0** | 19.2 |
| Proceeds from disposal of property, plant and equipment | **0.1** | 0.4 |
| Returns from equity investments | **-** | 0.2 |
| Net cash used in investing activities[(B)] | **(35.2)** | (109.2) |
| | | |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Payment under building financing obligation | **(0.7)** | (0.7) |
| Proceeds from exercise of options | **1.5** | 0.1 |
| Tax benefit of stock based compensation | **4.8** | - |
| Net cash provided by/(used in) financing activities[(C)] | **5.6** | (0.6) |
| | | |
| Effect of foreign exchange rate changes on cash and cash equivalents[(D)] | **2.0** | (1.4) |
| | | |
| Net increase in cash and cash equivalents[(A) +(B) +(C) +(D)] | **158.6** | 72.9 |
| Cash and cash equivalents at beginning of period | **498.9** | 218.2 |
| Cash and cash equivalents at end of period | **657.5** | 291.1 |

**Unaudited US GAAP results for the three months to March 31, 2010**
**Selected Notes to the Financial Statements**

**(1) Earnings per share**

| **3 months to March 31,** | **2010 $M** | 2009 $M |
|---|---|---|
| Income from continuing operations | **165.9** | 216.1 |
| Loss from discontinued operations | **-** | (2.6) |
| Noncontrolling interest in subsidiaries | **-** | 0.1 |
| Numerator for basic EPS | **165.9** | 213.6 |
| Interest on convertible bonds, net of tax[1] | **8.4** | 8.4 |
| Numerator for diluted EPS | **174.3** | 222.0 |
| Weighted average number of shares: | | |
| | **Millions** | Millions |
| Basic[2] | **543.9** | 539.2 |
| Effect of dilutive shares: | | |
| Stock options[3] | **9.0** | 5.3 |
| Convertible bonds 2.75% due 2014[1] | **33.2** | 32.7 |
| Diluted | **586.1** | 577.2 |

(1) Calculated using the "if-converted" method.
(2) Excludes shares purchased by the Employee Share Ownership Trust ("ESOT") and presented by Shire as treasury stock.
(3) Calculated using the treasury stock method.

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

| **3 months to March 31,** | **2010 No. of shares Millions[1]** | 2009 No. of shares Millions[1] |
|---|---|---|
| Stock options out of the money | **16.1** | 16.6 |

[1] For the three month periods ended March 31, 2010 and 2009, 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.

**(2) Analysis of revenues**

| **3 months to March 31,** | **2010** | 2009 | **2010** | **2010** |
|---|---|---|---|---|
| | | | **%** | **% of total** |
| | **$M** | $M | **change** | **revenue** |
| **Net product sales:** | | | | |
| *Specialty Pharmaceuticals ("Speciality")* | | | | |
| ADHD | | | | |
| ADDERALL XR | **91.8** | 295.8 | **-69%** | **11%** |
| VYVANSE | **154.4** | 116.6 | **32%** | **19%** |
| DAYTRANA | **18.4** | 19.9 | **-7%** | **2%** |
| EQUASYM | **2.4** | - | **n/a** | **<1%** |
| INTUNIV | **34.5** | - | **n/a** | **4%** |
| | **301.5** | 432.3 | **-30%** | **37%** |
| GI | | | | |
| PENTASA | **58.2** | 51.2 | **14%** | **7%** |
| LIALDA / MEZAVANT | **63.6** | 49.4 | **29%** | **8%** |
| | **121.8** | 100.6 | **21%** | **15%** |
| General products | | | | |
| FOSRENOL | **47.1** | 39.8 | **18%** | **6%** |
| CALCICHEW | **9.4** | 9.6 | **-2%** | **1%** |
| CARBATROL | **20.1** | 18.1 | **11%** | **2%** |
| REMINYL/REMINYL XL | **12.5** | 7.4 | **69%** | **2%** |
| XAGRID | **23.3** | 20.1 | **16%** | **3%** |
| | **112.4** | 95.0 | **18%** | **14%** |
| Other product sales | **5.7** | 4.6 | **24%** | **1%** |
| Total Specialty product sales | **541.4** | 632.5 | **-14%** | **66%** |
| *Human Genetic Therapies ("HGT")* | | | | |
| ELAPRASE | **100.8** | 82.8 | **22%** | **12%** |
| REPLAGAL | **68.0** | 40.2 | **69%** | **8%** |
| VPRIV | **5.8** | - | **n/a** | **1%** |
| FIRAZYR | **2.2** | 0.5 | **340%** | **<1%** |
| Total HGT product sales | **176.8** | 123.5 | **43%** | **22%** |
| Total product sales | **718.2** | 756.0 | **-5%** | **88%** |
| **Royalties:** | | | | |
| 3TC and ZEFFIX | **36.6** | 38.8 | **-6%** | **4%** |
| ADDERALL XR | **40.8** | - | **n/a** | **5%** |
| Other | **17.9** | 11.8 | **52%** | **2%** |
| Total royalties | **95.3** | 50.6 | **88%** | **11%** |
| Other revenues | **2.7** | 11.2 | **-76%** | **<1%** |
| Total Revenues | **816.2** | 817.8 | **0%** | **100%** |

**Unaudited results for the three months to March 31, 2010**
**Non GAAP reconciliation**

| | US GAAP | Adjustments | | | | Non GAAP |
|---|---|---|---|---|---|---|
| **3 months to,** | March 31, 2010 | Amortization & asset impairments (a) | Acquisitions & integration activities (b) | Divestments, reorganizations & discontinued operations (c) | Reclassify depreciation (d) | March 31, 2010 |
| | $M | $M | $M | $M | $M | $M |
| **Total revenues** | **816.2** | **-** | **-** | **-** | **-** | **816.2** |
| **Costs and expenses:** | | | | | | |
| Cost of product sales | 101.9 | - | - | (7.2) | (2.5) | 92.2 |
| Research and development | 131.0 | - | - | - | (3.7) | 127.3 |
| Selling, general and administrative | 359.9 | (34.6) | - | - | (16.3) | 309.0 |
| Reorganization costs | 5.0 | - | - | (5.0) | - | - |
| Integration and acquisition costs | 0.6 | - | (0.6) | - | - | - |
| Depreciation | - | - | - | - | 22.5 | 22.5 |
| Total operating expenses | 598.4 | (34.6) | (0.6) | (12.2) | - | 551.0 |
| **Operating income** | **217.8** | **34.6** | **0.6** | **12.2** | **-** | **265.2** |
| Interest income | 0.4 | - | - | - | - | 0.4 |
| Interest expense | (9.0) | - | - | - | - | (9.0) |
| Other income/(expenses), net | 10.8 | - | - | (11.1) | - | (0.3) |
| Total other income/(expense), net | 2.2 | - | - | (11.1) | - | (8.9) |
| Income from continuing operations before income taxes and equity in losses of equity method investees | 220.0 | 34.6 | 0.6 | 1.1 | - | 256.3 |
| Income taxes | (53.6) | (9.7) | (0.1) | (3.1) | - | (66.5) |
| Equity in losses of equity method investees, net of tax | (0.5) | - | - | - | - | (0.5) |
| **Net income attributable to Shire plc** | **165.9** | **24.9** | **0.5** | **(2.0)** | **-** | **189.3** |
| Impact of convertible debt, net of tax | 8.4 | - | - | - | - | 8.4 |
| **Numerator for diluted EPS** | **174.3** | **24.9** | **0.5** | **(2.0)** | **-** | **197.7** |
| Weighted average number of shares (millions) – diluted | 586.1 | - | - | - | - | 586.1 |
| Diluted earnings per ADS | **89.1c** | **12.8c** | **0.3c** | **(1.0c)** | **-** | **101.2c** |

The following items are included in Adjustments:

(a) Amortization and asset impairments: Amortization of intangible assets relating to intellectual property rights acquired ($34.6 million) and tax effect of adjustment;
(b) Acquisitions and integration activities Costs associated with the acquisition of EQUASYM ($0.6 million) and tax effect of adjustments;
(c) Divestments, reorganizations and discontinued operations: Accelerated depreciation ($6.1 million), dual running costs ($1.1 million) and reorganization costs ($5.0 million) primarily for the transfer of manufacturing from Owings Mills; gain on disposal of investment in Virochem ($11.1 million); and tax effect of adjustments; and
(d) Depreciation: Depreciation of $22.5 million included in Cost of product sales, R&D costs and SG&A costs for US GAAP separately disclosed for the presentation of Non GAAP earnings.

**Unaudited results for the three months to March 31, 2009**
**Non GAAP reconciliation**

| | US GAAP | Adjustments | | | | Non GAAP |
|---|---|---|---|---|---|---|
| **3 months to,** | March 31, 2009 | Amortization & asset impairments (a) | Acquisitions & integration activities (b) | Divestments, reorganizations & discontinued operations (c) | Reclassify depreciation (d) | March 31, 2009 |
| | $M | $M | $M | $M | $M | $M |
| **Total revenues** | **817.8** | **-** | **-** | **-** | **-** | **817.8** |
| **Costs and expenses:** | | | | | | |
| Cost of product sales | 83.6 | - | - | - | (3.6) | 80.0 |
| Research and development | 185.9 | - | - | (65.0) | (4.0) | 116.9 |
| Selling, general and administrative | 318.9 | (32.5) | - | - | (14.8) | 271.6 |
| Reorganization costs | 2.2 | - | - | (2.2) | - | - |
| Integration and acquisition costs | 1.4 | - | (1.4) | - | - | - |
| Depreciation | - | - | - | - | 22.4 | 22.4 |
| Total operating expenses | 592.0 | (32.5) | (1.4) | (67.2) | - | 490.9 |
| **Operating income** | **225.8** | **32.5** | **1.4** | **67.2** | **-** | **326.9** |
| Interest income | 0.6 | - | - | - | - | 0.6 |
| Interest expense | (11.0) | - | - | - | - | (11.0) |
| Other income, net | 50.3 | - | - | (55.2) | - | (4.9) |
| Total other expense, net | 39.9 | - | - | (55.2) | - | (15.3) |
| Income from continuing operations before income taxes and equity in losses of equity method investees | 265.7 | 32.5 | 1.4 | 12.0 | - | 311.6 |
| Income taxes | (49.5) | (9.9) | (0.2) | (15.2) | - | (74.8) |
| Equity in losses of equity method investees, net of tax | (0.1) | - | - | - | - | (0.1) |
| **Income from continuing operations, net of tax** | **216.1** | **22.6** | **1.2** | **(3.2)** | **-** | **236.7** |
| Loss from discontinued operations | (2.6) | - | - | 2.6 | - | - |
| Net income | 213.5 | 22.6 | 1.2 | (0.6) | - | 236.7 |
| Add: Net loss attributable to noncontrolling interest in subsidiaries | 0.1 | - | - | - | - | 0.1 |
| **Net income attributable to Shire plc** | 213.6 | 22.6 | 1.2 | (0.6) | - | 236.8 |
| Impact of convertible debt, net of tax | 8.4 | - | - | - | - | 8.4 |
| **Numerator for diluted EPS** | **222.0** | **22.6** | **1.2** | **(0.6)** | **-** | **245.2** |
| Weighted average number of shares (millions) – diluted | 577.2 | - | - | - | - | 577.2 |
| Diluted earnings per ADS | **115.5c** | **11.7c** | **0.6c** | **(0.3c)** | **-** | **127.5c** |

The following items are included in Adjustments:

(a) Amortization and asset impairments: Amortization of intangible assets relating to intellectual property rights acquired ($32.5 million), and tax effect of adjustment;

(b) Acquisitions & integration activities: Integration and transaction related costs in respect of the acquisition of Jerini and EQUASYM ($1.4 million) and tax effect of adjustments;

(c) Divestments, reorganizations and discontinued operations: Costs associated with agreement to terminate development of Women's Health products with Duramed ($65.0 million); reorganization costs for the transition of manufacturing from Owings Mills ($2.2 million); gain on disposal of the investment in Virochem ($55.2 million); discontinued operations in respect of Jerini businesses held for sale ($2.6 million); and tax effect of adjustments; and

(d) Depreciation: Depreciation of $22.4 million included in Cost of product sales, R&D costs and SG&A costs for US GAAP separately disclosed for the presentation of Non GAAP earnings.

**Unaudited results for the three months to March 31, 2010**
**Non GAAP reconciliation**

The following table reconciles US GAAP net cash provided by operating activities to Non GAAP cash generation:

| **3 months to March 31,** | **2010** | 2009 |
|---|---|---|
| | **$M** | $M |
| **Net cash provided by operating activities** | **186.2** | 184.1 |
| Tax and interest payments, net | **90.1** | 51.2 |
| Foreign exchange on cash | **2.0** | (1.4) |
| **Non GAAP cash generation** | **278.3** | 233.9 |

**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 and hyperactivity disorder, human genetic therapies and gastrointestinal 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.

**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, Shire's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of research, development, approval, reimbursement, manufacturing and commercialization of Shire's Specialty Pharmaceutical and Human Genetic Therapies products, as well as the ability to secure new products for commercialization and/or development; government regulation of Shire's products; Shire's ability to manufacture its products in sufficient quantities to meet demand; the impact of competitive therapies on Shire's products; Shire's ability to register, maintain and enforce patents and other intellectual property rights relating to its products; Shire's ability to obtain and maintain government and other third-party reimbursement for its products; and other risks and uncertainties detailed from time to time in Shire's filings with the Securities and Exchange Commission.

**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 ADS; effective tax rate on Non GAAP income from continuing operations before income taxes and earnings of equity method investees ("Effective tax rate on Non GAAP income"); Non GAAP cost of product sales; Non GAAP research and development; Non GAAP selling, general and administrative; Non GAAP other income; and Non GAAP cash generation*. 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 Shire's performance to historical results and to competitors' results. Shire's Remuneration Committee uses certain key Non GAAP measures when assessing the performance and compensation of employees, including Shire's executive directors.

The Non GAAP measures are presented in this press release as Shire's management believe that they will provide investors with a means of evaluating, and an understanding of how Shire's management evaluates, Shire'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 Shire'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 items, including their tax effect, have been excluded from both Q1 2010 and 2009 Non GAAP earnings, and from our 2010 outlook:

*Amortization and asset impairments:*
- Intangible asset amortization and impairment charges; and
- Other than temporary impairment of investments.

*Acquisitions and integration activities:*
- Upfront payments and milestones in respect of in-licensed and acquired products;
- Costs associated with acquisitions, including transaction costs, and fair value adjustments on contingent consideration and acquired inventory; and
- Costs associated with the integration of companies.

*Divestments, re-organizations and discontinued operations*
- Gains and losses on the sale of non-core assets;
- Costs associated with restructuring and re-organization activities;
- Termination costs;
- Costs associated with the introduction of the new holding company; and
- Income / (losses) from discontinued operations.

Depreciation, which is included in Cost of product sales, Research and development and Selling, general and administrative costs in our US GAAP results, has been separately disclosed for the presentation of 2009 and 2010 Non GAAP earnings. A reconciliation of Non GAAP financial measures to the most directly comparable measure under US GAAP is presented on pages 17 and 18.

Sales growth at CER, which is a Non GAAP measure, is computed by restating 2010 results using average 2009 foreign exchange rates for the relevant period.

Average exchange rates for Q1 2010 were $1.56:£1.00 and $1.38:€1.00 (2009: $1.44:£1.00 and $1.31:€1.00).

**TRADEMARKS**



1 REMINYL® and REMINYL XL™ are both trademarks of Shire in the UK and Republic of Ireland.