

## New Chief Executive reports Q1 results and sets out strategy for growth

### Shire delivers 10% increase in Non GAAP earnings; full year EPS guidance in line with consensus <sup>(1)</sup>

May 2, 2013 – Shire (LSE: SHP, NASDAQ: SHPG) announces results for the three months to March 31, 2013.

Financial Highlights	Q1 2013	Reported Growth <sup>(2)</sup>
Product sales	\$1,117 million	+1% <sup>(3)</sup>
Total revenues	\$1,162 million	-1% <sup>(3)</sup>
Non GAAP operating income	\$393 million	+9%
US GAAP operating income	\$129 million	-56% <sup>(4)</sup>
Non GAAP diluted earnings per ADS	\$1.63	+10%
US GAAP diluted earnings per ADS	\$0.35	-72%
Non GAAP cash generation	\$257 million	-17%
Non GAAP free cash flow	\$113 million	-54%
US GAAP net cash provided by operating activities	\$160 million	-38%

(1) See page 4 for assumptions.

(2) Percentages compare to equivalent 2012 period.

(3) Percentage growth on a Constant Exchange Rate ("CER") basis is in line with the reported growth for the quarter.

(4) US GAAP operating income includes the impact of goodwill impairment, see page 11 for details.

The Non GAAP financial measures included within this release are explained on page 21, and are reconciled to the most directly comparable financial measures prepared in accordance with US GAAP on pages 18 - 20.

#### Flemming Ornskov, M.D., Chief Executive Officer, commented:

"In Q1 2013 we experienced continued strong performance from VYVANSE, INTUNIV, LIALDA, VPRIV and FIRAZYR offset by the challenge of lower sales of DERMAGRAFT and REPLAGAL which we are actively managing. We generated \$257 million of cash during the quarter and delivered 10% Non GAAP earnings growth while investing in our R&D pipeline.

Shire has consistently delivered growth significantly above the industry levels of mid single digit and we intend that this will be the case in the future. As we look forward to the remainder of the year, we continue to expect to deliver earnings growth in line with current consensus earnings expectations for 2013 <sup>(1)</sup>.

On becoming Shire Chief Executive Officer, I am pleased to confirm the direction we will take, in order to continue to deliver significantly above industry average growth. We intend to continue to be a high-growth innovation business providing differentiated specialist medicines in areas of high unmet need for patients treated by specialist physicians. Shire's strategic priorities are to grow sales of our existing portfolio and to bring new innovative treatments to market through both R&D and Business Development.

To deliver this we are evolving the way the business works, introducing a flatter and more scalable structure of initially five commercially focused business units (Rare Diseases, Neuroscience, GI, Regenerative Medicine and Internal Medicine) and a single R&D organization supported by centralized corporate functions.

In the first quarter we added to our pipeline with three acquisitions: Lotus Tissue Repair, Premacure and SARcode BioSciences. The last two provide us with the foundation to build a potential new business unit in ophthalmology – a growing market with many unmet patient needs. We're reviewing our pipeline to prioritize investment in our innovative, late stage pipeline assets. We also aim to focus our business development on acquiring later stage assets and to grow our sales in Latin America and Asia.

As the new Chief Executive, I am excited by the potential opportunities for delivering even greater value to Shire's patients and shareholders and I look forward to updating you in the many quarters to come."

## SHIRE STRATEGY

Flemming Ornskov, Chief Executive Officer (“CEO”) today sets out his strategy for Shire’s future and outlines a re-alignment of its business structure to drive future growth and innovation. Shire will continue to grow through focusing on its core strengths of developing and marketing innovative specialist medicines to meet significant unmet patient needs.

The growth strategy will be delivered through a sharpened focus on two key priorities:

- Commercial Excellence - driving optimum performance of currently marketed products
- Pipeline Innovation - building the pipeline of specialty medicines to deliver future value through both Research & Development (“R&D”) and Business Development (“BD”)

These priorities will be underpinned by a simplification of the business structure in order to drive commercial excellence and pipeline innovation. Shire will have an “In-Line” marketed product group and a “Pipeline” group, supported by a single technical operations group and simplified, centralized corporate functions.

### Delivering the strategy

The newly established “In-Line” marketed products group will consist of five business units (“BU”s) focused exclusively on commercial delivery; Rare Diseases, Neuroscience (formerly Behavioral Health), Gastrointestinal (“GI”), Regenerative Medicine (“RM”) and Internal Medicine. More BUs will be formed when significant assets are either acquired or reach the appropriate stage of development.

The Pipeline group, consisting of R&D and BD, will prioritize its activities towards late stage development programs. Pre-clinical development focus will be primarily in rare diseases. As part of the delivery of this strategy, Shire's R&D will be led by a single R&D organization. BD will continue to be a key activity for Shire, focused on identifying later stage development programs and in market products in target specialist areas.

In addition to chairing a newly formed Executive Committee, Flemming Ornskov will also chair the “In-Line” and “Pipeline” group teams, which will be the engines accountable for driving the profitable growth.

### Geographic expansion

Shire will work to increase profitability of its existing international business while also investing in Asia and Latin America. Plans are underway for more focused growth in Japan where Shire recently announced the establishment of a new office, and in Brazil which is already the 5<sup>th</sup> largest country for Shire’s rare disease business sales. China has also been identified as a priority and Shire is evaluating options for expanding more of the business into this dynamic market.

## FINANCIAL SUMMARY

### First Quarter 2013 Unaudited Results

	Q1 2013			Q1 2012		
	US GAAP	Adjustments	Non GAAP	US GAAP	Adjustments	Non GAAP
	\$M	\$M	\$M	\$M	\$M	\$M
Total revenues	1,162	-	1,162	1,172	-	1,172
Operating income	129	264	393	295	67	362
Diluted earnings per ADS	\$0.35	\$1.28	\$1.63	\$1.24	\$0.24	\$1.48

- Product sales in Q1 2013 were \$1,117 million, up 1% compared against a strong set of comparatives in Q1 2012.

Five of our top ten products delivered double digit growth: VYVANSE<sup>®</sup> (up 15% to \$298 million), LIALDA<sup>®</sup>/MEZAVANT<sup>®</sup> (up 12% to \$101 million), VPRIV<sup>®</sup> (up 14% to \$82 million), INTUNIV<sup>®</sup> (up 13% to \$78 million) and FIRAZYR<sup>®</sup> (up 112% to \$42 million).

Total product sales were held back this quarter by DERMAGRAFT<sup>®</sup> (down 62% to \$19 million), resulting from the ongoing restructuring of the RM commercial organization; REPLAGAL<sup>®</sup> (down 15% to \$114 million) due to some shipment timings and as increased competition outweighed continued growth in new naïve patients; and ELAPRASE<sup>®</sup> (down 9% to \$114 million) due to uneven ordering patterns in Latin America.

The rate of growth in total product sales (Q1 2013: +1%) is expected to improve to mid-to-high single digit growth for the full year as our portfolio continues to deliver growth and we benefit from easing comparatives over the second half of the year.

- Total revenues decreased 1% to \$1,162 million (Q1 2012: \$1,172 million) as growth in product sales was offset, as expected, by lower royalties, particularly ADDERALL XR<sup>®</sup> royalties received from Impax Laboratories Inc. ("Impax") due to both lower volumes and a lower royalty rate payable since the launch of a new generic product.
- On a Non GAAP basis:  
Operating income was up 9% to \$393 million (Q1 2012: \$362 million), as combined total operating costs decreased at a higher rate (down 5%) than total revenues, driven by lower Selling, General and Administrative ("SG&A") expenditure (down 16% reflecting both lower SG&A this year and comparison to high SG&A in Q1 2012). The effect was moderated by higher R&D expenditure, which was up 15% as we continue to progress a number of early and late stage pipeline programs expected to drive future growth.

On a US GAAP basis:

Operating income was down 56% to \$129 million (Q1 2012: \$295 million) primarily due to an impairment charge for goodwill (\$199 million) relating to Shire's RM business. Following a review of future forecasts for the RM business unit, management determined in Q1 2013 that future sales are now expected to be lower than anticipated at the time of acquisition and consequently in accordance with US GAAP it has been determined that the goodwill attributable to the RM business unit is impaired.

- Non GAAP diluted earnings per ADS increased 10% to \$1.63 (Q1 2012: \$1.48) due to higher Non GAAP operating income and a lower effective tax rate on Non GAAP income of 19% (Q1 2012: 20%).

On a US GAAP basis, diluted earnings per ADS decreased 72% to \$0.35 (Q1 2012: \$1.24), due to lower US GAAP operating income and a higher US GAAP effective tax rate of 46% (Q1 2012: 17%) both of which reflect the impact of the impairment of RM goodwill.

- Cash generation, a Non GAAP measure, decreased by 17% to \$257 million (Q1 2012: \$310 million) as higher cash receipts from gross product sales were more than offset by the payment to settle the litigation with Impax (\$48 million), lower royalty receipts and higher sales deduction payments in the quarter.

Free cash flow, also a Non GAAP measure, decreased by 54% to \$113 million (Q1 2012: \$248 million) primarily due to the lower cash generation and the effect of higher cash tax payments in Q1 2013 as compared to Q1 2012.

On a US GAAP basis, net cash provided by operating activities was down 38% to \$160 million (Q1 2012: \$257 million).

## OUTLOOK

We reiterate our confidence in delivering Non GAAP earnings growth in line with consensus earnings expectations for 2013<sup>(1)</sup>.

For the full year we now anticipate product sales growth in the mid-to-high single digits. The rate of growth in total product sales will improve from that seen in the first quarter as our portfolio continues to deliver growth and we benefit from an easing of comparatives over the second half of the year.

Specifically we expect ELAPRASE to post double digit growth for the full year and we expect REPLAGAL sales to recover from the first quarter decline to be more in line with 2012 for the full year. We expect DERMAGRAFT to return to growth in the second half but sales for the full year will still be lower than in 2012.

We continue to expect Royalties and other revenues to be 30-40% lower than 2012, and our Non GAAP gross margin is expected to remain at a similar level to 2012.

We expect low-to-mid teens growth in Non GAAP R&D as we continue to invest increasing amounts in our promising pipeline and to progress our late stage clinical trials. As a result of lower Non GAAP SG&A in Q1, and continued careful management of our cost base, we now expect Non GAAP SG&A for the full year to be marginally lower than 2012. Taken together, we now expect low single digit growth in combined Non GAAP R&D and SG&A, creating operating leverage for the full year.

Our core effective tax rate on Non GAAP income is anticipated to remain in the range of 18-20%.

As we look forward to the remainder of the year, we continue to expect to deliver earnings growth in line with current consensus earnings expectations for 2013<sup>(1)</sup>.

(1) Based on the most recent consensus estimates compiled by Consensus Forecast Ltd, as of the date of this press release, of \$6.67 Non GAAP diluted earnings per ADS for the year ended 31 December 2013, available on Shire's website (<http://www.shire.com/shireplc/en/investors/forecasts>).

## FIRST QUARTER 2013 AND RECENT PRODUCT AND PIPELINE DEVELOPMENTS

### Products

VYVANSE – for the treatment of Attention Deficit Hyperactivity Disorder (“ADHD”)

- On May 1, 2013 Shire announced that the US Food and Drug Administration (“FDA”) approved VYVANSE as a maintenance treatment in children and adolescents with ADHD. With this new approval, VYVANSE is currently the only stimulant approved for maintenance treatment in children and adolescents aged 6 to 17 years with ADHD, as well as in adults with ADHD.

DERMAGRAFT – for the treatment of Diabetic Foot Ulcers (“DFU”) in Canada

- On March 25, 2013 Shire announced that DERMAGRAFT is now available in Canada for the treatment of DFU, following its approval by Health Canada as a class IV medical device for the treatment of DFU in September 2012.

VPRIV – for the treatment of Gaucher disease (Type 1)

- On March 21, 2013 the Committee for Medicinal Products for Human Use of the European Medicines Agency issued a positive opinion regarding an update to the clinical efficacy and safety section of the VPRIV Summary of Product Characteristics to include information on long term clinical data relating to efficacy and safety in skeletal pathology from the TKT025 extension study in Type 1 Gaucher patients.

### Pipeline

Lisdexamfetamine dimesylate<sup>(1)</sup> (“LDX”) – for the treatment of negative symptoms of schizophrenia (“NSS”)

- Shire has cancelled the NSS Phase 3 program after a review and prioritization of Shire’s development portfolio and taking into account investment requirements for recent acquisitions. No patients had been dosed in the studies and this decision was not due to any safety issues with LDX in any patient population. Shire remains committed to continuing Phase 3 trials for MDD and BED and these are enrolling as expected.

<sup>(1)</sup> Currently marketed as VYVANSE in the US and ELVANSE<sup>®</sup> in certain territories in the EU for the treatment of ADHD.

HGT4510 – for Duchenne Muscular Dystrophy (“DMD”)

- In April 2013, following analysis of the results of toxicology studies, Shire discontinued development of HGT4510 and returned Shire’s rights in the asset to Acceleron Pharma Inc. The development of HGT4510 was placed on clinical hold in February 2011, subject to the completion of the toxicology studies.

VASCUGEL<sup>®</sup> – for the treatment of end-stage renal disease.

- In March 2013, Shire enrolled the first patient in its Phase 2 clinical program for VASCUGEL.

## OTHER DEVELOPMENTS

### Legal Proceedings

INTUNIV patent litigation

- On April 25, 2013, Shire settled all pending litigation with Actavis, Inc., Actavis LLC, and Actavis Elizabeth LLC (collectively “Actavis”) and Watson Laboratories, Inc.-Florida, Watson Pharma, Inc. and ANDA, Inc. (collectively “Watson”) in connection with Actavis’s and Watson’s Abbreviated New Drug Applications (“ANDAs”) for generic versions of INTUNIV for the treatment of ADHD.

The settlement provides Actavis with a license to make and market Actavis’s generic versions of INTUNIV in the United States on December 1, 2014, or earlier in certain limited circumstances. Such sales will require the payment of a royalty of 25% of gross profits to Shire during the 180 day period of Actavis’s exclusivity. The settlement also provides Watson with a license to make and market Watson’s generic versions of INTUNIV in the United States, 181 days after Actavis’s launch of generic INTUNIV, or earlier in certain limited circumstances.

### **Acquisition of SARcode Bioscience Inc. (“SARcode”)**

- On April 17, 2013 Shire completed the acquisition of SARcode, a privately held biopharmaceutical company based in Brisbane, California. This acquisition brings a new Phase 3 compound, lifitegrast, currently under development for the signs and symptoms of dry eye disease, into Shire’s portfolio. Shire anticipates launching lifitegrast in the United States as early as 2016 pending a positive outcome of the Phase 3 clinical development program and regulatory approvals. Shire is acquiring the global rights to lifitegrast and will evaluate an appropriate regulatory filing strategy for markets outside of the United States. After customary closing adjustments, cash consideration paid on closing amounted to \$150 million with further potential contingent payments upon achievement of certain clinical, regulatory, and commercial milestones.

### **Acquisition of Premacure AB (“Premacure”)**

- On March 8, 2013 Shire completed the acquisition of Premacure, a privately held biotechnology company based in Uppsala, Sweden, developing PREMIPLEX<sup>®</sup>, a protein replacement therapy in Phase 2 development for the prevention of retinopathy of prematurity (“ROP”). Shire purchased Premacure for an up-front payment of \$31 million with further potential contingent payments based on the achievement of pre-specified development and commercial milestones.

Shire will continue the ongoing Phase 2 study, the primary goal of which is to compare the severity of ROP among patients treated with PREMIPLEX, versus an untreated control population matched for gestational age.

The acquisition of SARcode and Premacure will provide Shire with the foundation to build a potential new business unit in ophthalmology – a growing market with many unmet patient needs.

### **Acquisition of Lotus Tissue Repair, Inc. (“Lotus”)**

- On February 12, 2013 Shire completed the acquisition of Lotus, a privately held biotechnology company, based in Cambridge, MA, with a protein replacement therapy in pre-clinical development currently being investigated for the treatment of dystrophic epidermolysis bullosa (“DEB”). DEB is a devastating orphan disease for which there is no currently approved treatment option other than palliative care. Shire purchased the company for an up-front cash payment of \$49 million and further contingent cash payments may be payable in future periods, depending on the achievement of certain safety and development milestones.

### **Share buy-back Program**

- In Q4 2012 Shire commenced a share buy-back program, for the purpose of returning funds to shareholders, of up to \$500 million, through both direct purchases of ordinary shares and through the purchase of ordinary shares underlying American Depositary Receipts. As of April 30, 2013 Shire had made on-market repurchases totaling 7,374,182 ordinary shares at a cost of \$222.7 million (excluding transaction costs).

For the weighted average number of shares used for Non GAAP diluted earnings per ADS, please refer to the Non GAAP reconciliation tables on pages 18 - 19.

### **BOARD AND COMMITTEE CHANGES**

- Shire announces that Susan Kilsby, Non Executive Director of Shire becomes the Chairman of Shire’s Audit, Compliance & Risk Committee with immediate effect. Susan has been a member of this Committee since September 2011 when she joined the Board. She takes over the Chairmanship from David Kappler who remains a member of the Committee.
- Shire also announces that Dr David Ginsburg becomes Chairman of Shire’s Science & Technology Committee with immediate effect. Dr David Ginsburg has been a member of the Committee and the Board since June 2010 and he has more recently been the acting Chairman of the Science & Technology Committee.

## ADDITIONAL INFORMATION

The following additional information is included in this press release:

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Dial in details for the **live conference call** for investors 13:00 BST / 08:00 EDT on May 2, 2013:

UK dial in: 0808 237 0030 or 0203 139 4830

US dial in: 1 866 928 7517 or 1 718 873 9077

International Access Numbers: [Click here](#)

Password/Conf ID: 29454716#

Live Webcast: [Click here](#)



## OVERVIEW OF FIRST QUARTER 2013 FINANCIAL RESULTS

### 1. Product sales

For the three months to March 31, 2013 product sales increased by 1% to \$1,117 million (Q1 2012: \$1,107 million) and represented 96% of total revenues (Q1 2012: 94%).

Product sales	Sales \$M	Year on year growth			US Exit Market Share <sup>(1)</sup>
		Sales	Non GAAP CER	US Rx <sup>(1)</sup>	
VYVANSE	298.4	+15%	+15%	+6%	17%
ELAPRASE	114.3	-9%	-9%	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
REPLAGAL	114.0	-15%	-15%	n/a <sup>(3)</sup>	n/a <sup>(3)</sup>
LIALDA/MEZAVANT	100.5	+12%	+12%	+9%	23%
VPRIV	81.6	+14%	+14%	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
INTUNIV	77.7	+13%	+13%	+12%	4%
PENTASA®	71.0	+8%	+8%	-3%	14%
FIRAZYR	41.7	+112%	+111%	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
DERMAGRAFT	18.5	-62%	-62%	n/a <sup>(2)</sup>	n/a <sup>(2)</sup>
OTHER	99.2	-11%	-11%	n/a	n/a
<b>Excluding ADDERALL XR</b>	<b>1,016.9</b>	<b>+2%</b>	<b>+2%</b>		
ADDERALL XR	99.8	-10%	-10%	-20%	5%
<b>Total</b>	<b>1,116.7</b>	<b>+1%</b>	<b>+1%</b>		

(1) Data provided by IMS Health National Prescription Audit ("IMS NPA"). Exit market share represents the average monthly US market share in the month ended March 31, 2013.

(2) IMS NPA Data not available.

(3) Not sold in the US in Q1 2013.

#### VYVANSE – ADHD

VYVANSE product sales showed strong growth (up 15%) in Q1 2013 compared to Q1 2012, primarily as a result of higher prescription demand (up 6%) and the effect of a price increase taken since Q1 2012. Shire also experienced further destocking in the retail channel which was offset by the positive impact of some shipment slippage from Q4 2012.

#### ELAPRASE – Hunter syndrome

Product sales from ELAPRASE in Q1 2013 were down 9% compared to Q1 2012 due to the impact of the timing of large orders to certain markets which order less frequently. The underlying number of patients being treated with ELAPRASE continues to grow.

#### REPLAGAL – Fabry disease

REPLAGAL sales for the quarter were down 15% primarily due to the impact of ordering patterns in Latin America and lower volumes in Europe, where the impact of increased competition outweighed the continued growth in new naïve patients. On a global basis, total patient numbers continue to show good long term growth.

#### LIALDA/MEZAVANT – Ulcerative colitis

Product sales for LIALDA/MEZAVANT increased (up 12%) in Q1 2013 primarily due to higher market share in the US and the effect of a price increase taken since Q1 2012. These positive factors were to a lesser extent offset by the effect of higher US sales deductions and higher destocking at the retail level.



### VPRIV – Gaucher disease

Growth in VPRIV product sales (up 14%) in Q1 2013 was driven by the continued growth in the number of patients on therapy.

### INTUNIV – ADHD

The strong growth in INTUNIV product sales (up 13%) in Q1 2013 was driven by growth in US prescription demand (up 12%) and the effect of price increases taken since Q1 2012. These positive factors were partially offset by the effect of destocking in Q1 2013 as compared to slight stocking in Q1 2012.

### PENTASA – Ulcerative colitis

PENTASA product sales (up 8%) benefited from price increases taken since Q1 2012, the impact of which was moderated by a small amount of retail pipeline destocking in Q1 2013.

### FIRAZYR – Hereditary Angioedema (“HAE”)

The significant growth in FIRAZYR sales (up 112%) reflects the continued success of the product in the US market.

### DERMAGRAFT – DFU

DERMAGRAFT product sales were down 62%, reflecting the impact of an ongoing restructuring of the RM sales and marketing organization and the implementation of a new commercial model. Whilst our future expectations for long term growth of DERMAGRAFT have been revised downwards, we still expect the product to return to growth over coming quarters.

### ADDERALL XR – ADHD

ADDERALL XR product sales decreased (down 10%) in Q1 2013 primarily as a result of lower US prescription demand (down 20%) following the introduction of a new generic competitor in Q2 2012 and to a lesser extent the effect of higher sales deductions as a percentage of sales in Q1 2013 compared to Q1 2012. These negative factors were partially offset by the benefit of a price increase taken since Q1 2012.

## 2. Royalties

Product	Royalties to Shire \$M	Year on year growth	
		Royalties	CER
3TC <sup>®</sup> and ZEFFIX <sup>®</sup>	12.5	-8%	-8%
FOSRENOL <sup>®</sup>	9.0	-10%	-10%
ADDERALL XR	8.1	-68%	-68%
Other	8.9	+20%	+18%
Total	38.5	-32%	-32%

As expected, royalty income from 3TC and ZEFFIX continued to decline due to increased competition from other products and the expiry of patents in certain territories.

Royalties from ADDERALL XR in Q1 2013 were significantly impacted by reduced sales volume as well as a lower royalty rate payable on sales of authorized generic ADDERALL XR by Impax, since the launch of a new generic version in Q2 2012.

### 3. Financial details

#### Cost of product sales

	Q1 2013	% of product sales	Q1 2012	% of product sales
	\$M		\$M	
Cost of product sales (US GAAP)	155.9	14%	158.4	14%
Depreciation	(7.8)		(7.2)	
Cost of product sales (Non GAAP)	148.1	13%	151.2	14%

Non GAAP cost of product sales as a percentage of product sales decreased slightly in Q1 2013, due to improved margins in the ADHD portfolio which were only partially offset by lower margins on other products.

#### Research and Development (“R&D”)

	Q1 2013	% of product sales	Q1 2012	% of product sales
	\$M		\$M	
R&D (US GAAP)	224.2	20%	220.3	20%
Payments in respect of in-licensed and acquired products	-		(23.0)	
Depreciation	(4.6)		(6.4)	
R&D (Non GAAP)	219.6	20%	190.9	17%

Non GAAP R&D increased by \$28.7 million, or 15%, due to our increased investment in a number of targeted R&D programs including non-ADHD programs for LDX, and spend on SPD602 for Iron Overload and SRM003 for Acute Vascular Repair, acquired since Q1 2012.

US GAAP R&D increased by \$3.9 million, or 2%, a lower rate of increase than on a Non GAAP basis as Q1 2012 included payments in respect of acquired and in-licensed products, not repeated in Q1 2013.

#### Selling, General and Administrative (“SG&A”)

	2013	% of product sales	2012	% of product sales
	\$M		\$M	
SG&A (US GAAP)	438.7	39%	500.0	45%
Intangible asset amortization	(45.9)		(45.6)	
Legal and litigation costs <sup>(1)</sup>	(4.2)		-	
Depreciation	(16.7)		(13.6)	
SG&A (Non GAAP)	371.9	33%	440.8	40%

(1) In Q2 2012 Shire amended its Non GAAP policy to exclude costs related to the settlement of litigation, government investigations and other disputes, together with related external legal costs. Non GAAP SG&A in Q1 2012 has not been restated as the amounts incurred in that period were not significant.

Non GAAP SG&A decreased by \$68.9 million, or 16%, partly due to the benefit of actions taken during last year, in addition to careful management of our cost base. The rate of decline in SG&A in Q1 2013 was accentuated by the high level of SG&A in Q1 2012 relative to the level of spend in subsequent quarters in 2012.

US GAAP SG&A decreased by \$61.3 million, or 12% primarily due to legal and litigation costs excluded from Non GAAP SG&A in Q1 2013.

### **Goodwill impairment charges**

For the three months to March 31, 2013 Shire recorded an impairment charge for goodwill of \$198.9 million (Q1 2012: \$nil) relating to Shire's RM business. Following a review of future forecasts for the RM business unit, management determined in Q1 2013 that future sales are now expected to be lower than anticipated at the time of acquisition and consequently in accordance with US GAAP, it has been determined that the goodwill attributable to the RM business unit is impaired. Whilst our future expectations for long term growth of DERMAGRAFT have been revised downwards, we still expect the product to return to growth over coming quarters.

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

For the three months to March 31, 2013 Shire recorded a gain on sale of product rights of \$6.5 million (2012: \$7.2 million) following re-measurement of the contingent consideration receivable from the divestment of DAYTRANA®.

### **Reorganization costs**

For the three months to March 31, 2013 Shire recorded reorganization costs of \$17.5 million (Q1 2012: \$nil) relating to the collective dismissal and closure of Shire's facility at Turnhout, Belgium.

### **Integration and acquisition costs**

For the three months to March 31, 2013 Shire recorded integration and acquisition costs of \$4.1 million primarily associated with the acquisition of Lotus and integration of FerroKin Biosciences, Inc. ("FerroKin") in addition to charges related to the change in fair value of deferred contingent consideration. In Q1 2012 integration and acquisition costs (\$5.3 million) primarily related to the integration of Advanced BioHealing Inc. ("ABH").

### **Interest expense**

For the three months to March 31, 2013 Shire incurred interest expense of \$9.1 million (Q1 2012: \$10.2 million). Interest expense in Q1 2013 principally relates to the coupon on Shire's \$1,100 million 2.75% convertible bonds due 2014.

### **Taxation**

The effective rate of tax on Non GAAP income in Q1 2013 was 19% (Q1 2012: 20%), and on a US GAAP basis the effective rate of tax was 46% (Q1 2012: 17%).

The effective rate of tax in Q1 2013 on a Non GAAP basis is lower than the same period in 2012 due primarily to the recognition of the 2012 US R&D credit in the first quarter of 2013, partially offset by adverse changes in profit mix. The US R&D credit was recognized in Q1 2013 following the enactment of legislation on January 2, 2013, approving the extension of the regular R&D credit retrospectively.

The effective rate of tax in Q1 2013 on a GAAP basis is higher than the same period in 2012 primarily due to the impact of the impairment of RM goodwill which is non-deductible for tax purposes, an increase in unrecognised tax losses and adverse changes in profit mix but partially offset by the recognition of the 2012 US R&D credit in the first quarter of 2013.

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**Unaudited US GAAP financial position as of March 31, 2013**  
**Consolidated Balance Sheets**

	March 31, 2013 \$M	December 31, 2012 \$M
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	1,450.7	1,482.2
Restricted cash	19.3	17.1
Accounts receivable, net	884.4	824.2
Inventories	471.4	436.9
Deferred tax asset	224.3	229.9
Prepaid expenses and other current assets	283.2	221.8
Total current assets	<u>3,333.3</u>	<u>3,212.1</u>
Non-current assets:		
Investments	39.3	38.7
Property, plant and equipment ("PP&E"), net	951.0	955.8
Goodwill	522.8	644.5
Other intangible assets, net	2,657.2	2,388.1
Deferred tax asset	47.3	46.5
Other non-current assets	34.7	31.5
Total assets	<u>7,585.6</u>	<u>7,317.2</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	1,477.2	1,501.5
Other current liabilities	142.5	144.1
Total current liabilities	<u>1,619.7</u>	<u>1,645.6</u>
Non-current liabilities:		
Convertible bonds	1,100.0	1,100.0
Deferred tax liability	607.3	520.8
Other non-current liabilities	476.5	241.6
Total liabilities	<u>3,803.5</u>	<u>3,508.0</u>
Equity:		
Common stock of 5p par value; 1,000 million shares authorized; and 562.8 million shares issued and outstanding (2012: 1,000 million shares authorized; and 562.5 million shares issued and outstanding)	55.7	55.7
Additional paid-in capital	3,002.1	2,981.5
Treasury stock: 11.3 million shares (2012: 10.7 million)	(341.6)	(310.4)
Accumulated other comprehensive income	49.1	86.9
Retained earnings	1,016.8	995.5
Total equity	<u>3,782.1</u>	<u>3,809.2</u>
Total liabilities and equity	<u>7,585.6</u>	<u>7,317.2</u>

**Unaudited US GAAP results for the three months to March 31, 2013**  
**Consolidated Statements of Income**

<b>3 months to March 31,</b>	<b>2013</b>	<b>2012</b>
	<b>\$M</b>	<b>\$M</b>
Revenues:		
Product sales	1,116.7	1,106.9
Royalties	38.5	56.3
Other revenues	6.7	8.6
Total revenues	<u>1,161.9</u>	<u>1,171.8</u>
Costs and expenses:		
Cost of product sales <sup>(1)</sup>	155.9	158.4
R&D	224.2	220.3
SG&A <sup>(1)</sup>	438.7	500.0
Goodwill impairment charge	198.9	-
Gain on sale of product rights	(6.5)	(7.2)
Reorganization costs	17.5	-
Integration and acquisition costs	4.1	5.3
Total operating expenses	<u>1,032.8</u>	<u>876.8</u>
Operating income	129.1	295.0
Interest income	0.7	0.8
Interest expense	(9.1)	(10.2)
Other income, net	(1.1)	1.9
Total other expense, net	<u>(9.5)</u>	<u>(7.5)</u>
Income from continuing operations before income taxes and equity in earnings of equity method investees	119.6	287.5
Income taxes	(55.2)	(50.0)
Equity in earnings of equity method investees, net of taxes	0.4	0.9
Net income	<u><u>64.8</u></u>	<u><u>238.4</u></u>

<b>3 months to March 31,</b>	<b>2013</b>	<b>2012</b>
Earnings per ordinary share – basic	<u>11.7c</u>	<u>43.1c</u>
Earnings per ADS – basic	<u>35.1c</u>	<u>129.3c</u>
Earnings per ordinary share – diluted	<u>11.7c</u>	<u>41.4c</u>
Earnings per ADS – diluted	<u>35.1c</u>	<u>124.2c</u>
Weighted average number of shares:		
	<u>Millions</u>	<u>Millions</u>
Basic	551.5	553.5
Diluted <sup>(2)</sup>	<u>555.3</u>	<u>595.6</u>

(1) Cost of product sales includes amortization of intangible assets relating to favorable manufacturing contracts of \$nil for the three months to March 31, 2013 (2012: \$0.2 million). SG&A costs include amortization of intangible assets relating to intellectual property rights acquired of \$45.9 million for the three months to March 31, 2013 (2012: \$45.6 million).

(2) For the weighted average number of shares used for Non GAAP diluted earnings per ADS, please refer to the Non GAAP reconciliation tables on pages 18 - 19.

**Unaudited US GAAP results for the three months to March 31, 2013**  
**Consolidated Statements of Cash Flows**

3 months to March 31,	2013 \$M	2012 \$M
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	64.8	238.4
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	75.0	73.0
Share based compensation	16.6	22.0
Goodwill impairment charge	198.9	-
Other	(4.6)	(5.9)
Movement in deferred taxes	1.4	(20.8)
Equity in earnings of equity method investees	(0.4)	(0.9)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(51.3)	(65.2)
Increase in sales deduction accrual	44.4	54.5
Increase in inventory	(29.1)	(25.0)
(Increase)/decrease in prepayments and other assets	(61.8)	17.2
Decrease in accounts and notes payable and other liabilities	(93.5)	(30.3)
Net cash provided by operating activities <sup>(A)</sup>	<u>160.4</u>	<u>257.0</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Movements in restricted cash	(2.2)	5.7
Purchases of subsidiary undertakings and businesses, net of cash acquired	(77.2)	-
Purchases of non-current investments	(2.8)	(4.1)
Purchases of PP&E	(47.3)	(31.7)
Purchases of intangible assets	-	(22.0)
Proceeds received on sale of product rights	4.8	5.6
Proceeds from capital expenditure grants	2.7	8.4
Proceeds from disposal of non-current investments and PP&E	0.7	3.8
Returns from equity investments	-	0.1
Net cash used in investing activities <sup>(B)</sup>	<u>(121.3)</u>	<u>(34.2)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Payments to acquire shares under the share buy-back program	(70.6)	-
Deferred contingent consideration payments	(6.0)	-
Excess tax benefit associated with exercise of stock options	4.4	34.8
Other	(0.7)	0.6
Net cash (used in)/provided by financing activities <sup>(C)</sup>	<u>(72.9)</u>	<u>35.4</u>
Effect of foreign exchange rate changes on cash and cash equivalents <sup>(D)</sup>	2.3	1.2
Net (decrease)/increase in cash and cash equivalents <sup>(A) +(B) +(C) +(D)</sup>	<u>(31.5)</u>	<u>259.4</u>
Cash and cash equivalents at beginning of period	1,482.2	620.0
Cash and cash equivalents at end of period	<u>1,450.7</u>	<u>879.4</u>



**Unaudited US GAAP results for the three months to March 31, 2013**  
**Selected Notes to the Financial Statements**

**(1) Earnings Per Share (“EPS”)**

<b>3 months to March 31,</b>	<b>2013</b>	<b>2012</b>
	<b>\$M</b>	<b>\$M</b>
Net Income	<u>64.8</u>	<u>238.4</u>
Numerator for basic EPS	<b>64.8</b>	238.4
Interest on convertible bonds, net of tax <sup>(1)</sup>	<u>-</u>	<u>8.4</u>
Numerator for diluted EPS	<u>64.8</u>	<u>246.8</u>
Weighted average number of shares:		
	<b>Millions</b>	<b>Millions</b>
Basic <sup>(2)</sup>	<b>551.5</b>	553.5
Effect of dilutive shares:		
Share based awards to employees <sup>(3)</sup>	<b>3.8</b>	8.6
Convertible bonds 2.75% due 2014 <sup>(4)</sup>	<u>-</u>	<u>33.5</u>
Diluted <sup>(5)</sup>	<u>555.3</u>	<u>595.6</u>

- (1) For the three month period ended March 31, 2013 interest on convertible bond has not been added back as the effect would be anti-dilutive.  
(2) Excludes shares purchased by the EBT and under the share buy-back program and presented by Shire as treasury stock.  
(3) Calculated using the treasury stock method.  
(4) Calculated using the “if converted” method.  
(5) For the weighted average number of shares used for Non GAAP diluted earnings per ADS, please refer to the Non GAAP reconciliation tables on pages 18 - 19.

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

<b>3 months to March 31,</b>	<b>2013</b>	<b>2012</b>
	<b>No. of shares</b>	<b>No. of shares</b>
	<b>Millions</b>	<b>Millions</b>
Share based awards to employees <sup>(1)</sup>	<b>5.6</b>	6.1
Convertible bonds 2.75% due 2014 <sup>(2)</sup>	<u>33.6</u>	<u>-</u>

- (1) Certain stock options have been excluded from the calculation of diluted EPS because (a) their exercise prices exceeded Shire’s average share price during the calculation period or (b) the required performance conditions were not satisfied as at the balance sheet date.  
(2) For the three month period ended March 31, 2013 the ordinary shares underlying the convertible bonds have not been included in the calculation of the diluted weighted average number of shares, as the effect of their inclusion would be anti-dilutive.

**Unaudited US GAAP results for the three months to March 31, 2013**  
**Selected Notes to the Financial Statements**

**(2) Analysis of revenues**

3 months to March 31,	2013	2012	2013	2013
	\$M	\$M	%	% of total
			change	revenue
<b>Net product sales:</b>				
<b><i>Specialty Pharmaceuticals</i></b>				
<u>Behavioral Health</u>				
VYVANSE	298.4	260.0	15%	26%
ADDERALL XR	99.8	111.4	-10%	9%
INTUNIV	77.7	68.5	13%	7%
EQUASYM®	6.7	7.2	-7%	<1%
	<u>482.6</u>	<u>447.1</u>	<u>8%</u>	<u>42%</u>
<u>Gastro Intestinal</u>				
LIALDA/MEZAVANT	100.5	90.0	12%	9%
PENTASA	71.0	65.8	8%	6%
RESOLOR®	3.2	2.4	33%	<1%
	<u>174.7</u>	<u>158.2</u>	<u>10%</u>	<u>15%</u>
<u>General products</u>				
FOSRENOL	42.3	45.5	-7%	4%
XAGRID®	23.4	23.2	1%	2%
	<u>65.7</u>	<u>68.7</u>	<u>-4%</u>	<u>6%</u>
Other product sales	23.6	32.7	-28%	2%
Total SP product sales	<u>746.6</u>	<u>706.7</u>	<u>6%</u>	<u>64%</u>
<b><i>Human Genetic Therapies</i></b>				
ELAPRASE	114.3	125.6	-9%	10%
REPLAGAL	114.0	134.4	-15%	10%
VPRIV	81.6	71.7	14%	7%
FIRAZYR	41.7	19.7	112%	3%
Total HGT product sales	<u>351.6</u>	<u>351.4</u>	<u>0%</u>	<u>30%</u>
<b><i>Regenerative Medicine</i></b>				
DERMAGRAFT	18.5	48.8	-62%	2%
Total RM product sales	<u>18.5</u>	<u>48.8</u>	<u>-62%</u>	<u>2%</u>
Total product sales	<u>1,116.7</u>	<u>1,106.9</u>	<u>1%</u>	<u>96%</u>
<b>Royalties:</b>				
3TC and ZEFFIX	12.5	13.6	-8%	1%
FOSRENOL	9.0	10.0	-10%	1%
ADDERALL XR	8.1	25.3	-68%	<1%
Other	8.9	7.4	20%	1%
Total royalties	<u>38.5</u>	<u>56.3</u>	<u>-32%</u>	<u>3%</u>
Other revenues	<u>6.7</u>	<u>8.6</u>	<u>-22%</u>	<u>&lt;1%</u>
<b>Total revenues</b>	<u><b>1,161.9</b></u>	<u><b>1,171.8</b></u>	<u><b>-1%</b></u>	<u><b>100%</b></u>

**Unaudited results for the three months to March 31, 2013**  
**Non GAAP reconciliation**

3 months to March 31, 2013	US GAAP	Adjustments					Non GAAP
		(a)	(b)	(c)	(d)	(e)	
	\$M	\$M	\$M	\$M	\$M	\$M	\$M
<b>Total revenues</b>	<b>1,161.9</b>	-	-	-	-	-	<b>1,161.9</b>
<b>Costs and expenses:</b>							
Cost of product sales	155.9	-	-	-	-	(7.8)	148.1
R&D	224.2	-	-	-	-	(4.6)	219.6
SG&A	438.7	(45.9)	-	-	(4.2)	(16.7)	371.9
Gain on sale of product rights	(6.5)	-	-	6.5	-	-	-
Goodwill impairment charge	198.9	(198.9)	-	-	-	-	-
Reorganization costs	17.5	-	-	(17.5)	-	-	-
Integration and acquisition costs	4.1	-	(4.1)	-	-	-	-
Depreciation	-	-	-	-	-	29.1	29.1
Total operating expenses	1,032.8	(244.8)	(4.1)	(11.0)	(4.2)	-	768.7
<b>Operating income</b>	<b>129.1</b>	<b>244.8</b>	<b>4.1</b>	<b>11.0</b>	<b>4.2</b>	<b>-</b>	<b>393.2</b>
Interest income	0.7	-	-	-	-	-	0.7
Interest expense	(9.1)	-	-	-	-	-	(9.1)
Other expense, net	(1.1)	-	-	-	-	-	(1.1)
Total other expense, net	(9.5)	-	-	-	-	-	(9.5)
Income before income taxes and equity in earnings of equity method investees	119.6	244.8	4.1	11.0	4.2	-	383.7
Income taxes	(55.2)	(14.6)	(0.5)	-	(1.5)	-	(71.8)
Equity in earnings of equity method investees, net of tax	0.4	-	-	-	-	-	0.4
<b>Net income</b>	<b>64.8</b>	<b>230.2</b>	<b>3.6</b>	<b>11.0</b>	<b>2.7</b>	<b>-</b>	<b>312.3</b>
Impact of convertible debt, net of tax <sup>(1)</sup>	-	7.6	-	-	-	-	7.6
<b>Numerator for diluted EPS</b>	<b>64.8</b>	<b>237.8</b>	<b>3.6</b>	<b>11.0</b>	<b>2.7</b>	<b>-</b>	<b>319.9</b>
Weighted average number of shares (millions) – diluted <sup>(1)</sup>	555.3	33.6	-	-	-	-	588.9
Diluted earnings per ADS	<b>35.1c</b>	<b>118.8c</b>	<b>1.8c</b>	<b>5.7c</b>	<b>1.5c</b>	<b>-</b>	<b>162.9c</b>

(1) The impact of convertible debt, net of tax has a dilutive effect on Non GAAP basis.

The following items are included in Adjustments:

- Amortization and asset impairments: Amortization of intangible assets relating to intellectual property rights acquired (\$45.9 million), impairment of RM goodwill (\$198.9 million), and tax effect of adjustments;
- Acquisition and integration activities: Costs primarily associated with the acquisition of Lotus and integration of FerroKin (\$2.3 million), charges related to the change in fair value of deferred contingent consideration (\$1.8 million), and tax effect of adjustments;
- Divestments, reorganizations and discontinued operations: Re-measurement of DAYTRANA contingent consideration to fair value (\$6.5 million), costs relating to the collective dismissal and closure of Shire's facility at Turnhout, Belgium (\$17.5 million), and tax effect of adjustments;
- Legal and litigation costs: Costs related to litigation, government investigations, other disputes and external legal costs (\$4.2 million), and tax effect of adjustments; and
- Depreciation reclassification: Depreciation of \$29.1 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, 2012**  
**Non GAAP reconciliation**

3 months to March 31, 2012	US GAAP	Adjustments				Non GAAP
		(a)	(b)	(c)	(d)	
	\$M	\$M	\$M	\$M	\$M	\$M
<b>Total revenues</b>	<b>1,171.8</b>	-	-	-	-	<b>1,171.8</b>
<b>Costs and expenses:</b>						
Cost of product sales	158.4	-	-	-	(7.2)	151.2
R&D	220.3	-	(23.0)	-	(6.4)	190.9
SG&A	500.0	(45.6)	-	-	(13.6)	440.8
Gain on sale of product rights	(7.2)	-	-	7.2	-	-
Integration and acquisition costs	5.3	-	(5.3)	-	-	-
Depreciation	-	-	-	-	27.2	27.2
Total operating expenses	876.8	(45.6)	(28.3)	7.2	-	810.1
<b>Operating income</b>	<b>295.0</b>	<b>45.6</b>	<b>28.3</b>	<b>(7.2)</b>	-	<b>361.7</b>
Interest income	0.8	-	-	-	-	0.8
Interest expense	(10.2)	-	-	-	-	(10.2)
Other income, net	1.9	-	-	-	-	1.9
Total other expense, net	(7.5)	-	-	-	-	(7.5)
Income before income taxes and equity in earnings of equity method investees	287.5	45.6	28.3	(7.2)	-	354.2
Income taxes	(50.0)	(13.2)	(6.6)	-	-	(69.8)
Equity in earnings of equity method investees, net of tax	0.9	-	-	-	-	0.9
<b>Net income</b>	<b>238.4</b>	<b>32.4</b>	<b>21.7</b>	<b>(7.2)</b>	-	<b>285.3</b>
Impact of convertible debt, net of tax	8.4	-	-	-	-	8.4
<b>Numerator for diluted EPS</b>	<b>246.8</b>	<b>32.4</b>	<b>21.7</b>	<b>(7.2)</b>	-	<b>293.7</b>
Weighted average number of shares (millions) – diluted	595.6	-	-	-	-	595.6
Diluted earnings per ADS	<b>124.2c</b>	<b>16.3c</b>	<b>10.9c</b>	<b>(3.5c)</b>	-	<b>147.9c</b>

The following items are included in Adjustments:

- (a) Amortization and asset impairments: Amortization of intangible assets relating to intellectual property rights acquired (\$45.6 million), and tax effect of adjustments;
- (b) Acquisition and integration activities: Up-front payments made to Sangamo Biosciences Inc. and for the acquisition of the US rights to prucalopride (marketed in certain countries in Europe as RESOLOR) (\$23.0 million), costs associated with the acquisition of FerroKin and the integration of ABH (\$5.3 million); and tax effect of adjustments;
- (c) Divestments, reorganizations and discontinued operations: Re-measurement of DAYTRANA contingent consideration to fair value (\$7.2 million), and tax effect of adjustments; and
- (d) Depreciation reclassification: Depreciation of \$27.2 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, 2013

### 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,	
	2013	2012
	\$M	\$M
<b>Net cash provided by operating activities</b>	<b>160.4</b>	257.0
Tax and interest payments, net	97.1	29.8
Up-front payments in respect of in-licensed and acquired products	-	23.0
<b>Non GAAP cash generation</b>	<b>257.5</b>	<b>309.8</b>

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

	3 months to March 31,	
	2013	2012
	\$M	\$M
<b>Net cash provided by operating activities</b>	<b>160.4</b>	257.0
Up-front payments in respect of in-licensed and acquired products	-	23.0
Capital expenditure	(47.3)	(31.7)
<b>Non GAAP free cash flow</b>	<b>113.1</b>	<b>248.3</b>

Non GAAP net cash comprises:

	March 31,	December 31,
	2013	2012
	\$M	\$M
Cash and cash equivalents	1,450.7	1,482.2
Convertible bonds	(1,100.0)	(1,100.0)
Other debt	(8.8)	(9.3)
<b>Non GAAP net cash</b>	<b>341.9</b>	<b>372.9</b>

## NOTES TO EDITORS

### Shire enables people with life-altering conditions to lead better lives.

Our strategy is to focus on developing and marketing innovative specialty medicines to meet significant unmet patient needs.

We provide treatments in Neuroscience, Rare Diseases, Gastrointestinal, Internal Medicine and Regenerative Medicine and we are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas.

[www.shire.com](http://www.shire.com)

## FORWARD - LOOKING STATEMENTS - "SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Statements included in this announcement that are not historical facts are forward-looking statements. 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, that:

- Shire's products may not be a commercial success;
- revenues from ADDERALL XR are subject to generic erosion;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payors in a timely manner for Shire's products may impact future revenues and earnings;
- Shire relies on a single source for manufacture of certain of its products and a disruption to the supply chain for those products may result in Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis;
- Shire uses third party manufacturers to manufacture many of its products and is reliant upon third party contractors for certain goods and services, and any inability of these third party manufacturers to manufacture products, or any failure of these third party contractors to provide these goods and services, in each case in accordance with its respective contractual obligations, could adversely affect Shire's ability to manage its manufacturing processes or to operate its business;
- the development, approval and manufacturing of Shire's products is subject to extensive oversight by various regulatory agencies and regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- the actions of certain customers could affect Shire's ability to sell or market products profitably and fluctuations in buying or distribution patterns by such customers could adversely impact Shire's revenues, financial conditions or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to Shire's activities in the highly regulated markets in which it operates may result in the distraction of senior management, significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters and other disputes, including Shire's ability to obtain, maintain, enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on Shire's revenues, financial condition or results of operations;

and other risks and uncertainties detailed from time to time in Shire's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K.

### 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 before income taxes and earnings/(losses) 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/expense; Non GAAP cash generation; Non GAAP free cash flow and Non GAAP net cash/(debt)*. These Non GAAP measures exclude the effect of certain cash and non-cash items, 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 non-recurring, 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.

Where applicable the following items, including their tax effect, have been excluded when calculating Non GAAP earnings for both 2013 and 2012, and from our Outlook:

*Amortization and asset impairments:*

- Intangible asset amortization and impairment charges; and
- Other than temporary impairment of investments.

*Acquisitions and integration activities:*

- Up-front payments and milestones in respect of in-licensed and acquired products;
- Costs associated with acquisitions, including transaction costs, fair value adjustments on contingent consideration and acquired inventory;
- Costs associated with the integration of companies; and
- Noncontrolling interests in consolidated variable interest entities.

*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; and
- Income/(losses) from discontinued operations.

*Legal and litigation costs:*

- Net legal costs related to the settlement of litigation, government investigations and other disputes (excluding internal legal team costs).

Depreciation, which is included in Cost of product sales, R&D and SG&A costs in our US GAAP results, has been separately disclosed for the presentation of 2013 and 2012 Non GAAP earnings.

Cash generation represents net cash provided by operating activities, excluding up-front and milestone payments for in-licensed and acquired products, tax and interest payments.

Free cash flow represents net cash provided by operating activities, excluding up-front and milestone payments for in-licensed and acquired products, but including capital expenditure in the ordinary course of business.

A reconciliation of Non GAAP financial measures to the most directly comparable measure under US GAAP is presented on pages 18 to 20.

Growth at CER, which is a Non GAAP measure, is computed by restating 2013 results using average 2012 foreign exchange rates for the relevant period.

Average exchange rates for Q1 2013 were \$1.58:£1.00 and \$1.33:€1.00 (2012: \$1.57:£1.00 and \$1.31:€1.00).

## **TRADE MARKS**

All trade marks designated ® and ™ used in this press release are trade marks of Shire plc or companies within the Shire group except for 3TC® and ZEFFIX® which are trade marks of GlaxoSmithKline, PENTASA® which is a registered trade mark of FERRING B.V., LIALDA® and MEZAVANT® which are trade marks of Nogra Pharma Limited and DAYTRANA® which is a trade mark of Noven Pharmaceuticals Inc. Certain trade marks of Shire plc or companies within the Shire group are set out in Shire's Annual Report on Form 10-K for the year ended December 31, 2012.