

Financial review



Graham Hetherington—Chief Financial Officer

Excellent results in a transformational year

We continue to extend the platform to achieve our aspirational target of mid-teen revenue growth between 2009 and 2015.

The following discussion should be read in conjunction with the Company's US GAAP consolidated financial statements included in the Company's Annual Report on Form 10-K for the year to December 31, 2009. A copy of the Company's Annual Report on Form 10-K is available on its website www.shire.com and is also available on the SEC's website at www.sec.gov.

Results of operations

Key financial highlights for the year to December 31, 2009 are as follows:

- product sales excluding ADDERALL XR increased by 25% to \$2,067.2 million (2008: \$1,652.5 million) following continued strong growth from VYVANSE, LIALDA/MEZAVANT, ELAPRASE and REPLAGAL;
- product sales including ADDERALL XR decreased by 2% to \$2,693.7 million (2008: \$2,754.2 million)
- due to the expected decline in ADDERALL XR product sales following the launch of authorized generic versions by Teva Pharmaceutical Industries, Ltd. ('Teva') and Impax Laboratories, Inc. ('Impax'), with the strong performance in Shire's other products offsetting the decrease;
- total revenues decreased marginally to \$3,007.7 million in 2009 (2008: \$3,022.2 million) as the increase in product sales excluding ADDERALL XR and royalty income received on Teva and Impax's sales of authorized generic ADDERALL XR offset the decline in ADDERALL XR product sales;
- operating income in 2009 increased by 51% to \$620.2 million (2008: \$412.0 million); and
- net income attributable to Shire plc increased by \$335.6 million to \$491.6 million (2008: \$156.0 million) and diluted earnings per Ordinary Share increased to 89.7¢ in 2009 (2008: 28.6¢).

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Total revenues

The following table provides an analysis of the Company's total revenues:

Year to December 31,	2009 \$'M	2008 \$'M	Product sales growth %	Non GAAP CER growth %	US prescription growth ⁽¹⁾ %	Exit market share ⁽¹⁾ %
Net product sales:						
SPECIALTY PHARMACEUTICALS ('Specialty')						
ADHD						
VYVANSE	504.7	318.9	+58	+58	+65	13
DAYTRANA	71.0	78.7	-10	-10	-13	1
EQUASYM	22.8	—	n/a	n/a	n/a	n/a ⁽²⁾
INTUNIV	5.4	—	n/a	n/a	n/a	1 ⁽³⁾
ADDERALL XR	626.5	1,101.7	-43	-43	-42	8
Gastrointestinal						
PENTASA	214.8	185.5	+16	+16	-2	16
LIALDA/MEZAVANT	235.9	140.4	+68	+69	+43	18
Other products						
FOSRENOL	184.4	155.4	+19	+23	-2	8
CALCICHEW	43.7	52.8	-17	-3	n/a	n/a ⁽³⁾
CARBATROL	82.4	75.9	+9	+9	-4	55
REMINYL/REMINYL XL	42.4	34.4	+23	+42	n/a	n/a ⁽³⁾
XAGRID	84.8	78.7	+8	+16	n/a	n/a ⁽²⁾
Other product sales	19.4	50.1	-61	-59	n/a	n/a ⁽³⁾
Total Specialty product sales	2,138.2	2,272.5	-6			
HUMAN GENETIC THERAPIES ('HGT')						
ELAPRASE	353.1	305.1	+16	+20	n/a	n/a ⁽³⁾
REPLAGAL	193.8	176.1	+10	+16	n/a	n/a ⁽²⁾
FIRAZYR	6.1	0.5	n/a	n/a	n/a	n/a
VPRIV ⁽⁴⁾	2.5	—	n/a	n/a	n/a	n/a ⁽²⁾
Total HGT product sales	555.5	481.7	+15			
Total product sales	2,693.7	2,754.2	-2			
Royalty income:						
3TC and ZEFFIX	164.0	180.5	-9	-6	n/a	n/a
ADDERALL XR	68.0	—	n/a	n/a	n/a	n/a
Other	60.5	65.0	-7	-3	n/a	n/a
Total royalties	292.5	245.5	+19			
Other revenues	21.5	22.5	-4			
Total revenue	3,007.7	3,022.2	—			

(1) US prescription growth and market share data provided by IMS Health ('IMS') National Prescription Audit. Exit market share represents the US market share in the last week of December 2009.

(2) Not sold in the US or awaiting approval in the US.

(3) IMS data not available.

(4) Not approved at December 31, 2009. Sales achieved under early access programs.

The Company's management analyzes product sales growth for certain products sold in markets outside of the US on a constant exchange rate ("CER") basis, so that product sales growth can be considered excluding movements in foreign exchange rates. Product sales growth on a CER basis is a Non GAAP financial measure, computed by comparing 2009 product sales restated using 2008 average foreign exchange rates to 2008 actual product sales. Average exchange rates for the year to December 31, 2009 were \$1.57:£1.00 and \$1.39:€1.00 (2008: \$1.85:£1.00 and \$1.47:€1.00).

SPECIALTY PHARMACEUTICALS

VYVANSE—ADHD

The increase in VYVANSE product sales was driven by higher US prescription demand in 2009 compared to 2008, 9% growth in the US ADHD market and price increases. Product sales growth was lower than prescription growth due to lower stocking in 2009 compared to 2008.

INTUNIV—ADHD

INTUNIV was launched in the US in November 2009. In line with Shire's revenue recognition policy for launch shipments, initial stocking shipments have been deferred and are being recognized into revenue in line with end-user prescription demand. At December 31, 2009 deferred revenues on the balance sheet represented gross sales of \$38.8 million.

ADDERALL XR—ADHD

The launch by Teva and Impax of their authorized generic versions of ADDERALL XR led to the expected decline in 2009 of branded ADDERALL XR prescription demand, and resulted in higher US sales deductions in 2009 compared to 2008. These factors more than offset the positive impacts of price increases taken since the fourth quarter of 2008, and the inclusion in product sales of shipments of authorized generic ADDERALL XR to Teva and Impax in 2009.

Sales deductions represented 47% of branded ADDERALL XR gross sales in the year to December 31, 2009 compared to 25% in the same period in 2008, following higher Medicaid and Managed Care rebates subsequent to the authorized generic launches.

There are potentially different interpretations as to how shipments of authorized generic ADDERALL XR to Teva and Impax should be included in the Medicaid rebate calculation pursuant to Medicaid rebate legislation, including the Deficit Reduction Act of 2005 ('Medicaid rebate legislation'). As a result more than one unit rebate amount ('URA') is calculable for the purpose of determining the Group's Medicaid rebate liability to States after the authorized generic launch. During 2009 the Group highlighted the different interpretations to the Centers for Medicare and Medicaid Services ('CMS') and submitted data to the CMS for the purpose of computing the URA, based on the Group's reasonable interpretation of the Medicaid rebate legislation and related guidance. The State Medicaid agencies have invoiced the Group for Medicaid rebates, and the Group has paid these Medicaid rebate invoices, based on this URA. Despite this CMS has the ability to subsequently challenge the Group's interpretation of the Medicaid rebate legislation, and require an alternative interpretation to be applied (both retrospectively and prospectively), which could result in a significantly higher Medicaid liability.

Throughout 2009 the Group's management has recorded its accrual for Medicaid rebates based on its best estimate of the rebate payable. For the first three quarters of 2009, the Group's management based this best estimate on an amount that the Group could pay were CMS to challenge the Group's interpretation and require an alternative interpretation of the Medicaid rebate legislation to be applied. In the fourth quarter of 2009, the Group's management lowered its best estimate of the Medicaid rebate payable down to be consistent with (i) the Group's interpretation of the Medicaid rebate legislation, (ii) the Group's repeated and consistent submission of price reporting to CMS using the Group's interpretation of the Medicaid rebate legislation, (iii) CMS calculating the URA based on that interpretation, (iv) States submitting Medicaid rebate invoices using this URA and (v) Shire paying these invoices. This change of estimate increased ADDERALL XR product sales by \$97.7 million in the fourth quarter of 2009 (of which \$73.6 million related to ADDERALL XR product sales recognized in the first three quarters of 2009).

In determining its best estimate of the Medicaid rebate liability at December 31, 2009 the Group's management has considered a number of factors taken in combination (including the receipt of a further quarter's invoices from the States with a URA based on the Group's interpretation of the Medicaid rebate legislation and related guidance, and the Group's likely response were CMS to employ an alternative interpretation of the Medicaid rebate legislation). Any future change in the Group's interpretation which results in a change of estimate could significantly decrease sales of ADDERALL XR in the period of any such change in estimate.

The Group strongly believes that its interpretation of the Medicaid rebate legislation is reasonable and correct. However, CMS could disagree with the Group's interpretation, and require the Group to apply an alternative interpretation of the Medicaid rebate legislation and pay up to \$210 million above the recorded liability. This would represent a URA substantially in excess of the unit sales price of ADDERALL XR and accordingly be in excess of the approximate amount of the full cost to the States of reimbursement for Medicaid prescriptions of ADDERALL XR. Should CMS take such an approach, the Group could seek to limit any additional payments to a level approximating the full, un-rebated cost to the States of ADDERALL XR, or \$98 million above the recorded liability. Further, the Group believes it has a strong legal basis supporting its interpretation of the Medicaid rebate legislation, and that there would be a strong basis to initiate litigation to recover any amount paid in excess of its recorded liability. The result of any such litigation cannot be predicted and could result in additional rebate liability above the Group's current best estimate.

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LIALDA/MEZAVANT—Ulcerative colitis

Strong product sales of LIALDA/MEZAVANT continued in the year to December 31, 2009 driven by an increase in market share over 2008, growth in the US oral mesalamine market and price increases taken during 2009.

PENTASA—Ulcerative colitis

Product sales of PENTASA continued to grow despite a decrease in US prescription demand in 2009 compared to 2008 due to the impact of price increases taken during 2009.

FOSRENOL—Hyperphosphatemia

Product sales increased as FOSRENOL entered new countries and grew in existing markets outside the US. In the US, FOSRENOL sales grew despite lower prescriptions due to a price increase in 2009.

Litigation proceedings regarding certain Shire patents are ongoing. Further information about these litigation's can be found in our filings with the Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K for the year to December 31, 2009.

HUMAN GENETIC THERAPIES

ELAPRASE—Hunter syndrome

The growth in sales of ELAPRASE was driven by increased volumes across all regions where ELAPRASE is sold. On a Non GAAP constant exchange rate basis sales grew by 20% (66% of ELAPRASE sales are made outside of the US).

REPLAGAL—Fabry disease

The growth in REPLAGAL product sales in 2009 over 2008 was driven by a significant increase in demand in the fourth quarter of 2009 due to an acceleration of patients switching to REPLAGAL in the EU, attributable in part to supply shortages of a competitor product. Sales increased 16% on a Non GAAP constant exchange rate basis (REPLAGAL is sold primarily in Euros and Pounds sterling).

Royalties

Royalty revenue increased by 19% to \$292.5 million for the year to December 31, 2009 (2008: \$245.5 million).

3TC (HIV⁽¹⁾ infection and AIDS⁽²⁾) and ZEFFIX (Chronic hepatitis B infection)

Shire receives royalties from GSK on worldwide 3TC and ZEFFIX sales which decreased mainly due to competition from other HIV and hepatitis B treatments.

(1) Human Immunodeficiency Virus ("HIV").

(2) Acquired Immunodeficiency Syndrome.

ADDERALL XR—ADHD

Royalties were received on Teva's sales of an authorized generic version of ADDERALL XR between April 2009 and September 2009, and on Impax's sales of an authorized generic version of ADDERALL XR from October 2009.

Other

Other royalties are received primarily on worldwide (excluding UK and Republic of Ireland) sales of REMINYL and REMINYL XL (known as RAZADYNE and RAZADYNE ER in the US). Royalties on sales of these products decreased in the year to December 31, 2009 to \$47.7 million (2008: \$63.5 million) due to generic competition in the US from August 2008.

Cost of product sales

Cost of product sales decreased to \$388.0 million for the year to December 31, 2009 (14% of product sales), down from \$408.0 million in the corresponding period in 2008 (2008: 15% of product sales). Cost of product sales in the year to December 31, 2008 included charges relating to DYNEPO exit costs of \$48.8 million (2% of product sales). Excluding this item, cost of product sales as a percentage of product sales in 2009 compared to 2008 has increased by 1% to 14%. This increase primarily resulted from changes in product mix following the launch by Teva and Impax of their authorized generic versions of ADDERALL XR in 2009. Higher sales deductions on Shire's sales of branded ADDERALL XR, together with lower margin sales of the authorized generic version of ADDERALL XR to Teva and Impax have both depressed gross margins in 2009.

For the year to December 31, 2009 cost of product sales included depreciation of \$21.8 million (2008: \$16.2 million). Depreciation charged in 2009 is higher than 2008 due to accelerated depreciation of \$12.0 million in 2009 following a change in the estimate of the useful lives of the property, plant and equipment at Shire's Owings Mills facility as a result of the anticipated closure of the facility in 2011.

Research and development ('R&D')

R&D expenditure increased by 29% to \$638.3 million in the year to December 31, 2009 (24% of product sales), up from \$494.3 million in the corresponding period in 2008 (18% of product sales). R&D for the year to December 31, 2009 included a charge of \$36.9 million (1% of product sales) relating to the amendment of an INTUNIV in-license agreement and costs of \$62.9 million (2% of product sales) following the agreement with Duramed Pharmaceuticals, Inc. to terminate the Women's Health development agreement. R&D in the year to December 31, 2008 included costs of \$6.5 million for DYNEPO exit costs. Excluding these items, R&D increased in the year to December 31, 2009 compared to the same period in 2008 due to continued investment in R&D programs, including the acceleration of investment in VPRIV and REPLAGAL in the US, and the inclusion within R&D of an upfront payment of \$6.5 million to Santaris Pharma A/S for technology access and R&D funding.

For the year to December 31, 2009 R&D included depreciation of \$15.5 million (2008: \$12.5 million).

Selling, general and administrative ('SG&A')

SG&A expenses decreased to \$1,342.6 million (50% of product sales) for the year to December 31, 2009 from \$1,455.2 million (53% of product sales) in the corresponding period in 2008. The decrease was due to the Company's continued focus on cost management, and lower intangible asset impairment charges in the year to December 31, 2009 compared to the same period in 2008. SG&A in the year to December 31, 2009 includes intangible asset amortization of \$136.9 million (2008: \$126.2 million), the increase resulting from a full year amortization of the FIRAZYR intangible asset. Intangible asset impairment charges in the year to December 31, 2009 were \$nil (2008: \$97.1 million). Impairment charges in 2008 included \$94.6 million related to DYNEPO which the Company ceased to commercialize. Depreciation included in SG&A was \$67.7 million in 2009 (2008: \$48.5 million).

Gain on sale of product rights

For the year to December 31, 2009 Shire recorded gains of \$6.3 million (2008: \$20.7 million) arising from the sale of non-core products to Laboratorios Almirall S.A. in 2007. These gains had been deferred since 2007 pending obtaining the relevant consents to transfer certain assets.

In-process R&D ('IPR&D') charge

During the year to December 31, 2009 the Company recorded an IPR&D charge of \$1.6 million (2008: \$128.1 million), in respect of FIRAZYR in markets outside of the EU which, have not been approved by the relevant regulatory authorities. Also included in IPR&D in 2008 was a charge of \$135.0 million relating to the acquisition of METAZYM from Zymenex A/S.

The IPR&D charge in respect of FIRAZYR relates to the US (\$64.9 million) and the Rest of the World ('ROW') (\$64.8 million) markets. In the US FIRAZYR received a not approvable letter from the US Food and Drug Administration ('FDA') in April 2008, and in certain ROW territories it has not been approved by the regulatory authorities.

Reorganization costs

For the year to December 31, 2009 Shire recorded reorganization costs of \$12.7 million (2008: \$nil) relating to the transfer of manufacturing from its Owings Mills facility.

Integration and acquisition costs

For the year to December 31, 2009 Shire recorded integration and acquisition costs of \$10.6 million (2008: \$10.3 million) primarily relating to the integration of Jerini AG.

Interest income

For the year to December 31, 2009 Shire received interest income of \$1.9 million (2008: \$25.5 million), primarily earned on cash and cash equivalents. Interest income for the year to December 31, 2009 is lower than the same period in 2008 due to significantly lower average interest rates in 2009 compared to 2008 and lower average cash and cash equivalent balances.

Interest expense

For the year to December 31, 2009 the Company incurred interest expense of \$39.8 million (2008: \$139.0 million). Interest expense in 2009 primarily related to interest expense on the Company's convertible bonds totaling \$33.3 million (2008: \$33.3 million). Interest expense in 2008 was higher than 2009 due to interest expense of \$87.3 million recorded in respect of the Transkaryotic Therapies, Inc. ('TKT') appraisal rights litigation, of which \$73.0 million was additional interest arising from the settlement of the litigation in November 2008.

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Other income/(expense), net

For the year to December 31, 2009 the Company recognized Other income, net of \$60.7 million. Other income in 2009 includes a gain of \$55.2 million on disposal of the Company's investment in Virochem Pharma Inc. ('Virochem') to Vertex Pharmaceuticals Inc. ('Vertex') in a cash and stock transaction. Shire received total consideration of \$19.2 million in cash and two million Vertex shares (valued at \$50.8 million at the date these shares were acquired). Other income, net in 2009 also includes a gain of \$5.7 million on the substantial modification of a property lease.

For the year ended December 31, 2008, the Company recognized Other expense, net of \$32.9 million. Other expense, net includes other-than-temporary impairment charges of \$58.0 million. Impairment charges in 2008 include \$44.3 million relating to the Company's available-for-sale investment in Renovo Group plc. Offsetting this in 2008 is a gain of \$9.4 million from the disposal of the Company's available-for-sale investment in Questcor Pharmaceutical Inc. ('Questcor') for cash consideration.

Taxation

In the year to December 31, 2009 the effective tax rate was 22% (2008: 37%). Excluding the impact of IPR&D charges of \$263.1 million in 2008, which are either not tax deductible or for which no tax benefit is currently recognized, the effective tax rate in 2008 was 19%.

The effective rate of tax in 2009 was higher than 2008 (excluding the impact of IPR&D charges) due to increased profits in higher tax territories, and the recognition of valuation allowances against EU and US deferred tax assets. These factors more than offset reductions to the effective rate of tax in 2009 due to: the decrease in valuation allowances relating to state tax credits and loss carry forwards following Massachusetts State tax changes in 2009; the benefit of the effect of the change in the effective state tax rate on the net state deferred tax balance; and higher R&D tax credits in the US, principally the acceleration of the VPRIV program.

Discontinued operations

The loss from discontinued operations for the year to December 31, 2009 was \$12.4 million (2008: \$17.6 million). The loss in 2009 related to net losses on discontinued Jerini businesses which were either divested or closed during the second quarter of 2009, the loss on disposal of Jerini's Peptides business and the write-off of assets previously classified as held-for-sale. The loss in 2008 related to certain businesses acquired through the Jerini acquisition, including a charge of \$12.9 million arising on the re-measurement of assets held-for-sale to their fair value less cost to sell.