

# Second Quarter Results to June 30, 2011

Shire plc  
July 28, 2011

**Angus Russell**  
Chief Executive Officer

**Michael Cola**  
President, Specialty  
Pharmaceuticals

**Graham Hetherington**  
Chief Financial Officer

**Sylvie Grégoire**  
President, Human  
Genetic Therapies



**Our purpose**

We enable people with life-altering conditions to lead better lives.

## 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 Pharmaceuticals 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.



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# Agenda

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- **Q2 2011 Highlights** | Angus Russell

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- **Financial Review** | Graham Hetherington

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- **Concluding remarks** | Angus Russell

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- **Q & A** | All

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# Q2 2011 Highlights

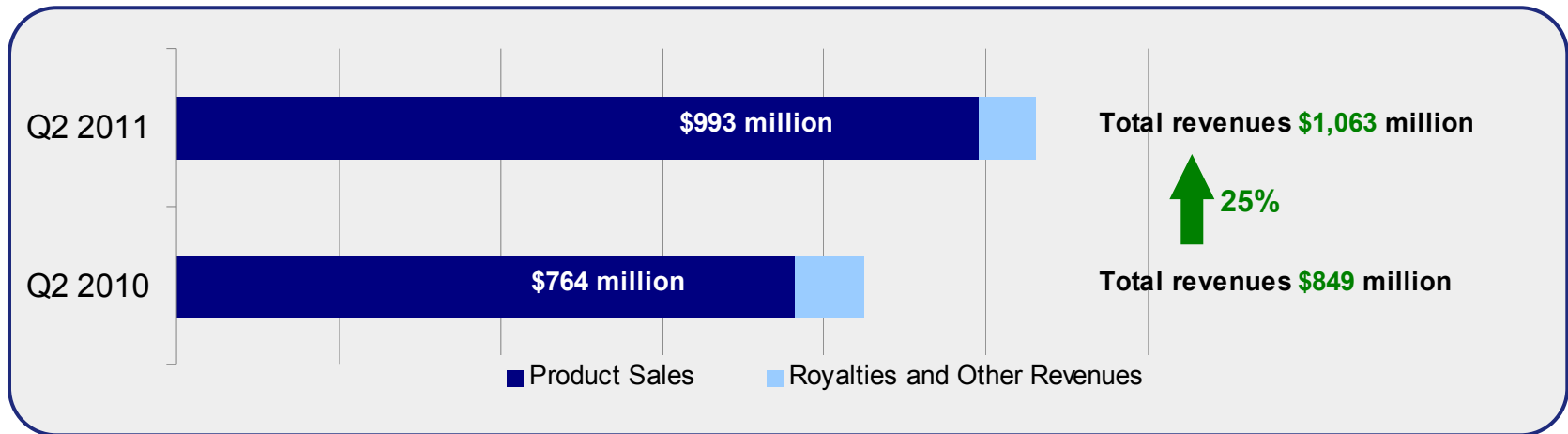
**Angus Russell**  
Chief Executive Officer



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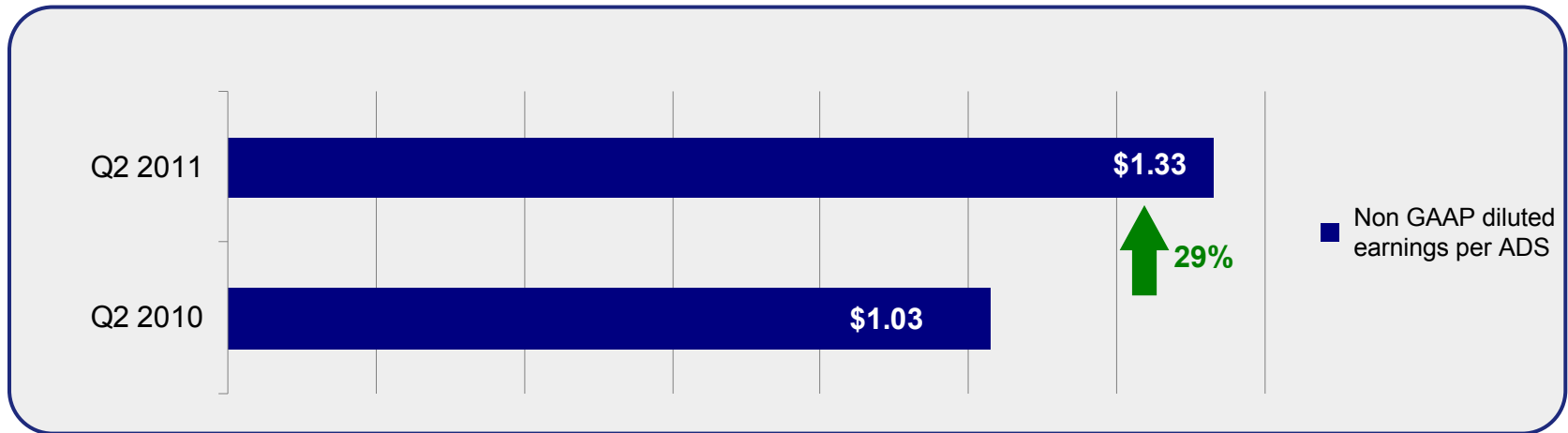
# Strong product sales growth driving Q2 revenue over \$1 billion




Product sales **↑ 30%** to \$993 million

Total revenues **↑ 25%** to \$1,063 million

## Product sales growth driving increase in Non GAAP earnings



Q2 2011 Non GAAP diluted earnings per ADS: \$1.33

Q2 2011 Non GAAP operating income  **26%** to \$342 million

# HGT: Recent highlights

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- ✓ FDA Advisory Committee recommended approval and self administration of FIRAZYR for acute attacks of Hereditary Angioedema
  - ✓ PDUFA date August 25
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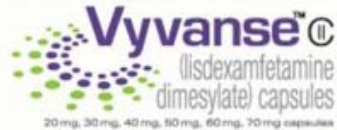


- ✓ European approval received for purification of REPLAGAL in new Lexington manufacturing facility
  - ✓ 46% growth in revenues vs Q2 2010
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- ✓ Process Validation Runs ongoing and nearing completion in new Lexington manufacturing facility
  - ✓ FDA and EMA filings on track for submission by year end
  - ✓ 121% growth in revenues vs Q2 2010
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# Specialty Pharma: Recent highlights



- ✓ Vyvanse Rx's increased 21% over Q2 2010; almost double the 11% quarterly market growth
- ✓ EU pivotal programs – progressing as planned; first MAA filings on track for Q4
- ✓ Potential Non-ADHD indications – continued progress



- ✓ Rx's increased 14% over Q1 2011; 88% over Q2 2010
- ✓ Favorable increase in market share trends driven by new consumer marketing and adjunctive therapy with stimulant launch
- ✓ Enrolling EU pivotal programs



- ✓ US Rx market share increased to 20.4%.
- ✓ FDA recently approved Lialda label change to add a maintenance of remission claim

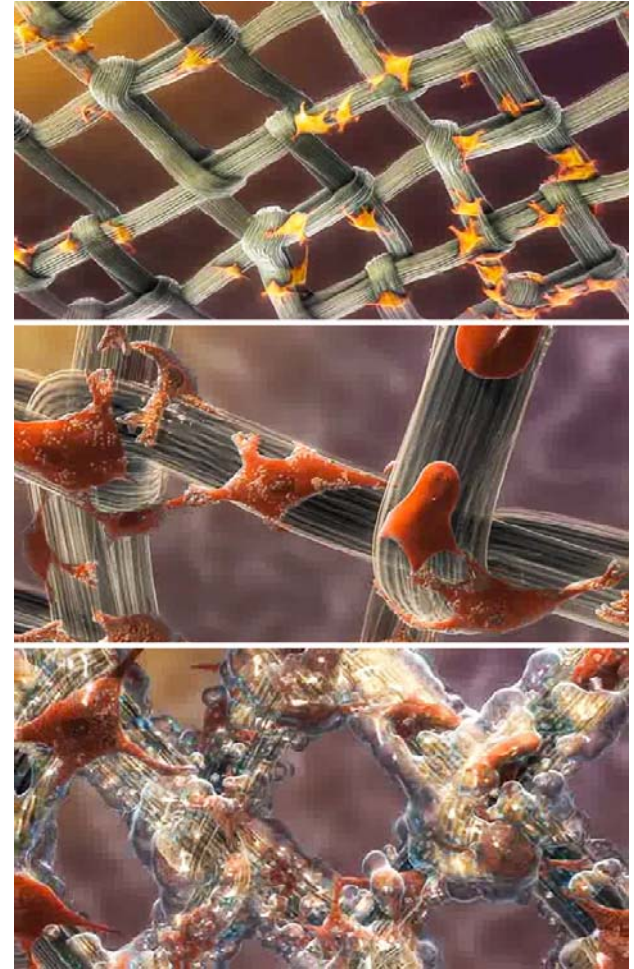


- ✓ Acquisition of Advanced BioHealing, Inc. provides valuable platform in promising field of regenerative medicine

\* IMS NPA (National Prescription Audit) June 2011

## Acquisition of Advanced BioHealing

- ABH's current biologic treatment for diabetic foot ulcers (DFU) addresses a significant patient need
- Dermagraft:
  - FDA-approved human dermal replacement which results in the generation of native human tissue
  - Scalable proprietary human fibroblast cell-line manufacturing
  - 2010 revenue of \$147 million

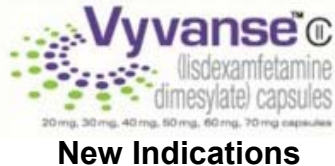


## Acquisition of Advanced BioHealing

- Deal closed on June 28th
- Potential growth opportunities
  - Dermagraft in development for Venous Leg Ulcers – Phase 3 trial fully enrolled – Expect data by year end
    - Leverages DFU commercial and manufacturing infrastructure
  - Expansion outside of the current US opportunity
  - Leverage ABH expertise for additional regenerative medicine products
  - Reviewing plans for additional manufacturing capacity to meet demand for Dermagraft and potential new pipeline opportunities

# Specialty Pharma: Pipeline highlights

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- ✓ Potential Non-ADHD indications – continued progress
  - ✓ Expect to begin Phase 3 for MDD before year end
  - ✓ Discussions with regulatory authorities continue and will help inform development of other indications
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## **Guanfacine Carrier Wave**

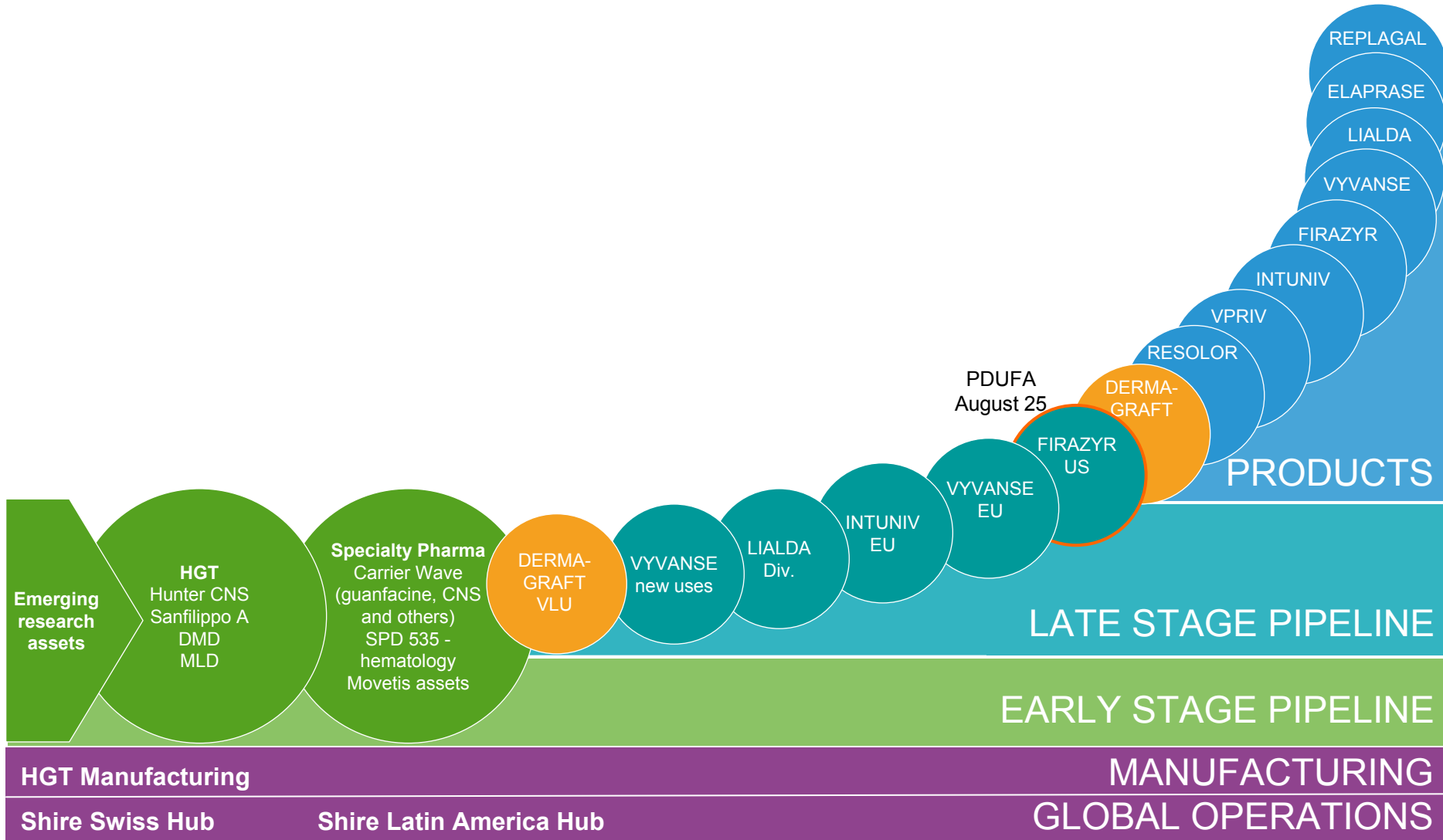
- ✓ An improved lead candidate has been selected for development and a Phase 1 program has initiated
  - ✓ Phase 1 program will be supportive of potentially 3 different CNS-related indications: ADHD, hyperactivity in Autism Spectrum Disorder and Pediatric Anxiety
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## **SPD 535**

(platelet lowering agent)

- ✓ Data from Phase 1 clinical trials demonstrated positive proof-of-principle with no safety concerns.
  - ✓ Additional Phase 1 studies on-going. Exploring indication for prevention of thrombotic complications associated with arteriovenous access in hemodialysis patients
-

# Delivering growth now and into the future



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# Financial Review

**Graham Hetherington**  
Chief Financial Officer



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## 2011 Q2 Performance summary

	Q2 2011 \$m	Q2 2010 \$m	Reported Growth	Like for Like Growth <sup>(1)</sup>
Product sales	993	764	+30%	+26%
Royalties and other revenues	70	85	-18%	-21%
<b>Total revenues</b>	<b>1,063</b>	<b>849</b>	<b>+25%</b>	<b>+21%</b>
<b>EBITDA <sup>(2)</sup></b>	<b>371</b>	<b>294</b>	<b>+26%</b>	<b>+25%</b>
<b>EBITDA % of product sales <sup>(2)(3)</sup></b>	<b>30%</b>	<b>27%</b>		
<b>EPS - ADS <sup>(2)</sup></b>	<b>\$1.33</b>	<b>\$1.03</b>	<b>+29%</b>	
<b>Cash generation <sup>(2)</sup></b>	<b>440</b>	<b>411</b>	<b>+7%</b>	

(1) 'Like for Like Growth' excludes movements in exchange rates by applying 2010 exchange rates to 2011 results.

(2) These are Non GAAP financial measures. See appendix for a list of items excluded from the US GAAP equivalent used to calculate these measures.

(3) Excluding royalties and other revenues

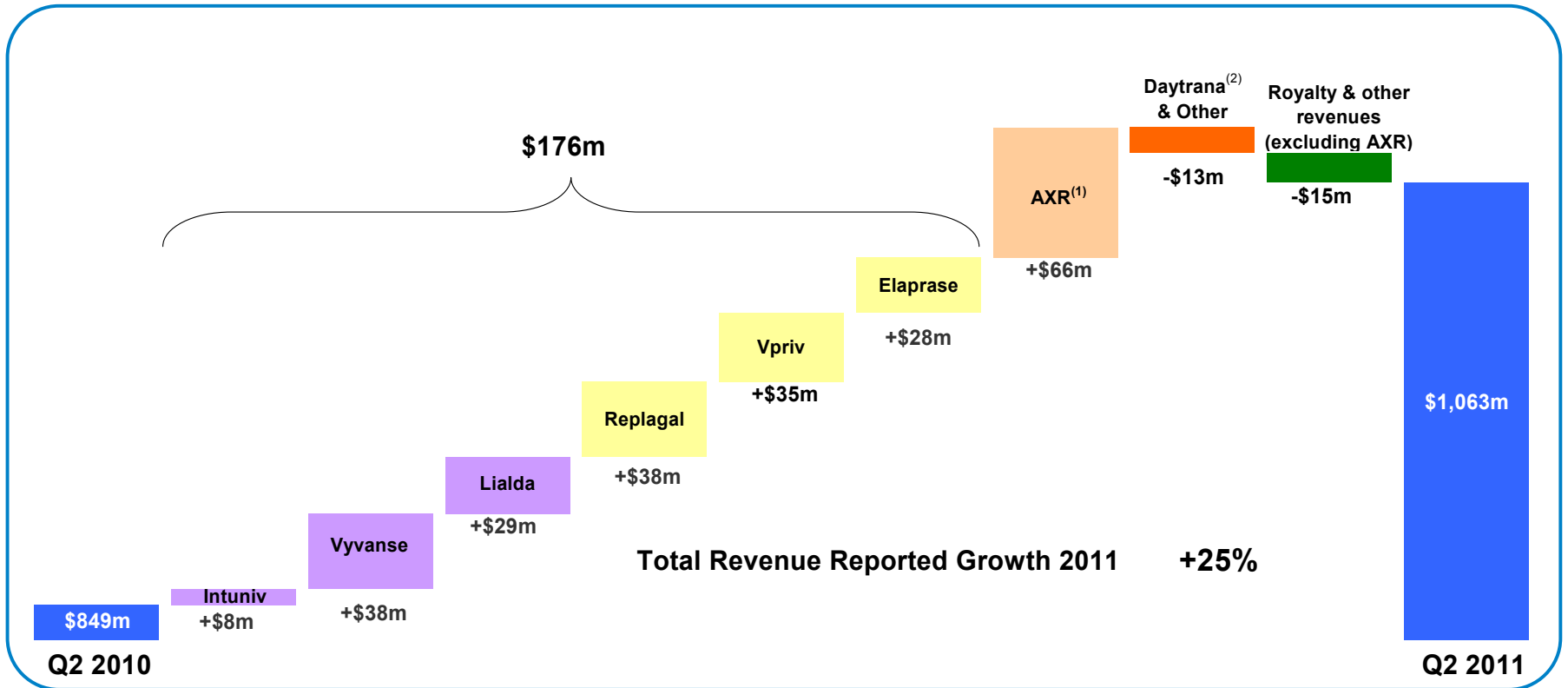


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## 2011 Q2 Royalties

	Q2 2011 \$m	Q2 2010 \$m	Reported Change
3TC and ZEFFIX	11	38	-70%
ADDERALL XR	27	28	-2%
FOSRENOL	12	6	+107%
OTHER	13	11	+15%
<b>Total Royalties</b>	<b>63</b>	<b>83</b>	<b>-23%</b>

# Growth across portfolio drives \$214m revenue increase



(1) Product sales ( +\$67m ) and royalties ( -\$1m )

(2) Daytrana was divested on October 1, 2010

# Operating leverage – Key Financial Ratios

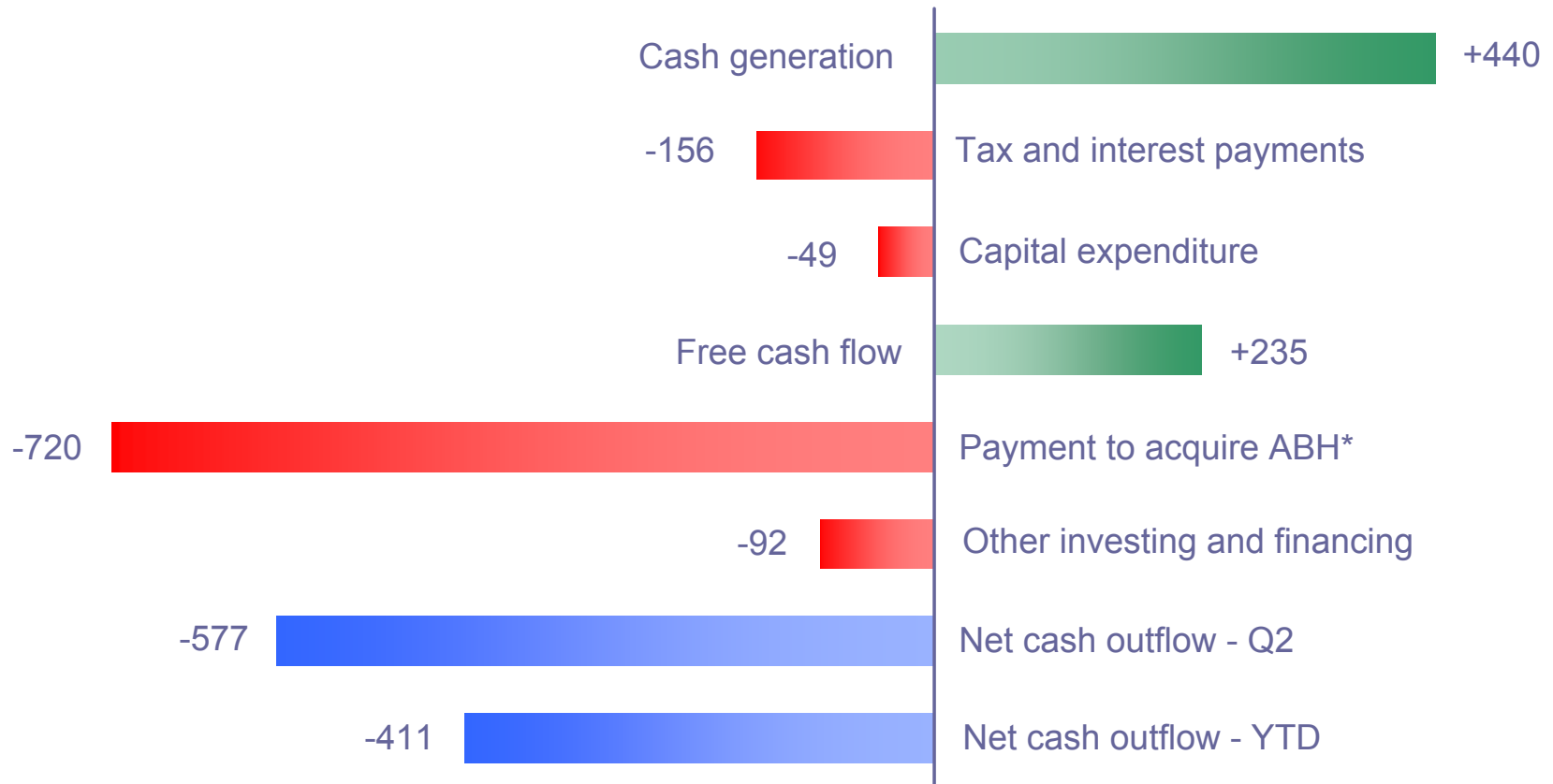
Year on Year:	2011 YTD	2010 YTD
<b>Product sales</b>	+27%	+13%
<b>R&amp;D<sup>(1)</sup></b>	+27%	+15%
<b>SG&amp;A<sup>(1)</sup></b>	+21%	+10%
<b>Ratios:</b>		
<b>% of product sales</b>		
<b>Gross margin<sup>(1)</sup></b>	87%	87%
<b>R&amp;D<sup>(1)</sup></b>	18%	18%
<b>SG&amp;A<sup>(1)</sup></b>	39%	41%
<b>EBITDA<sup>(1) (2)</sup></b>	29%	27%

(1) These are Non GAAP financial measures. See appendix for a list of items excluded from the US GAAP equivalents used to calculate these measures.

(2) Excluding royalties and other revenues.

# 2011 Q2 Cash flow

Millions of USD



\* Net of cash acquired of \$15m

- (1) Shire has a revolving 5 year credit facility of \$1.2bn signed in November 2010 of which \$30m was drawn at June 30, 2011 (repaid post June 30, 2011).
- (2) Included in cash generation are cash outflows of \$13m related to the settlement of Shire and ABH's acquisition related costs.
- (3) Other investing and financing includes dividend payments (\$61m), purchase of shares by ESOT (\$64m), offset by drawing of the RCF (\$30m).



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# Shire 2011 outlook

## Full year 2011 dynamics

Including marginal dilution from recent ABH acquisition

Direction  
versus FY 2010

<b>Product sales</b>	↑	Continued product sales growth and Dermagraft sales
<b>Royalties</b>	↓	Generic erosion (total royalties & other revenue -10%)
<b>Total Revenues</b>	↑	H2 YoY growth marginally less than the 22% seen in H1
<b>Gross margins</b>	≈	Marginal dilution from ABH
<b>R&amp;D and SG&amp;A</b>	↑	Growth of 20% (5% due to ABH)
<b>Tax rate</b>	≈	22-24% tax rate
<b>Reported EPS-ADS</b>	↑	Good Earnings growth

# Concluding remarks

**Angus Russell**  
**Chief Executive Officer**



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# Key events for the second half of 2011



Launch of maintenance of remission indication in the US



File MAA in Europe  
Begin Phase 3 for Major Depressive Disorder



PDUFA date August 25, 2011 & US launch



Lexington manufacturing plant validation and submission

## Strategy continues to deliver

**Strong financial results in a challenging environment**

**Investing in promising pipeline opportunities, including regenerative medicine**

**Delivering meaningful therapies to enable patients to lead better lives**

**Collaborating with patients, physicians, payors and policymakers to deliver real value**

# Questions and Answers



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# APPENDIX



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## 2011 Portfolio Strength and Diversity – Q2 Product Sales

	Q2 2011 \$m	Q2 2010 \$m	Reported Growth	Like for Like Growth <sup>(1)</sup>
VYVANSE	186	148	+26%	+25%
ADDERALL XR	147	80	+83%	+82%
ELAPRASE	128	100	+28%	+20%
REPLAGAL	120	82	+46%	+32%
LIALDA / MEZAVANT	99	70	+43%	+41%
PENTASA	66	61	+9%	+9%
VPRIV	63	29	+121%	+110%
INTUNIV	60	51	+16%	+16%
FOSRENOL	45	45	-	-5%
FIRAZYR	6	3	+115%	+89%
DERMAGRAFT	2	-	n/a	n/a
RESOLOR	2	-	n/a	n/a
OTHER	69	95 <sup>(2)</sup>	-27%	-32%
<b>PRODUCT SALES</b>	<b>993</b>	<b>764</b>	<b>+30%</b>	<b>+26%</b>

(1) 'Like for Like Growth' excludes movements in exchange rates by applying 2010 exchange rates to 2011 results.

(2) 2010 'Other' includes DAYTRANA sales of \$16.3m.



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# 2011 Emerging shape of Shire income statement

								FY 2011 Dynamics	
	2010 Q1	2010 Q2	2010 Q3	2010 Q4	2010 FY	2011 Q1	2011 Q2	Direction V. FY 10	Explanations
Total Product Sales	\$718m	\$764m	\$794m	\$852m	\$3,128m	\$889m	\$993m	↑	Continued product sales growth and Dermagraft sales
<i>versus prior year <sup>(1)</sup></i>	-9%	+37%	+24%	+21%	+16%	+24%	+30%		
Royalties & Other revenues	\$98m	\$85m	\$80m	\$80m	\$343m	\$83m	\$70m	↓	Generic erosion (total royalties & other revenue - 10%)
<i>versus prior year</i>	+58%	+19%	+24%	-31%	+9%	-15%	-18%		
Total Revenues	\$816m	\$849m	\$874m	\$932m	\$3,471m	\$972m	\$1,063m	↑	H2 YOY growth marginally less than the 22% seen in H1
<i>versus prior year <sup>(1)</sup></i>	-5%	+35%	+24%	+14%	+15%	+19%	+25%		
Gross Margin <sup>(2) (3)</sup>	87%	86%	87%	86%	87%	87%	87%	≈	Marginal dilution from ABH
R&D <sup>(3)</sup>	\$127m	\$144m	\$149m	\$178m	\$598m	\$173m	\$171m	↑	Growth of 20% (5% due to ABH)
<i>versus prior year</i>	+\$10m	+\$26m	+\$5m	+\$34m	+\$75m	+\$46m	+\$27m		
SG&A <sup>(3)</sup>	\$309m	\$304m	\$302m	\$373m	\$1,288m	\$352m	\$388m		
<i>versus prior year</i>	+\$38m	+\$19m	+\$35m	+\$58m	+\$150m	+\$43m	+\$84m		
Tax Rate <sup>(3)</sup>	26%	25%	24%	16%	23%	22%	23%	≈	22-24% tax rate

(1) Product sales growth for 2010 compared to 2009 product sales is on a “normalized Medicaid rebate” basis

(2) Gross margin calculated as a percentage of product sales.

(3) These are Non GAAP financial measures. See appendix for a list of items excluded from the US GAAP equivalents used to calculate these measures.



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## 2011 Q2 Non GAAP cash flow measures

Non GAAP cash generation reconciliation	Q2 2011 \$m	Q2 2010 \$m
<b>Net cash provided by operating activities</b>	<b>284</b>	284
Tax and interest payments, net	<b>156</b>	127
<b>Non GAAP cash generation<sup>(1)</sup></b>	<b>440</b>	411

Non GAAP free cash flow reconciliation	Q2 2011 \$m	Q2 2010 \$m
<b>Net cash provided by operating activities</b>	<b>284</b>	284
Capital expenditure <sup>(2)</sup>	<b>(49)</b>	(45)
<b>Non GAAP free cash flow<sup>(3)</sup></b>	<b>235</b>	239

- (1) Non GAAP cash generation represents net cash provided by operating activities, excluding upfront and milestone payments for in-licensed and acquired products, tax and interest payments
- (2) Capital expenditure in Q2 2010 excludes capital expenditure relating to the acquisition of Lexington Technology Park
- (3) Non GAAP free cash flow represents net cash provided by operating activities, excluding upfront and milestone payments for in-licensed and acquired products, but including capital expenditure in the normal course of business

## Non GAAP net debt

	June, 30 2011 \$m	Dec, 31 2010 \$m
Cash and cash equivalents	145	550
Restricted cash	22	27
Convertible bonds	(1,100)	(1,100)
Revolving credit facility	(30)	-
Building finance obligation	(9)	(8)
<b>Net debt</b>	<b>(972)</b>	<b>(531)</b>

# Non GAAP measures

- This presentation contains financial measures not prepared in accordance with US GAAP.
- These Non GAAP financial measures are used by Shire's management to make operating decisions because they facilitate internal comparisons of the Company's performance to historical results and to competitors' results. They should not be considered in isolation from, as substitutes for, or superior to financial measures prepared in accordance with US GAAP.
- The following items are excluded from these non-GAAP financial measures:

## **Amortization and asset impairments:**

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

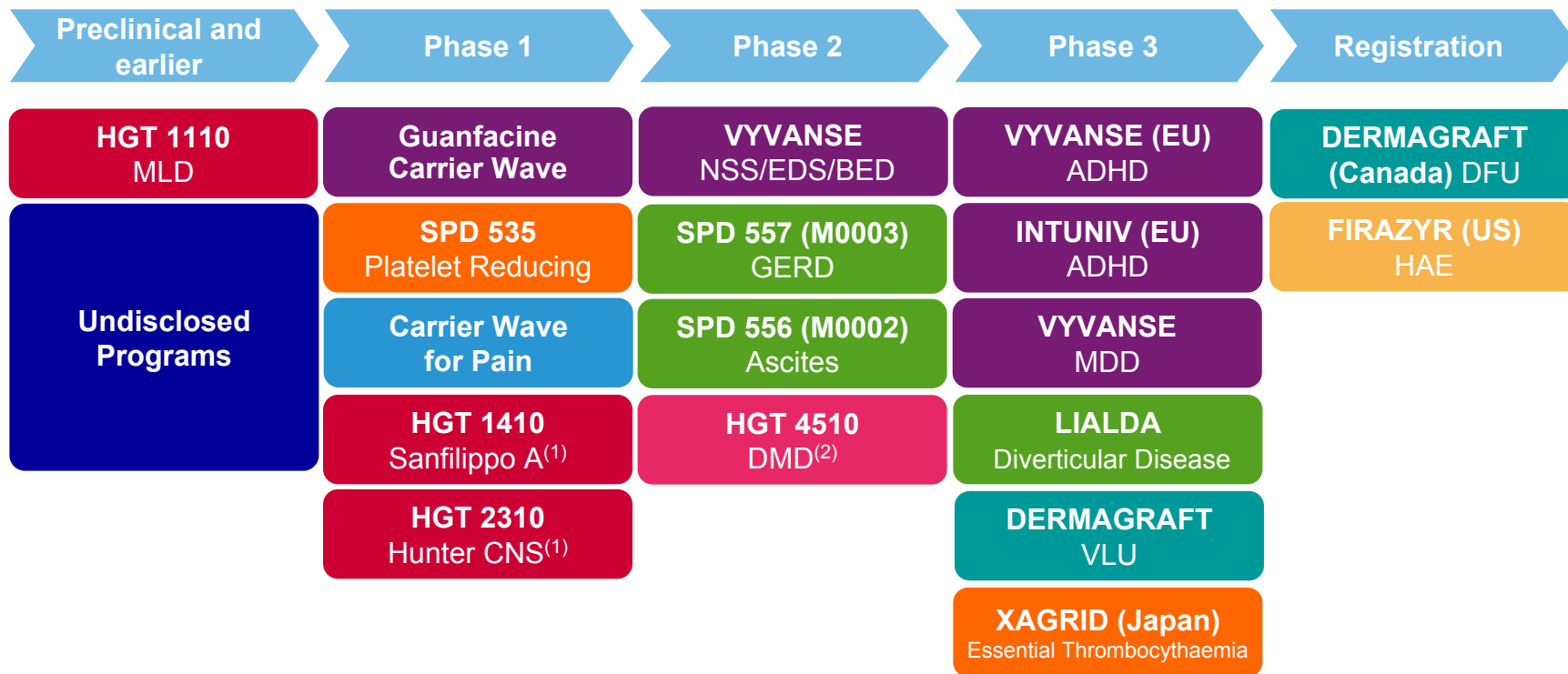
## **Acquisitions and integration activities:**

- 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;
- Costs associated with the integration of companies; and
- Noncontrolling interest 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.

# Current pipeline



Note

(1) HGT 1410 and HGT 2310 are currently in Phase 1/2 clinical trials

(2) Currently on clinical hold



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