## Third Quarter Results to September 30, 2009

Shire plc October 30, 2009

**Angus Russell** 

**Chief Executive Officer** 

**Michael Cola** 

President, Specialty Pharmaceuticals

**Graham Hetherington** 

**Chief Financial Officer** 

Sylvie Grégoire

President, Human Genetic Therapies



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

Statements included herein that are not historical facts are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, the Company's results could be materially 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 the Company's Specialty Pharmaceutical and Human Genetic Therapies products, as well as the ability to secure and integrate new products for commercialization and/or development; government regulation of the Company's products; the Company's ability to manufacture its products in sufficient quantities to meet demand; the impact of competitive therapies on the Company's products; the Company's ability to register, maintain and enforce patents and other intellectual property rights relating to its products; the Company'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 the Company's filings with the Securities and Exchange Commission.

### **Agenda**

Opening remarks

Financial review

Specialty Pharma update

HGT update

Concluding remarks

Q & A

**Angus Russell** 

**Graham Hetherington** 

Michael Cola

Sylvie Grégoire

**Angus Russell** 

All

# Transformational Change Delivering Excellent Growth In Core Products

Angus Russell CEO

### Core product portfolio delivering excellent growth

- Product sales excluding AXR up 20% to \$532 million
  - Up 23% on CER basis
- Q3 Non GAAP earnings per ADS: \$0.49
  - YTD Non GAAP earnings per ADS: \$2.38
  - Proactive cost management
- Cash generation of \$226 million during the quarter
- 2009 guidance framework reaffirmed

#### **Transformation continues**

#### 2004

- ADDERALL XR and ADHD the prime focus
- Small molecules
- Oral drug delivery (SLI)
- Hatch Waxman dependent
- US the dominant market
- Presence in Canada and 6 EU markets



#### 2009

- Leading Specialty Biopharmaceutical Company
- Business based on:
  - Small molecules
  - Peptides
  - Biologics
- Technology platforms
  - Human cell line biologics
  - Carrierwave
  - Locked Nucleic Acid Technology
- ADHD, GI and Human Genetic Therapies
  - Balanced product portfolio
- 8 growth-driving products
- Products with global rights
- Strong pipeline
- Robust Intellectual property
- Presence in 27 countries and growing

### Strategy is delivering

- Focused on the needs of patients and physicians
  - velaglucerase alfa available in US and EU pre-approval
  - REPLAGAL
    - increased demand in the EU
    - pre-approval access available for US patients
- Launching new products
  - INTUNIV Nov 2009
- Expanding the business through acquisition, progression of the R&D pipeline and targeted geographic expansion
- Aspiration to grow sales in the mid-teens range year-onyear on average over the course of 2009 through 2015

### **Financial Review**

**Graham Hetherington** CFO

### **2009 Q3 Performance summary**

	Q3 2009 \$m	Q3 2008 \$m	Reported Growth	Like for Like Growth (3)
Core Product Sales (1)	532	444	+20%	+23%
Product Sales	603	713	-15%	-13%
Royalty and other revenues	64	66	-2%	-1%
Total Revenues	667	779	-14%	-12%
EBITDA (2)	157	297	-47%	
EPS - ADS (diluted) (2)	\$0.49	\$1.17	-58%	
Cash generation (2)	226	313	-28%	

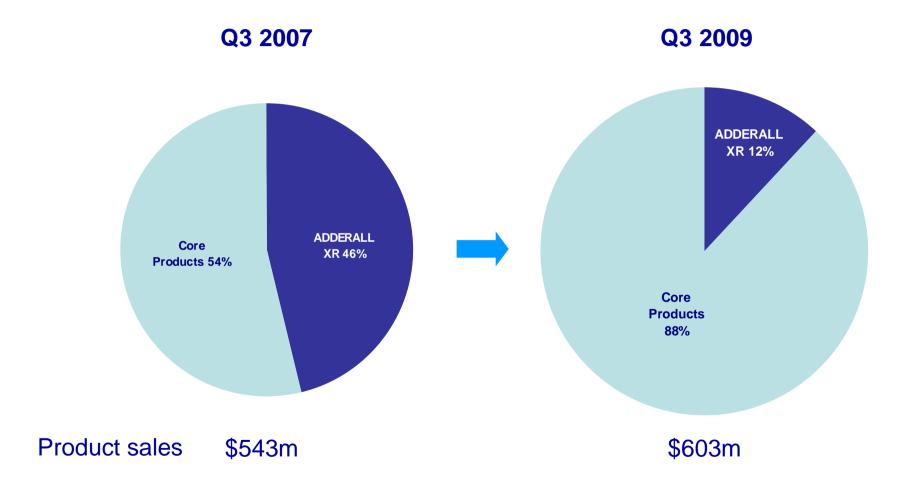
<sup>(1)</sup> Core product sales represent the Company's product sales excluding ADDERALL XR.

<sup>3) &#</sup>x27;Like for Like Growth' excludes movements in exchange rates by applying 2008 exchange rates to 2009 results.



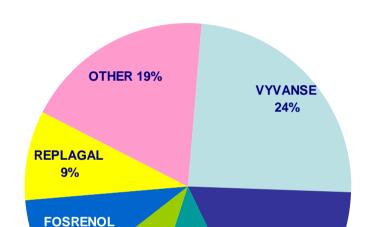
<sup>(2)</sup> These are non GAAP financial measures. See appendix for a list of items excluded from the GAAP equivalent to calculate these measures.

### **New phase for Shire**



### 2009 Q3 Balanced portfolio

	Q3 2009 \$m	Reported Growth	Like for Like Growth (2)
VYVANSE	129	+34%	+34%
ELAPRASE	91	+16%	+20%
LIALDA / MEZAVANT	65	+62%	+63%
PENTASA	51	+4%	+4%
FOSRENOL	48	+11%	+14%
REPLAGAL	48	+8%	+15%
OTHER	100	+7%	+14%
Core Product Sales <sup>(1)</sup>	532	+20%	+23%



LIALDA /

MEZAVANT 12% ELAPRASE 17%

9%

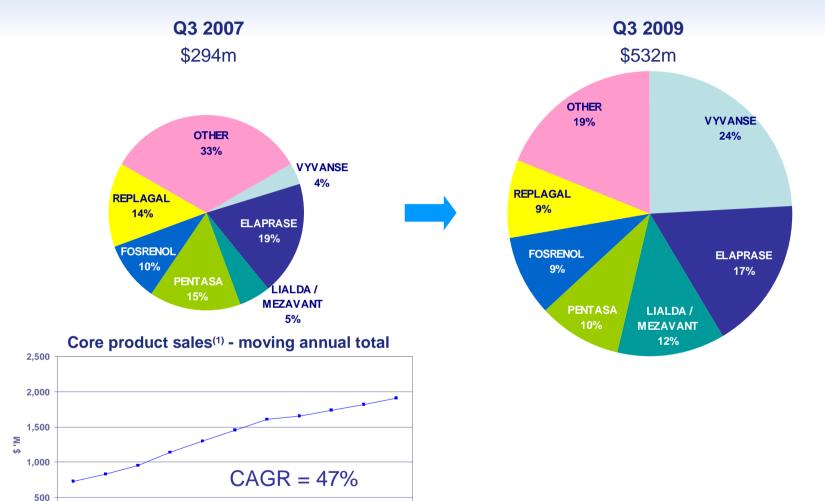
**PENTASA** 

10%

Q3 2009 Product sales

- (1) Core product sales represent the Company's product sales excluding ADDERALL XR.
- (2) 'Like for Like Growth' excludes movements in exchange rates by applying 2008 exchange rate to 2009 results.

### Core product sales growth

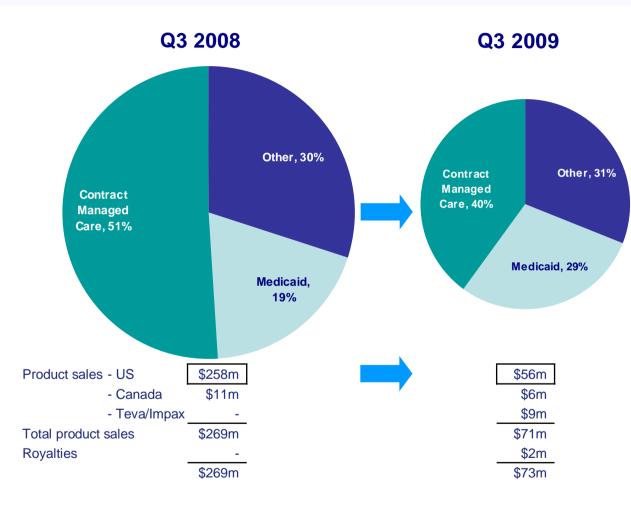






Q1 07 Q2 07 Q3 07 Q4 07 Q1 08 Q2 08 Q3 08 Q4 08 Q1 09 Q2 09 Q3 09

### **ADDERALL XR – Net sales analysis**

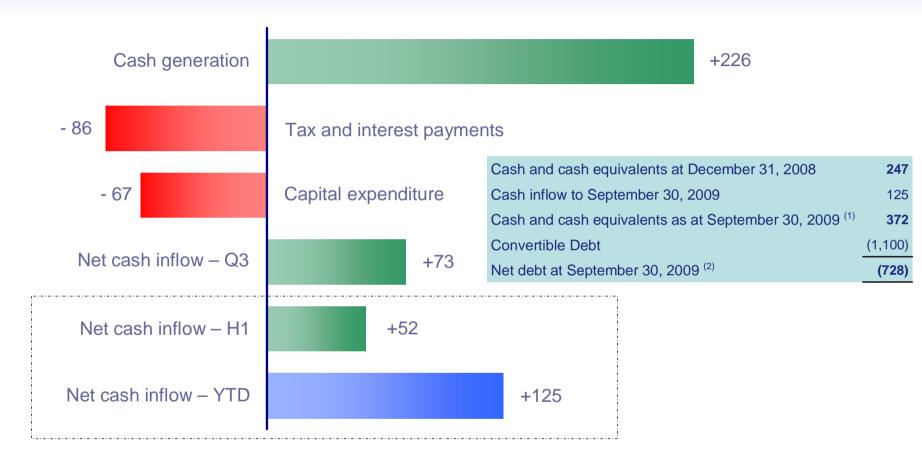


#### Influence of Medicaid

- Utilisation
  - 29% is higher than anticipated
  - Potential to increase further
- Unit rebate level
  - Impacted by authorized generic
  - Range of potential outcomes
  - Shire views lower end of range as correct
  - States invoicing at lower end of range
  - Current accounting at near mid point of range
  - Q3 cumulative provision is \$64m higher than invoiced
  - Provisioning level may change in future periods

#### 2009 Q3 Cash flow

Millions of USD



- (1) Shire's balance of cash and cash equivalents at September 30, 2009 includes \$39m of restricted cash.
- (2) Shire has a revolving credit facility of \$1.2bn which was undrawn at September 30, 2009.

### **Emerging shape of 2009 income statement**

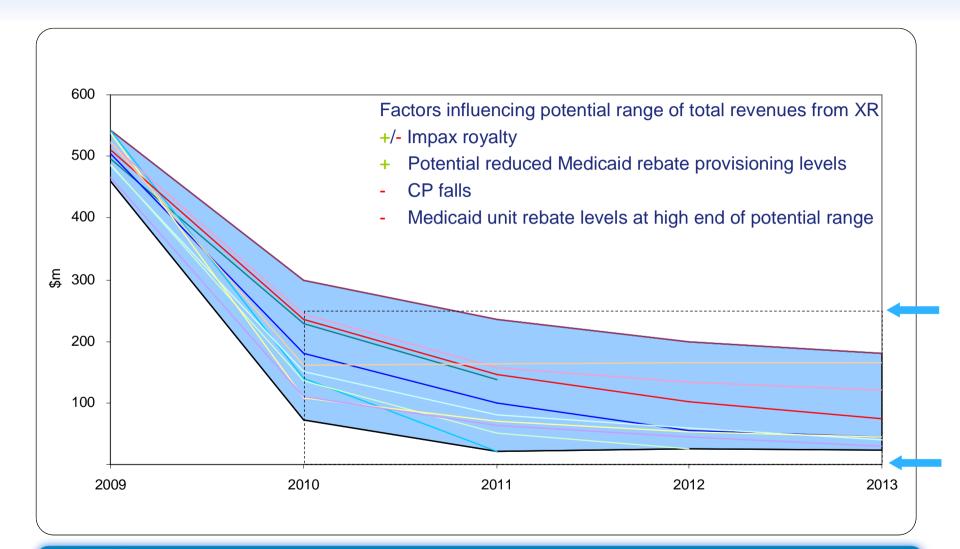
	2009	2009	2009	Q4		
	Q1	Q2	Q3	Direction Versus Q3 09	Dynamics	
Gross margin (1)	89%	84%	84%	=	Continued growth of higher margin core products Temporary adverse impact of XR erosion/mix effect	
R&D versus 2008	\$117m +\$8m	\$118m -\$9m	\$144m +\$27m	=	Continued investment in new products Velaglucerase program acceleration	
SG&A versus 2008	\$272m -\$26m	\$285m -\$14m	\$267m -\$16m	1	Velaglucerase program acceleration Continued proactive cost management	
Tax Rate	24%	2%	33%	I.	Q2 benefited from one-time Massachusetts State tax credit Full year guidance now 23%	

2009 EPS Guidance Framework unchanged

(1) Gross margin calculated as a percentage of product sales



### 2010 - ADDERALL XR dynamics



### **2010 Organic growth dynamics**

GROWTH DYNAMICS	KEY ELEMENTS
SUSTAINED CORE PRODUCT SALES GROWTH	Continued growth from existing portfolio     New product launches e.g. INTUNIV, Vela and REPLAGAL     Continued international growth
LEVERAGE INFRASTRUCTURE INVESTMENT	Limited real increase in SG&A     Sustained tax rate     Completion of manufacturing expansion
INVESTMENT IN PIPELINE	<ul> <li>Focused growth in R&amp;D \$</li> <li>Leverage technology platforms</li> <li>Incremental returns from investments</li> <li>Sustained future growth</li> </ul>

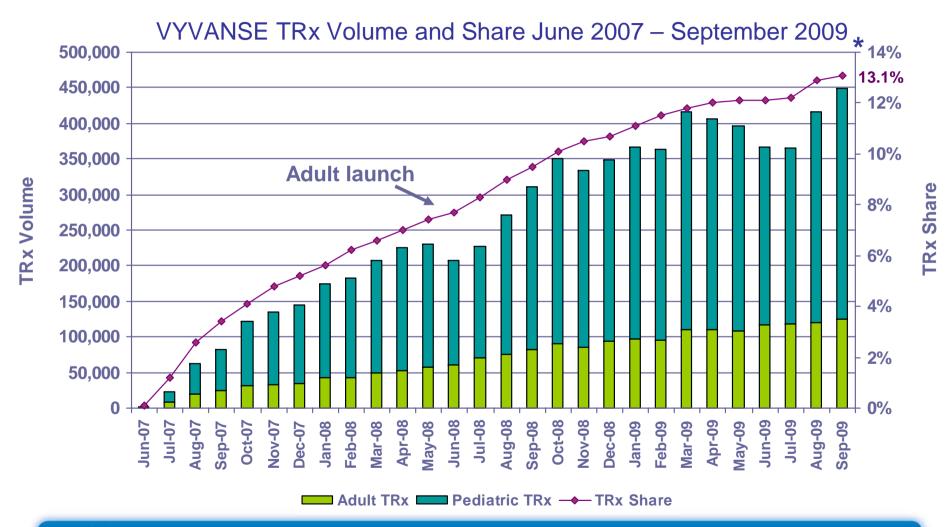
### **Specialty Pharma update**

Michael Cola President, Specialty Pharmaceuticals

#### **VYVANSE's Growth**

- Strong Back-to-School season
- Continued steady performance in the adult segment
- NO impact on VYVANSE from generic AXR
- Over \$1 Billion in cumulative gross Sales since launch

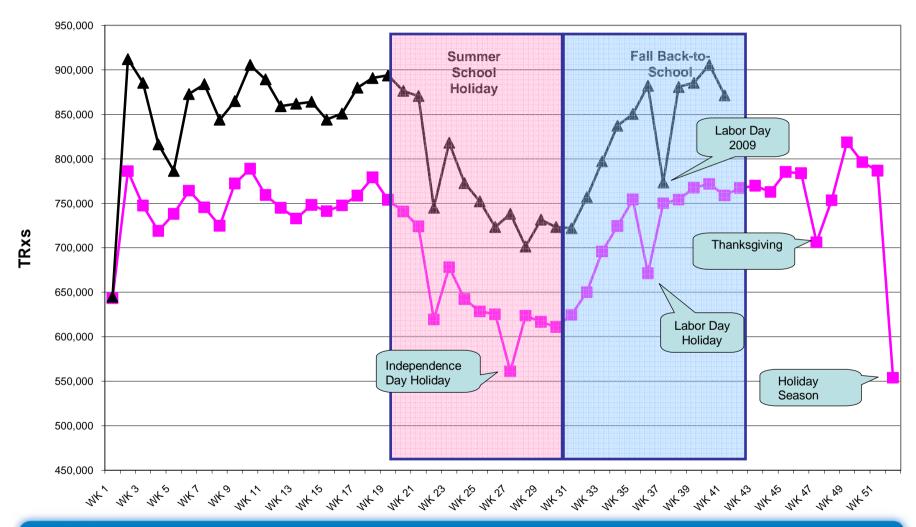
### VYVANSE continues to grow share and volume



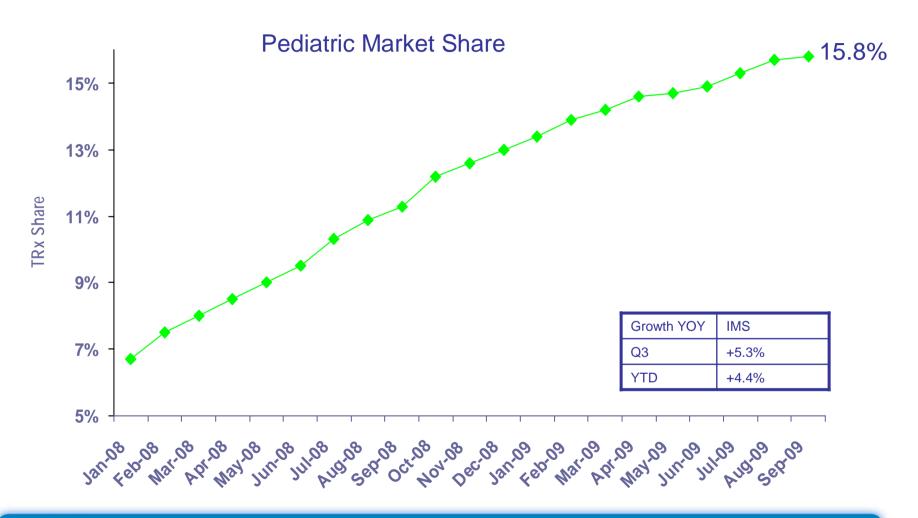


### The ADHD market continues growing year over year factoring in seasonality during the Summer holiday

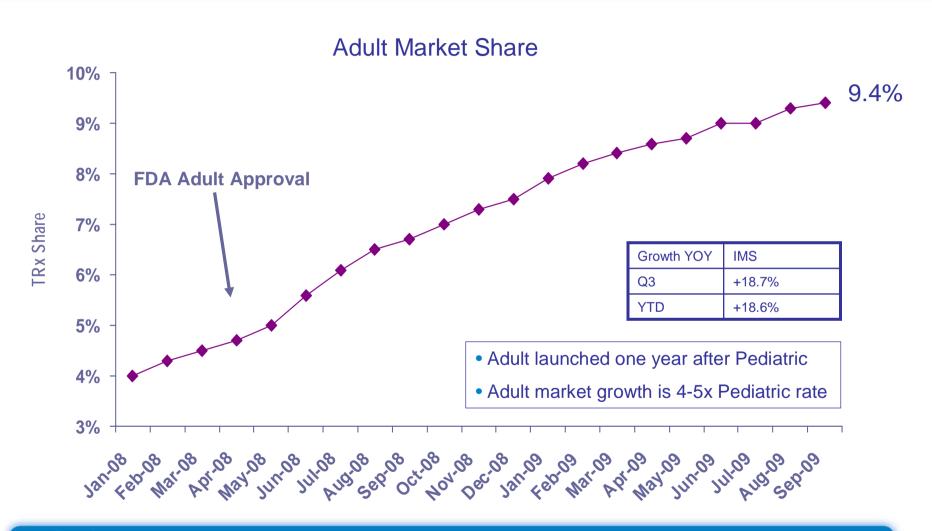
**─**2006-2008 Avg **→**2009



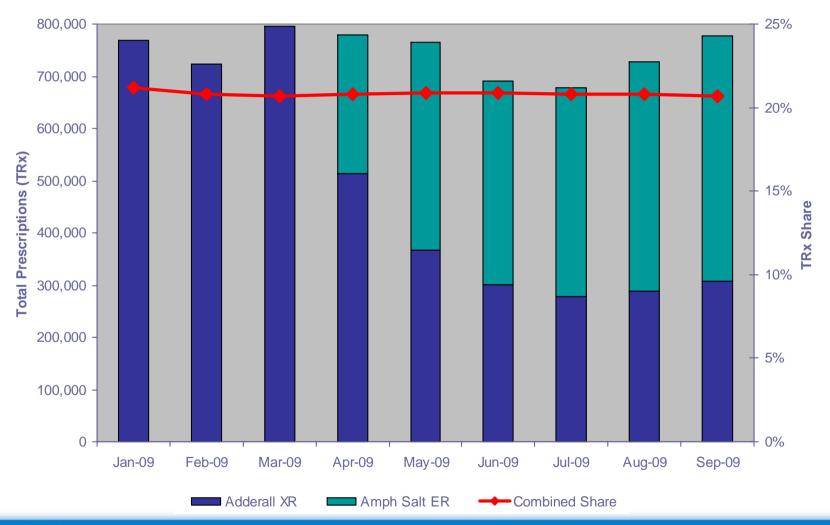
### VYVANSE Pediatric share has continued to grow through the summer and Back to School



### **VYVANSE Adult share continues to grow**



### Generic AXR has taken share from the brand while total molecule share has remained flat, indicating no therapeutic substitution





### **INTUNIV** is a significant opportunity for Shire in ADHD

- Approved September 2
- INTUNIV is positioned to complement, not compete, with our existing ADHD portfolio
  - VYVANSE remains the cornerstone of our ADHD franchise
- Opportunity to capture patients not previously available to Shire
- Drivers in place for near term and long term success

### **INTUNIV FDA approved**

- Once-daily treatment for ADHD in children and adolescents aged 6 to 17 years
- Novel mechanism selective alpha-2A receptor agonist
  - First non-stimulant approved for ADHD since Strattera in 2001
- Non-scheduled
  - Efficacy seen within 2 3 weeks
- Effective symptom improvement on a range of ADHD symptoms including those that are disruptive at home and school
- Available in pharmacies Nov-09

### Clear Positioning allows physicians to differentiate VYVANSE and INTUNIV on the basis of patient symptoms



 For the majority of ADHD patients exhibiting core symptoms of ADHD:



- inattention
- hyperactivity
- impulsivity
- lack of focus or distractibility

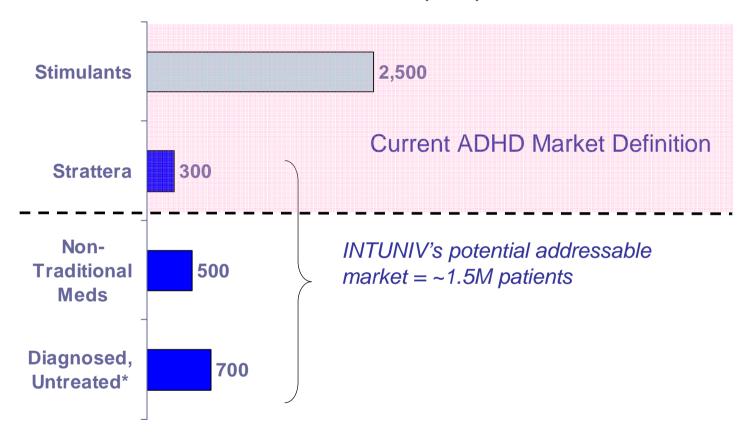




- ADHD patients whose symptoms are not limited to inattention, hyperactivity and impulsivity, and may include disruptive behaviors:
  - arguing
  - losing temper
  - deliberately annoying others

### Opportunity to capture patients not previously available to Shire

**Treatment Patterns for Pediatric ADHD Patients (000's)** 



\*60% of MDs indicate that they have diagnosed, untreated pediatric patients in their practice who are candidates for Intuniv

### **Other Specialty Pharma news**

- FOSRENOL Approval for new CKD indication received across EU through mutual recognition process (MRP)
  - EU launches anticipated from H1 2010
  - Continue assessment of path forward in US
- LIALDA global Phase 3 trials in diverticulitis are ongoing
- ALBA collaboration terminated
- VYVANSE non-ADHD: Phase 2 clinical trials planned or underway with data anticipated H2 2010
  - Adjunctive therapy in depression
  - Cognitive impairment in depression
  - Negative symptoms and cognitive impairment in schizophrenia

### **HGT** update

Sylvie Grégoire President, Human Genetic Therapies

### **Key growth drivers**

- HGT core products
  - Continued growth of ELAPRASE
  - REPLAGAL opportunity
    - Increase in demand/volume seen in the EU from switches
    - Sufficient supply on hand
    - Early Access for Fabry patients through treatment protocol and emergency IND in the US
    - BLA to be filed with the FDA in Q4 2009
  - FIRAZYR
    - Now launched in eleven countries, including the five largest European countries
    - Hospital product reimbursement / formulary listing
    - Well received by patients and treating physicians
  - International expansion continuing

### Velaglucerase alfa

### Achievements

- Early access programs in US and EU
- Home health care contract in place for home infusions
- Manufacturing timelines accelerated by 18 months
- NDA submitted end of August
- Submitted for approval in Canada

### Priorities for Q4 2009 onward

- Continue to service unmet need globally (300-600 patients by year-end)
- File in the EU
- Prepare for a Q1 US launch
- Present Ph 3 data at Lysosomal Disease Network (LDN) meeting in February 2010



### Other business highlights

- Execution of Pipeline Opportunities Fuel Long Term Growth
  - Collaboration with Santaris to develop its Locked Nucleic Acid technology
- Amicus Therapeutics mutual agreement to terminate collaboration
- Capital projects
  - Lexington roller bottle facility on track H1 2010 approval
  - Large scale manufacturing plant on track to begin validation runs in 2010
    - Long-term gross margin improvement
    - Risk mitigation in supply chain

### **Concluding remarks**

Angus Russell **CEO** 

### Solid foundation for future growth

- Strong financial performance
  - Excellent growth from core products
  - Proactive cost management
  - Strong cashflow
  - 2009 guidance reaffirmed
- Strategy is delivering
  - Driving growth from balanced portfolio of 8 core products
  - Launching INTUNIV in November
  - velaglucerase alfa now available pre-approval
  - REPLAGAL BLA to be filed end of year
  - Increasing our global reach
  - Developing, advancing and enhancing our strong pipeline
- Aspiration to grow sales in the mid-teens range on average between 2009 and 2015



### **Questions and Answers**

### **APPENDIX**

### 2009 Q3 Key financial ratios

FINANCIAL RATIOS (% of product sales)	Q3 09	y-o-y Growth	Q3 08	y-o-y Growth
Product sales		-15%		31%
Gross margin	84%		89%	
R&D	24%	23%	16%	22%
SG&A	44%	-6%	40%	6%
EBITDA <sup>(1)</sup> (% of product sales)	15%		32%	
EBITDA <sup>(2)</sup> (% total revenue)	23%		38%	

<sup>(1)</sup> Excluding royalties and other revenues.

Including royalties and other revenues.

This slide contains non GAAP financial measures. See appendix for a list of items excluded from the GAAP equivalent to calculate these measures.

### 2009 Q3 Royalties

	Q3 2009 \$m	Q3 2008 \$m	Reported Growth
3TC and ZEFFIX	42	45	-6%
ADDERALL XR	2	-	n/a
Other	16	16	-1%
Total Royalties	60	61	-1%



### 2009 Q3 Operating income / EPS

	Q3 09 \$m	Q3 08 \$m	Reported Growth
Operating income / (loss)			
GAAP	92	123	-25%
Adjustments	42	156	
Non GAAP <sup>(1)</sup>	134	279	-52%
<b>EPS - ADS (diluted)</b>			
GAAP	\$0.33	(\$0.20)	+\$0.52
Non GAAP <sup>(1)</sup>	\$0.49	\$1.17	-58%

<sup>(1)</sup> These are non GAAP financial measures. See appendix for a list of items excluded from the GAAP equivalent to calculate these measures.

### **ADDERALL XR Net sales**

	2008 Q4	2009 Q1	2009 Q2	2009 Q3	Q4 2009 trend
TRx ('000s)	2,281	2,288	1,181	875	
Value per TRx	\$174.46	\$209.53	\$210.20	\$229.20	
Demand sales	\$398m	\$479m	\$248m	\$201m	Consistent with Q3
Supply chain stocking/(destocking)	(\$29m)	(\$16m)	(\$67m)	\$6m	Further destocking expected
Gross sales	\$369m	\$463m	\$181m	\$207m	
Sales deductions	(\$99m)	(\$173m)	(\$131m)	(\$151m)	In line with lower gross sales versus Q3 Consistent sales deduction percentage compared to Q2 and Q3 (see below)
as % of Gross sales	27%	37%	72%	73%	Estimate: 70-80% subject to mix
Net sales - US	\$270m	\$290m	\$50m	\$56m	
Net sales - Canada	\$5m	\$6m	\$6m	\$6m	
Net sales – Teva / Impax	-	-	\$11m	\$9m	Reduced following initial Teva/Impax stocking
Total product revenue	\$275m	\$296m	\$67m	\$71m	

\$14m

\$81m

\$2m

\$73m

Royalties from Teva in Q3 replaced by Impax



XR royalties

**Total revenues** 

\$275m

\$296m

### 2009 Q3 EPS reconciliation

	Q3 09		C	3 08
	<b>\$</b> m	cents/ADS	<b>\$</b> m	cents/ADS
US GAAP Net income / Diluted EPS (ADS)	59.6	32.7c	(34.9)	(19.5c)
Amortization and asset impairments	34.8	19.0c	29.7	15.5c
Acquisitions and integration activities	6.8	3.7c	128.0	72.5c
Divestments and re-organizations	0.2	0.1c	(2.0)	(1.0c)
Non GAAP adjustments to operating income	41.8	22.8c	155.7	87.0c
Interest expense (TKT appraisal rights)	-	-	73.0	38.1c
Impairment of investments	-	-	54.1	28.3c
Discontinued operations	-	-	0.9	0.5c
Taxes on above adjustments	(12.2)	(6.6c)	(32.8)	(17.1c)
Non GAAP Net income / Diluted EPS (ADS)	89.2	48.9c	216.0	117.3c



### 2009 Q3 Cash generation reconciliation

	Q3 2009 \$m	Q3 2008 \$m
Net cash provided by operating activities	134	279
Tax and interest payments (net)	86	44
Effect of foreign exchange on cash	6	(10)
Cash Generation	226	313

### Presentation of 2008 R&D and SG&A

To be consistent with our 2009 presentation, for 2008 comparatives we have reclassified certain Medical Affairs costs related to promotional and marketing activities from R&D to SG&A, as follows:

All amounts in \$ mil	million 2008 Q1		2008	2008 Q2		2008 Q3		2008 Q4	
	As reported	Reclassified	As reported	Reclassified	As reported	Reclassified	As reported	Reclassified	
US GAAP									
R&D	122.0	111.8	145.3	136.4	127.1	120.2	132.2	125.9	
SG&A	334.5	344.7	428.8	437.7	320.4	327.3	339.2	345.5	
	456.5	456.5	574.1	574.1	447.5	447.5	471.4	471.4	
NON GAAP									
R&D	119.1	108.9	135.7	126.8	123.7	116.8	129.1	122.8	
SG&A	287.4	297.6	289.6	298.5	276.7	283.6	282.6	288.9	
	406.5	406.5	425.3	425.3	400.4	400.4	411.7	411.7	

#### 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
- Incremental interest charges arising on the settlement of litigation with the former dissenting shareholders of TKT.

#### Divestments, re-organizations and discontinued operations:

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

