## **Full Year 2009 Results**

Shire plc February 19, 2010

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, Shire's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of research, development, approval, reimbursement, manufacturing and commercialization of Shire's Specialty Pharmaceutical and Human Genetic Therapies products, as well as the ability to secure and integrate 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.

## 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

## **Opening remarks**

Angus Russell CEO

## **Excellent results in a transformational year**

- Core product sales<sup>(1)</sup> up 25% to \$2.1 billion
  - Up 28% on Like for Like<sup>(2)</sup> basis
  - Q4 2009 core product sales<sup>(1)</sup> up 36% versus Q4 2008
- FY 2009 Non GAAP diluted earnings per ADS: \$3.49
  - Q4 2009 Non GAAP diluted earnings per ADS: \$1.11
  - Leveraging our existing infrastructure
  - Decrease in full year SG&A expense versus 2008
- Cash generation of \$921 million during 2009
- (1) Core products represent Shire's products excluding ADDERALL XR
- (2) 'Like for Like Growth' excludes movements in exchange rates by applying 2008 exchange rates to 2009 results.



## Shire's business model has been the key to our success

#### **Business Model**

- Specialty biopharmaceutical company
- Treatment of symptomatic diseases
- Small sales forces
- Focus on lower risk projects with relatively fast development timelines and strong IP protection

Financial impact past 7 years (2003 – 2009)



Note: data covers timeframe of 1/1/2003 through 12/31/2009



## Strategy is delivering

Focused on the needs of patients

VPRIV (velaglucerase alfa) and REPLAGAL currently addressing unmet needs

Launching new products

INTUNIV – first and only selective a2A agonist indicated for the treatment of ADHD\*

Acquisitions and geographic expansion

Presence in 28 countries and growing

Acquisition of EQUASYM facilitates immediate access to EU ADHD market

Pipeline opportunities for long term growth

Progress in development programs, antithrombotic, CarrierWave technology, HGT research, and new technology (Santaris)

Sustaining our financial performance

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** 

## **Strong 2009 earnings**

Reported EPS-ADS\*: \$3.49

Adjusted EPS-ADS\*: \$3.17

(Excludes impact of ADDERALL XR change in best estimate)

#### **Ahead of Expectations**

- + Strong Q4 Product sales
- + XR Royalties
- + XR Product sales

- Higher R&D
- Higher SG&A

\$2.83

2009 Guidance framework (updated Oct 2009)



## **2009 Performance summary**

		Financial Year				Fourth Quarter		
	2009 \$m	2008 \$m	Reported Growth	Like for Like Growth <sup>(3)</sup>	2009 \$m	Reported Growth	Like for Like Growth <sup>(3)</sup>	
Total Revenues	3,008	3,022	-	+2%	893	+17%	+14%	
EBITDA (1)	982	1,035	-5%	-5%	336	+26%	+24%	
Adjusted EPS - ADS (1) (2)	\$3.17	n/a	n/a		\$0.79	n/a		
Reported EPS - ADS (1)	\$3.49	\$3.86	-10%		\$1.11	+9%		

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



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

<sup>(2)</sup> Adjusted EPS – ADS on a diluted basis excludes the 32c effect of the change in best estimate of Medicaid rebate liability for ADDERALL XR.

## **2009 Revenue summary**

		Financial Year			
	2009 \$m	2008 \$m	Reported Growth	Like for Like Growth <sup>(3)</sup>	
Core Product Sales (1)	2,067	1,653	+25%	+28%	
ADDERALL XR Sales	627	1,101	-43%	-43%	
Total Product Sales	2,694	2,754	-2%	-	
Royalty and Other Revenue	314	268	+17%	+20%	
Total Revenues	3,008	3,022	-	+2%	

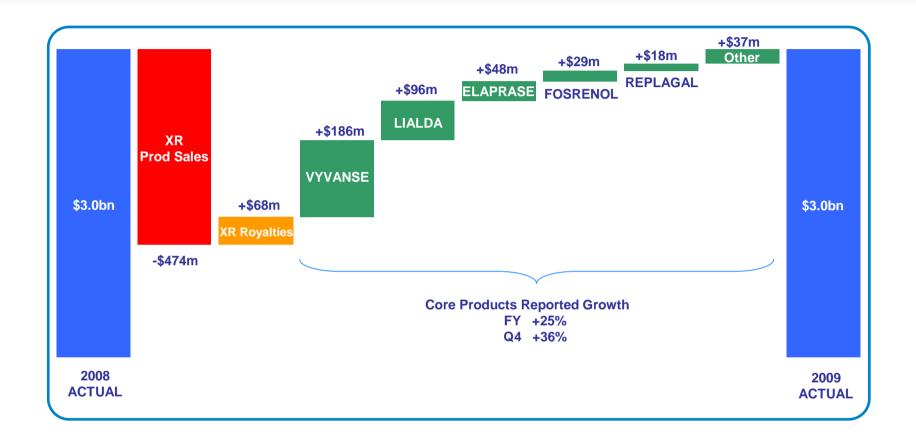
<sup>(3) &#</sup>x27;Like for Like Growth' excludes movements in exchange rates by applying 2008 exchange rates to 2009 results.



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

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

### 2009 Total revenues in-line with 2008



## 2009 Portfolio Strength and Diversity - Core Product Sales

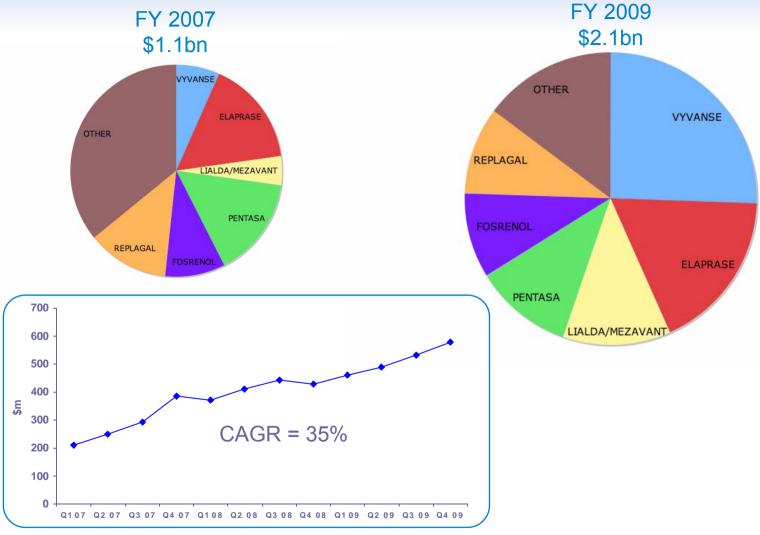
		Financial Year				Fourth Quarter			
	2009 \$m	2008 \$m	Reported Growth	Like for Like Growth <sup>(2)</sup>	2009 \$m	Reported Growth	Like for Like Growth <sup>(2)</sup>		
VYVANSE	505	319	+58%	+58%	145	+41%	+40%		
ELAPRASE	353	305	+16%	+20%	94	+26%	+19%		
LIALDA / MEZAVANT	236	140	+68%	+69%	67	+63%	+62%		
PENTASA	215	186	+16%	+16%	58	+23%	+23%		
REPLAGAL	194	176	+10%	+16%	61	+37%	+26%		
FOSRENOL	184	155	+19%	+23%	47	+40%	+33%		
FIRAZYR	6	-	n/a	n/a	2	n/a	n/a		
INTUNIV	5	-	n/a	n/a	5	n/a	n/a		
VPRIV	3	-	n/a	n/a	3	n/a	n/a		
OTHER	366	372	-2%	+5%	103	+21%	+16%		
CORE PRODUCT SALES (1)	2,067	1,653	+25%	+28%	585	+36%	+32%		

<sup>(2) &#</sup>x27;Like for Like Growth' excludes movements in exchange rates by applying 2008 exchange rates to 2009 results.



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

## Core product sales growth



Core product sales represent Shire's product sales excluding ADDERALL XR.



## **Operating leverage emerging – Key financial ratios**

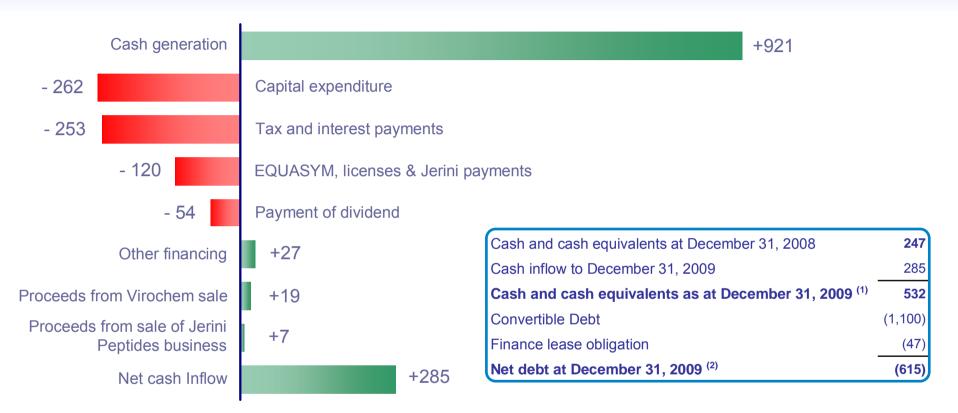
Year on Year Movements:	FY 2009	FY 2008
Total Product Sales	-2%	+27%
Core Product Sales (ex XR)	+25%	+45%
<b>R&amp;D</b> <sup>(1)</sup>	+10%	+27%
SG&A <sup>(1)</sup>	-3%	+13%
Ratios:		
% of Total Product Sales		
<b>R&amp;D</b> <sup>(1)</sup>	19%	17%
SG&A <sup>(1)</sup>	42%	42%
% of Core Product Sales		
R&D <sup>(1)</sup>	25%	29%
SG&A <sup>(1)</sup>	55%	71%

(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.



#### 2009 Cashflow

Millions of USD

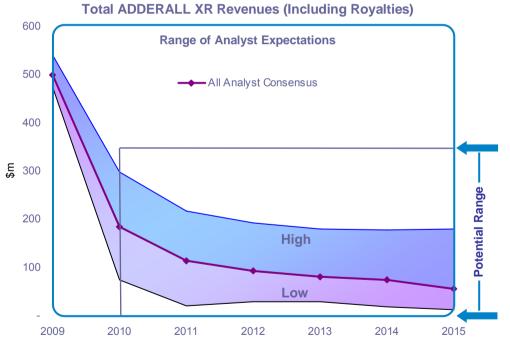


- (1) Shire's balance of cash and cash equivalents at December 31, 2009 includes \$33m of restricted cash.
- (2) Shire has a revolving credit facility of \$1.2bn which was undrawn at December 31, 2009.

## **ADDERALL XR dynamics**

#### **Macro assumptions:**

- Citizen Petition holds through 2010
- States continue to invoice for Medicaid rebates at 2009 levels



#### 2010 Dynamics versus Q4 2009

(see appendix for detailed analysis)







## **Emerging shape of Shire 2010 Income Statement**

		2010 Dynamics
	Direction Versus FY 09	(see Appendix for more analysis)
Core Product Sales	1	2009 growth continues, with potential to accelerate
Total Product Sales	1	Core product growth > AXR decline
Royalties	<b>↓</b>	Growth in AXR royalty offset by lower other royalty income
Gross Margins	=	
R&D and SG&A	1	<ul><li>5-10% growth in R&amp;D and SG&amp;A investment</li><li>Operating leverage on Core Product Sales</li></ul>
Tax rate	=	
Reported EPS-ADS	1	

0.03 **-0.05** 

Interest on convertible = \$34m pa

A 10 cent strengthening of the \$ against the £



## **2010 Organic growth dynamics**

#### **GROWTH DYNAMICS** KEY ELEMENTS

# SUSTAINED CORE PRODUCT SALES GROWTH

- · Continued growth from existing portfolio
- New product launches e.g. INTUNIV, VPRIV and REPLAGAL
- · Continued international growth

## LEVERAGE INFRASTRUCTURE INVESTMENT

- SG&A \$ increases less than product sales over time
- Sustained tax rate
- · Completion of manufacturing expansion

## INVESTMENT IN PIPELINE

- Focused growth in R&D \$
- Leverage technology platforms
- Incremental returns from investments
- Sustained future growth

## **Specialty Pharma update**

Michael Cola President, Specialty Pharmaceuticals

## **Specialty Pharma – 2009 key highlights**

- Successfully managed through AXR generic erosion by capturing significant cash flow while growing VYVANSE sales
- Gained FDA approval for and launched INTUNIV
- Initiated multiple VYVANSE non-ADHD programs
- Acquired EQUASYM to jump-start EU ADHD footprint
- Approaching \$0.5bn in net sales for the GI portfolio
- Expanded pipeline through multiple initiatives including the progression of multiple CarrierWave programs and SPD 535 (anagrelide analogue)

## VYVANSE demonstrated outstanding growth in 2009 in the face of ADDERALL XR going generic

Measure	2009 vs. 2008
Net Sales	+58%
TRx Volume	+65%
Dec Avg Market Share	13.3% (+2.6 share points)
Total ADHD Market TRx Volume	+9.2%

- Q409 growth vs. Q408 growth was similarly strong
- Market share grew in both the pediatric and adult patient segments

## **INTUNIV** Launch update

- Although it is still early post launch for INTUNIV, we are very encouraged by the early indicators
  - For the week ending February 5<sup>th</sup>, 2010, the overall national market share was 1.2%, and it is significantly higher in the important child / adolescent psychiatry and general psychiatry subsets of prescribers
  - Approximately 7,500 physicians have prescribed INTUNIV
  - Payors: formulary status still being reviewed by managed care plans. Currently most commercial managed care plans providing unrestricted access. Medicaid reimbursement progressing as expected



## Select growth opportunities for Specialty Pharma portfolio

- INTUNIV: continuing progress on life cycle opportunities
  - On-going studies to evaluate efficacy in combination with stimulants and evening dosing
- VYVANSE non-ADHD: Phase 2 clinical trials actively enrolling patients with data beginning in 2011
  - Adjunctive therapy in depression
  - Cognitive impairment in depression
  - Negative symptoms and cognitive impairment in schizophrenia
- Globalization of the ADHD portfolio
  - VYVANSE
    - Launched in Canada this month
    - Market authorization filings under review in Mexico and Brazil
    - Continued enrollment of EU registration trials
- LIALDA: global Phase 3 trials in diverticulitis are ongoing

## Efforts continue to progress early pipeline products

- SPD 535 (anagrelide analogue) platelet lowering ability without PDEIII inhibition
  - Initial PoC program targets prevention of thrombotic complications associated with arteriovenous grafts in hemodialysis
    - Proof-of-principle for broader utility as an anti-coagulant
    - Estimated data availability mid-2010
- CarrierWave
  - Primarily focused in pain and ADHD
  - Estimated data availability mid-2010

## **HGT** update

Sylvie Grégoire President, Human Genetic Therapies

## HGT – 2009 key highlights – current marketed products

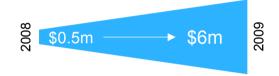
#### Hunter franchise – ELAPRASE

- 20% CER revenue growth vs. 2008
- Lexington roller bottle facility Approved in EU and on track for H1 2010 approval in the US



#### HAE franchise - FIRAZYR

- Now launched in twelve countries, including the five largest European countries
- Making good progress on reimbursement
- Well received by patients and treating physicians
- Additional marketing authorization submissions filed

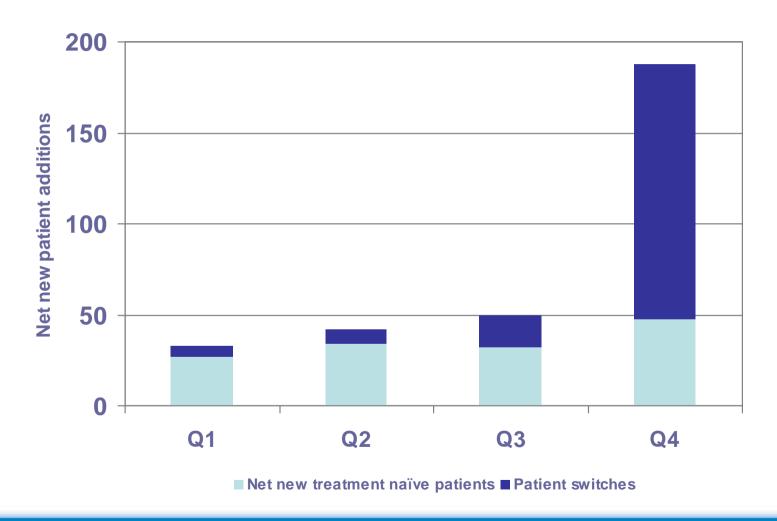


#### Fabry franchise – REPLAGAL

- 60% of 2009 patient accrual occurred in Q4 with the majority coming from patient switches
- Q4 '09 revenue increase 26% vs. Q3 '09 (20% CER)
- Exit 2009 as market leader in the EU
- Early access for patients through FDA-approved treatment protocol and emergency IND
- BLA filed December 2009



## More than 300 cumulative patients added to REPLAGAL therapy in 2009 with the majority coming from patient switches





## HGT – 2009 key highlights





- Responding to evolving market demands in 2009
  - All three Phase 3 studies demonstrated positive results
  - Manufacturing timelines accelerated by 18 months
  - Early access programs for patients implemented in the US and many countries around the world
    - Over 400 patients have received VPRIV
  - NDA submitted PDUFA date February 28, 2010
  - MAA submitted, accelerated assessment granted
  - Manufacturing and clinical site inspections complete

## Product launch preparations for 2010 and beyond

#### VPRIV

- Intended price at launch: \$1350 for 400Uvial
- Direct co-pay assistance to eligible patients in US to reduce patient burden/access barrier
- Continued financial assistance through patient associations
- Sales force training and readiness efforts complete

### REPLAGAL

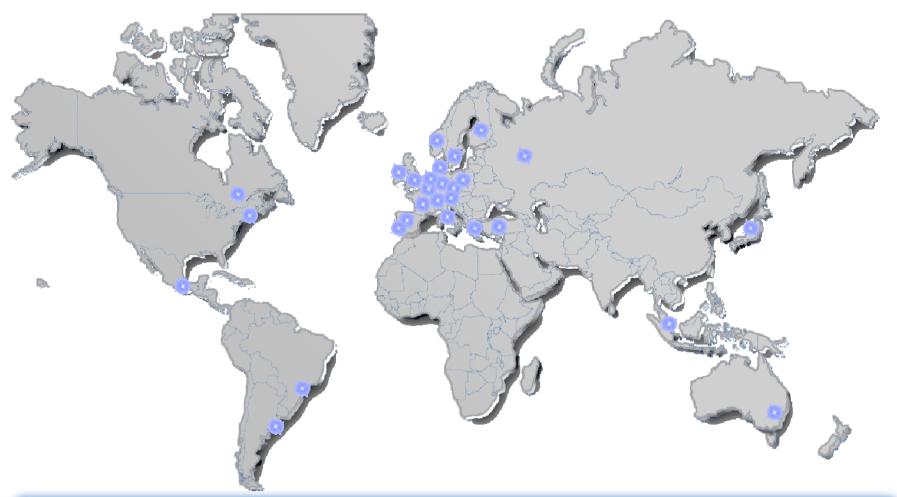
- Focus on market growth and switch
- Continue to address unmet need in the US
- Ongoing discussions with FDA regarding BLA submission

## **HGT** product development pipeline

- FIRAZYR
  - FAST-3 and self administration studies continue to enroll
  - Complete response to FDA by late 2010
- idursulfase-IT for Hunter CNS
  - First patient dosed
- Sanfilippo A
  - Phase 1 to begin H1 2010
- HGT 1110 for MLD
  - Focus shifted to direct CNS delivery
- HGT research and Santaris collaboration
  - Protein therapy
  - Locked nucleic acid technology

## Leveraging our infrastructure

### **Direct business in 28 countries and products** distributed in approximately 50 countries



## **Investment for future growth**



- Manufacturing to begin July 2010
- Additional capacity up to four 2000L bioreactors
- Alternate site for manufacturing
- Single use bioreactor technology further reduces manufacturing risk

## Concluding remarks

Angus Russell CEO

## Potential launches from 2010-2016\*

2010	2011	2012	2013-2016
<ul> <li>VYVANSE (Canada)</li> <li>FOSRENOL CKD (EU)</li> <li>VPRIV (US&amp;EU)</li> <li>FIRAZYR (ROW)</li> <li>REPLAGAL (US)</li> </ul>	<ul><li>VYVANSE (Latin America)</li><li>FIRAZYR (US)</li><li>VPRIV (ROW)</li></ul>	• VYVANSE (EU)	<ul> <li>HGT 1110 (MLD)</li> <li>IDURSULFASE-IT</li> <li>SANFILIPPO ERT</li> <li>HGT 2610 (GLD)</li> <li>JUVISTA</li> <li>LIALDA DIVERTICULITIS</li> <li>SPD 535</li> </ul>

<sup>\*</sup>Subject to regulatory approvals



## Solid foundation for future growth

- Strong financial performance
  - Core product sales\* up 25% in 2009
  - Proactive cost management
  - Strong cash generation
- Strategy is delivering
  - Driving growth from balanced portfolio of 8 key products
  - INTUNIV launch off to a strong start
  - VPRIV now available pre-approval
  - REPLAGAL BLA filed in December 2009
  - 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 Key financial ratios**

FINANCIAL RATIOS (% of product sales)	FY 09	y-o-y Growth	FY 08	y-o-y Growth
Product sales	2,694	-2%	2,754	27%
Gross margin	86%		88%	
R&D	19%	10%	17%	27%
SG&A	42%	-3%	42%	13%
EBITDA <sup>(1)</sup> (% of product sales)	25%		28%	
EBITDA <sup>(2)</sup> (% total revenue)	33%		34%	
FINANCIAL RATIOS (% of core product sa	iles)			
Core product sales	2,067	25%	1,653	45%
R&D - Core product sales	25%		29%	
SG&A - Core product sales	55%		71%	J

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

<sup>(2)</sup> Including royalties and other revenues.

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

## **ADDERALL XR Dynamics**

	2009 Q1	2009 Q2	2009 Q3	2009 Q4	2009 FY	Direction Versus Q4 09	2010 Dynamics
TRx ('000s)	2,288	1,181	875	911	5,255		
Value per Rx	\$209.53	\$210.20	\$229.20	\$226.44	\$215.88		
Demand Sales	\$479m	\$248m	\$201m	\$206m	\$1,134m		Further brand erosion by authorized generics
Supply Chain stocking/(destocking)	(\$16m)	(\$67m)	\$6m	\$23m	(\$54m)	I	Destocking due to lower demand
<b>Gross Sales</b>	\$463m	\$181m	\$207m	\$229m	\$1,080m		
Sales Deductions	(\$173m)	(\$131m)	(\$151m)	(\$52m)	(\$507m)		Sales deductions at 60–70% as Medicaid & Contract Managed care mix increases
as % of Gross Sales	37%	72%	73%	23%	47%		
Net Sales - US	\$290m	\$50m	\$56m	\$177m	\$573m		
Net Sales - Canada	\$6m	\$6m	\$6m	\$9m	\$27m		Promotion behind newly launched VYVANSE
Net Sales - Teva/Impax	-	\$11m	\$9m	\$6m	\$27m	=	
<b>Total Product Revenue</b>	\$296m	\$67m	\$71m	\$192m	\$627m		
XR Royalties	-	\$14m	\$2m	\$52m	\$68m		-Q4 includes Impax pipeline (c. 75% of royalty) + Potential for Impax to grow share
Total Revenues	\$296m	\$81m	\$73m	\$244m	\$695m		

Key assumptions: CP holds through 2010; and States continue to invoice for Medicaid rebates at 2009 levels.



## **Emerging Shape of Shire Income Statement**

		2009 Q1	2009 Q2	2009 Q3	2009 Q4	2009 FY	Direction Versus FY 09	2010 Dynamics
Core product	t sales	\$459m	\$491m	\$532m	\$585m	\$2,067m	1	2009 growth continues, with potential to accelerate
	versus 2008	+24%	+20%	+20%	+36%	+25%	•	potential to addictate
Total product	t sales	\$756m	\$558m	\$603m	\$777m	\$2,694m	1	Core product growth offsetting decline in ADDERALL XR sales
	versus 2008	+20%	-21%	-15%	+10%	-2%		
Royalties		\$51m	\$67m	\$60m	\$115m	\$293m	I I	Higher authorized generic AXR royalties offset by lower other royalty income
	versus 2008	-22%	+3%	-1%	+109%	+19%		
Gross margir	n <sup>(1) (2)</sup>	89%	84%	84%	87%	86%	=	
R&D (2)		\$117m	\$118m	\$144m	\$144m	\$523m		
K&D (=/	versus 2008	+\$9m	-\$9m	+\$27m	+\$21m	+\$48m		•5-10% growth in R&D and SG&A investment
SG&A <sup>(2)</sup>		\$271m	\$285m	\$267m	\$315m	\$1,138m		<ul> <li>Operating leverage on Core Product Sales</li> </ul>
JG&A V	versus 2008	-\$27m	-\$14m	-\$16m	+\$26m	-\$31m		
Tax Rate		24%	2%	33%	31%	25%	=	

<sup>(1)</sup> Gross margin calculated as a percentage of product sales

<sup>(2)</sup> These are Non GAAP financial measures. See appendix for a list of items excluded from the US GAAP equivalents used to calculate these measures. Interest on convertible = \$34m pa



## 2009 Royalties

	Fina		Fou	Fourth Quarter		
	2009 \$m	2008 \$m	Reported Growth	200 \$	09 m	Reported Growth
0T0 I 7FFFIV	404	404	00/		4.4	. 50/
3TC and ZEFFIX	164	181	-9%	4	14	+5%
ADDERALL XR	68	-	n/a		52	n/a
REMINYL	48	63	-25%	,	14	+1%
Other	13	2	n/a		5	n/a
Total Royalties	293	246	+19%	1	15	+109%

## 2009 FY Operating income / EPS

	F	inancial `	Fourth Quarter		
Operating income	2009 \$m	2008 \$m	Reported Growth	2009 \$m	Reported Growth
GAAP	620	412	+51%	268	+39%
Adjustments	269	546		45	
Non GAAP <sup>(1)</sup>	889	958	-7%	313	+30%
EPS - ADS (diluted)					
GAAP	\$2.69	\$0.86	+214%	\$0.94	+20%
Non GAAP <sup>(1)</sup>	\$3.49	\$3.86	-10%	\$1.11	+9%

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



## 2009 FY EPS reconciliation

	FY 09		FY 08	
	\$m	cents/ADS	\$m	cents/ADS
US GAAP Net income / Diluted EPS (ADS)	491.6	269.1c	156.0	85.8c
Amortization and asset impairments	136.9	72.6c	223.3	118.5c
Acquisitions and integration activities	51.0	26.3c	273.4	141.9c
Divestments and re-organizations	81.3	42.0c	49.4	25.6c
Non GAAP adjustments to operating income	269.2	140.9c	546.1	286.0c
Interest expense (TKT appraisal rights)	-	-	73.0	37.9c
Write down of investments	-	-	58.0	30.1c
Gain on disposal of investment	(55.2)	(28.5c)	(9.4)	(4.9c)
Discontinued operations	12.4	6.4c	17.6	9.1c
Taxes on above adjustments	(75.7)	(39.0c)	(112.4)	(58.2c)
Non GAAP Net income / Diluted EPS (ADS)	642.3	348.9c	728.9	385.8c



## 2009 Cash generation reconciliation

	Financi	al Year	Fourth Quarter	
	2009 \$m	2008 \$m	2009 \$m	2008 \$m
Net cash provided by operating activities	627	800	237	275
Payments for acquired and in-licensed products	37	-	-	-
Acquisition of METAZYM from Zymenex	-	135	-	-
Class action escrow payment	-	27	-	-
Interest on TKT appraisal rights settlement	-	147	-	147
Tax and interest payments (net)	253	134	32	27
Effect of foreign exchange on cash	4	(12)	-	(6)
Cash Generation	921	1,231	269	443

### 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 \$ million

	2008 Q1		2008 Q2		2008 Q3		2008 Q4	
	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.