

# First Quarter Results to March 31, 2008

Shire plc

April 25, 2008



### 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 affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of pharmaceutical research, product development including, but not limited to the successful development of JUVISTA® (Human TGFβ3) and velaglucerase alfa (GA-GCB); manufacturing and commercialization including, but not limited to, the establishment in the market of VYVANSE™ (lisdexamfetamine dimesylate) (Attention Deficit and Hyperactivity Disorder ("ADHD")); the impact of competitive products, including, but not limited to, the impact of those on Shire's ADHD franchise; patents, including but not limited to, legal challenges relating to Shire's ADHD franchise; government regulation and approval, including but not limited to the expected product approval date of INTUNIV™ (guanfacine extended release) (ADHD); Shire's ability to secure new products for commercialization and/or development; and other risks and uncertainties detailed from time to time in Shire plc's filings with the Securities and Exchange Commission, including Shire plc's Annual Report on Form 10-K for the year ended December 31, 2007.



#### **Agenda**

Q1 Highlights
Matthew Emmens

Q1 Financial Review Angus Russell

Acquisition of arylsulfatase-A
 Sylvie Grégoire

Concluding Remarks
Matthew Emmens

Questions & Answers
All



# Matthew Emmens CEO

Q1 Highlights



#### **Q1 Highlights**

- Great start to the year
- Reaffirming our full year 2008 guidance
- Acquisition of new orphan drug for MLD
- VYVANSE approved for treatment in adults
- LIALDA Co-promotion agreement with TAP
- New UK/US listed holding company to protect Shire's tax position
- Global expansion continues with product approvals in Spain,
   Russia, Mexico, Australia, South Korea, and Hong Kong



#### **Q1 Financial Highlights**

- Product sales up 37% to \$632 million
- New Product sales:
  - 34% of product sales for Q1 2008 versus 13% in Q1 2007
- Total revenues up 33% to \$702 million
- GAAP Operating income up 15% to \$163 million
- Non GAAP Operating income up 23% to \$192 million

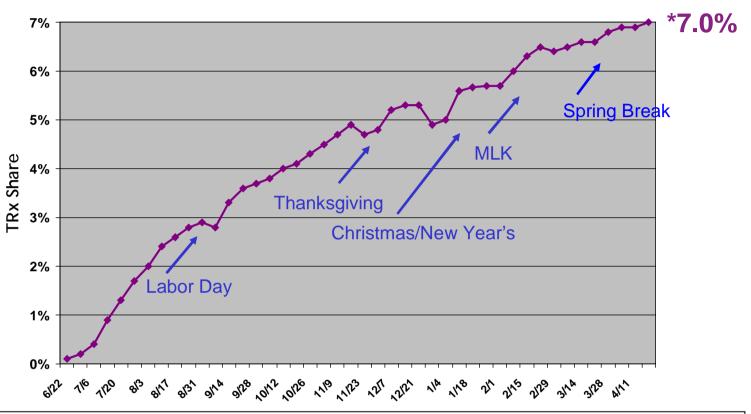




**The First Prodrug Stimulant** 

#### **Vyvanse Launch Performance**





- Over 1,300,000 prescriptions since launch
- +50,000 prescriptions for the past seven weeks
- 60% (25,000) of high volume physicians prescribing

\*Projection based on daily prescription volume

#### VYVANSE adult claim represents a significant Shire opportunity for growth in 2008



#### **VYVANSE** Adult Indication:

- Approved by FDA on April 23, 2008
- Commercial promotion will begin within several weeks
  - Strong effort to both physicians and consumers including physician training and patient screening
  - Duration important for adult day
  - Lower abuse related liking effect compared to equivalent oral dose of d-amphetamine
- New opportunity to grow the adult market
  - Efforts by all companies to expand adult market have been minimal since promotion of AXR was discontinued
  - No major consumer efforts in several years
  - No field force promotion for adult patients since VYVANSE launch
  - Branded and non-branded DTC planned
- Additional clinical studies in adults will be conducted in 2008 to provide further support

## VYVANSE demonstrated robust efficacy 13 hours after dosing in our 311 study



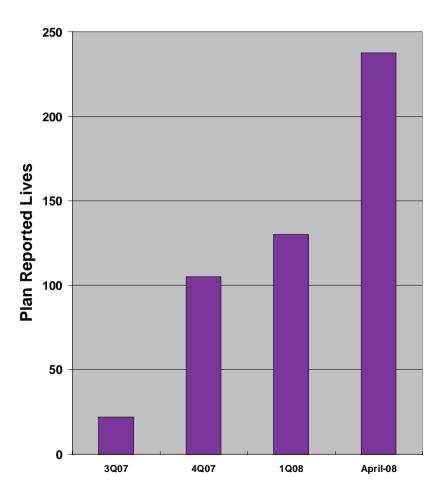
- Double-blind, placebo-controlled, crossover analog classroom study of 129 children 6-12 years old diagnosed with ADHD
- Patients were optimized to 30, 50, or 70 mg of Vyvanse over 4 weeks, and then randomized to Vyvanse then Placebo (or Placebo then Vyvanse), for one week each
- Statistically significant efficacy shown on the SKAMP scale across the day –
   the primary endpoint
- Significant efficacy at <u>all</u> time points measured throughout the day on the SKAMP scales
  - First time point measured was 1.5 hours post-dosing
  - Last time point measured was 13 hours post-dosing
- Adverse event profile was similar to that seen with Vyvanse in other trials



#### **Excellent VYVANSE Managed Care Coverage**

- ADDERALL XR has outstanding managed care formulary coverage
- In total, VYVANSE has ~80% parity formulary status to ADDERALL XR contracted lives as of April
- We have agreements with 7 of our top 10 managed care organizations

#### Lives Covered by MCOs with Vyvanse Executed Agreements









#### **TAP Co-promotion**

- Adds reach and frequency to a strong launch and winning product profile
- TAP is consistently one of the top-rated GI sales teams per Verispan
- More than 500 sales representatives will detail Lialda in addition to the 120 Shire GI specialist representatives
  - Provides dual Coverage of ~9,000 GI targets currently called on by Shire
  - TAP will cover 22,000 additional high-prescribing GI and PCP targets
  - TAP will provide 144,000 primary details
    - More than doubles number of details
- TAP began detailing April 14, 2008
- Latest weekly share: NRx 10.5%, TRx 9.8%

<sup>\*</sup> Source: IMS NGPS weekly data as at April 11, 2008







#### **ELAPRASE – Global expansion continues**

- Now approved in 39 countries
- 65%-70% of diagnosed patients in the US and EU on ELAPRASE
- Rapid adoption in Japan
- Recent approval in Mexico bolsters expansion in Latin America
- Approval in Russia 10 months ahead of schedule









# **Angus Russell CFO**

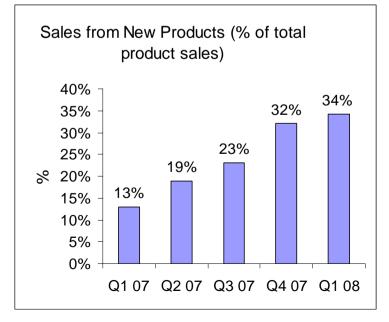
Q1 Financial Review

#### **Total Revenues**



	Q1 08 \$m	Q1 07 \$m	Growth
Product Sales	631.7	461.5	37%
Royalties	65.1	59.5	
Other Revenues	5.4	7.2	
Total Revenues	702.2	528.2	33%

		Q1 08 \$m	Q1 07 \$m	Growth
Established Products	66%	415.4	400.2	4%
ELAPRASE		71.5	26.6	
VYVANSE		54.4	-	
FOSRENOL		36.2	22.8	
LIALDA / MEZAVANT		27.2	-	
DAYTRANA		20.3	11.9	
DYNEPO		6.7	-	
New Product Sales	34%	216.3	61.3	
Total Product Sales	100%	631.7	461.5	37%



#### **Product Sales Drivers**



	Q1 08 \$m	Q1 07 \$m	Sales Growth	US RX** Growth
ADDERALL XR	261.5	249.1	5%	-5%
ELAPRASE*	71.5	26.6	169%	n/a
VYVANSE*	54.4	-	n/a	n/a
PENTASA	44.2	43.8	1%	-1%
REPLAGAL	42.5	32.5	31%	n/a
FOSRENOL*	36.2	22.8	59%	-6%
LIALDA*	27.2	-	n/a	n/a
DAYTRANA*	20.3	11.9	71%	-5%
** Course : IMC Date				

<sup>\*\*</sup> Source : IMS Data

<sup>\* -</sup> New product sales

#### **Vyvanse – Gross to Net Sales**



		Q1 08					Q4 07			
	ADHD Mkt TRx ('000)*	Avg QTD M Share*	kt	\$M		ADHD Mkt TRx ('000)*	Avg QTD Mkt Share*	\$M	<b>-</b>	
Sales Demand	10,145	6.1%	(1)	66.6		9,818	4.7%	<sup>(2)</sup> 47.2		
Stocking				9.2				40.5		
Underlying Gross	Sales		_	75.8				87.7	_	
Sales Coupons				(8.6)	11%			( 12.4	) 14%	
Wholesaler discour	nts and rebates	S		( 12.8 )	17%	28%		( 9.4	) 11%	25%
Net Sales			_	54.4				65.9	_	

#### Notes

<sup>\*</sup> Per IMS data

<sup>1</sup> Qtr - Revenue per TRx = \$3.41 (price per unit) x 31.3 units per TRx

<sup>2</sup> Qtr - Revenue per TRx = \$3.41 (price per unit) x 30.2 units per TRx



#### **Royalties**

	Q1 08 \$m	Q1 07 \$m	Growth (%)
3ТС	37.3	35.5	5% *
ZEFFIX	10.4	9.1	14% **
Other ***	17.4	14.9	17%
Total	65.1	59.5	9%

<sup>\*</sup>Includes favourable foreign exchange movements of 7%

<sup>\*\*</sup>Includes favourable foreign exchange movements of 13%

<sup>\*\*\*</sup>Includes REMINYL/RAZADYNE

#### Key Financial Ratios (% of net product sales)



(on a non-GAAP basis, including FAS123R)	Q1 08	Q1 07	FY 07
COGS	14%	14%	14%
Gross margin	86%	86%	86%
R&D	19%	17%	19%
SG&A	45%	46%	46%
Operating EBITDA (% of product sales) <sup>(1)</sup>	22%	24%	21%
Operating EBITDA (% total revenue) <sup>(2)</sup>	29%	32%	29%

This slide contains non GAAP financial measures. They exclude intangible asset amortization in respect of acquired intellectual property and the effect of certain cash and non-cash items, both recurring and non-recurring, that Shire's management believes are not related to the core performance of Shire's business.

<sup>(1)</sup> Excluding royalties

<sup>(2)</sup> Including royalties

#### **Operating Income/EPS**



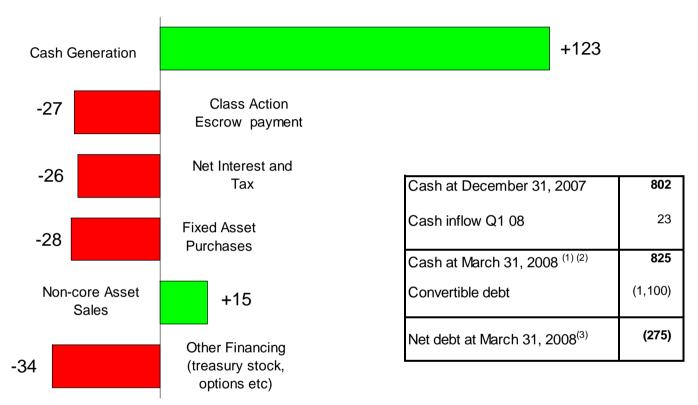
	Q1 08	Q1 07	Growth
Operating income (\$m)	, <u> </u>		
- GAAP	163.0	141.2	15%
- Adjustments	28.8	15.3	
- Non GAAP <sup>(1)</sup>	191.8	156.5	23%
EPS - ADS (diluted)			
- GAAP	68.1c	63.9c	7%
- Non GAAP <sup>(1)</sup>	73.8c	70.2c	5%

<sup>&</sup>lt;sup>(1)</sup> These are non GAAP financial measures. They exclude intangible asset amortization charges and the effect of certain cash and non-cash items, both recurring and non-recurring, that Shire's management believes are not related to the core performance of Shire's business.



#### **Cashflow - Q1 2008**

Millions of USD



Net cash inflow for Q1 2008: +23

- (1) Shire's balance of cash and cash equivalents at 31 March 2008 includes \$35m of restricted cash and is available to finance payments due to TKT dissenting shareholders (provision at 31 March 2008 of \$487m)
- (2) Shire has a revolving credit facility of \$1.2bn which was undrawn at 31 March 2008
- (3) Net debt does not include \$33m of other long term debt in respect of building financing obligations



#### 2008 Q1 Actual v Guidance

Non GAAP (Incl FAS 123R)	Q1 Actual	FY Guidance
Revenue growth	33%	Mid to high teens
VYVANSE sales	\$54m	\$350 - \$400m <sup>(1)</sup>
R&D	\$119m	\$465 - \$490m
SG&A - GAAP (\$m) Less New Top Company costs SG&A - Non GAAP (\$m)	\$293m (\$6m) \$287m	\$1,125 - \$1,165m
Capital expenditure	\$28m	\$320 - \$350m
Depreciation (\$m)	\$14m	~ 50% (~\$88m) <sup>(2)</sup>
Effective Tax rate - Non GAAP	28%	23%

<sup>(1)</sup> We expect 2008 total revenue growth to be in the mid to high teens range. Based on existing prescription trends and the recently received approval for the adult indication, we currently expect VYVANSE sales to be at the lower end of the previously stated range of \$350 to \$400 million.

<sup>(2)</sup> Increase compared to 2007



### Sylvie Grégoire President, Shire HGT

Acquisition of arylsulfatase-A for MLD



#### Shire enhances its HGT LSD clinical portfolio

- Acquisition of an Enzyme Replacement Therapy (ERT) to treat Metachromatic Leukodystrophy (MLD): arylsulfatase–A (ASA) from Zymenex A/S
- MLD is a life-limiting disease caused by a deficiency in the enzyme ASA which causes an excess levels of sulphatide in cells, breakdown of myelin and irreversible neurological damage.
- Phase I trial completed, extension ongoing. IND approved for phase 2 trial to start in 2008 and Orphan Designation granted in US and Europe.
- Approximately 2,000 MLD patients in developed world markets
- MLD prevalence and unmet medical need compares to Hunter Syndrome
- Expected to launch in the US and Europe in the 2011-2012 timeframe



# Matthew Emmens CEO

Concluding remarks



#### **Executing our Strategy**

- Excellent Q1 results
  - Young product portfolio represents 34% of Q1 product sales
- Rich pipeline with a focus on orphan drugs and specialist products treating symptomatic disorders
- ASA acquisition potentially brings an MLD treatment to patients two years earlier than anticipated
- VYVANSE adult indication represents opportunity for further growth
- Shire/TAP will have the highest share of voice in the UC marketplace
- Reaffirming full year 2008 guidance and positive revenue growth through 2010



### **Questions and Answers**

All



### **APPENDIX**





	Q1 08 \$m	Q1 08 cents/ADS	Q1 07 \$m	Q1 07 cents/ADS
Net income	128.6		112.7	
Interest on convertible debt, net of tax	3.4		-	
Numerator for diluted EPS (ADS)	132.0	68.1c	112.7	63.9c
Gain on sale of product rights	(7.6)	(3.9c)	-	-
Gain on disposal of minority equity investment	(9.4)	(4.8c)	-	-
New top company costs	5.6	2.8c	-	-
Intangible asset amortization	30.8	15.9c	15.3	8.6c
Taxes on above adjustments	(8.4)	(4.3c)	(4.1)	(2.3c)
Non GAAP numerator for diluted EPS (ADS) *	143.0	73.8c	123.9	70.2c

<sup>\*</sup> Includes FAS123R