

# Full Year 2008 Results

Shire plc

February 19, 2009

**Angus Russell**  
Chief Executive Officer

**Michael Cola**  
President, Specialty  
Pharmaceuticals

**Graham Hetherington**  
Chief Financial Officer

**Sylvie Grégoire**  
President, Shire HGT

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, 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 Angus Russell
- Financial review Graham Hetherington
- Specialty Pharma update Michael Cola
- HGT update Sylvie Grégoire
- Concluding remarks Angus Russell
- Q & A All

# Opening remarks

Angus Russell  
CEO

## Excellent performance in all areas of the business

- Product sales up 27% to \$2.75 billion
  - Product sales excluding ADDERALL XR up 45% to \$1.65 billion
- New product sales\* \$1 billion
  - 36% of product sales in 2008 (2007: 22%)
- Total revenues up 24% to \$3 billion
- Non GAAP earnings per ADS up 36% to \$3.86 (2007: \$2.84)
- 2008 FY Dividend increased
  - \$: +15%
  - £: +55%

## Executing our strategy

- Specialist focus; symptomatic diseases; high unmet needs; niche markets
- Focus on best opportunities and exit underperforming or low priority assets and businesses
- Building business through addition of bolt on products, “corner lots” and international expansion

## 2009 Key Events

H1-09

- MLD Phase 2/3 initiation
- SPD550 Phase 2 data
- idursulfase-IT Phase 1 initiation

H2-09

- INTUNIV launch
- DAYTRANA adolescent sNDA filing
- velaglucerase alfa submission US/EU
- FIRAZYR Phase 3 initiation in US
- AMIGAL Phase 3 initiation
- PLICERA Phase 2 data
- Pompe Phase 2 data

# Financial Review

Graham Hetherington  
CFO





## 2008 Performance Summary

	FY 2008 \$m	FY 2007 \$m	Reported Growth
<b>Total Revenues</b>	3,022	2,436	+24%
<b>Product Sales</b>	2,754	2,170	+27%
<b>EBITDA <sup>(1)</sup></b>	1,035	723	+43%
<b>EPS - ADS (diluted) <sup>(1)</sup></b>	\$3.86	\$2.84	+36%
<b>Cash generation <sup>(1)</sup></b>	1,231	645	+91%

## Total Revenues

	FY 2008 \$m	FY 2007 \$m	Reported Growth
<b>New Products</b> <sup>(1)</sup>	999	475	+110%
<b>Established Products</b>	653	664	-2%
	<b>1,652</b>	<b>1,139</b>	<b>+45%</b>
<b>ADDERALL XR</b>	1,102	1,031	+7%
<b>Total Product Sales</b>	<b>2,754</b>	<b>2,170</b>	<b>+27%</b>
<b>Royalties</b>	246	247	
<b>Other Revenues</b>	22	19	
<b>Total Revenues</b>	<b>3,022</b>	<b>2,436</b>	<b>+24%</b>

## 2008 Quarter 4 Performance Summary

	Q4 2008 \$m	Q4 2007 \$m	Reported Growth	Like for Like Growth <sup>(2)</sup>
<b>Total Revenues</b>	766	725	+6%	+12%
<b>Product Sales</b>	704	661	+7%	+13%
<b>EBITDA <sup>(1)</sup></b>	266	230	+16%	
<b>EPS - ADS (diluted) <sup>(1)</sup></b>	\$1.01	\$0.93	+9%	
<b>Cash generation <sup>(1)</sup></b>	443	166	+167%	

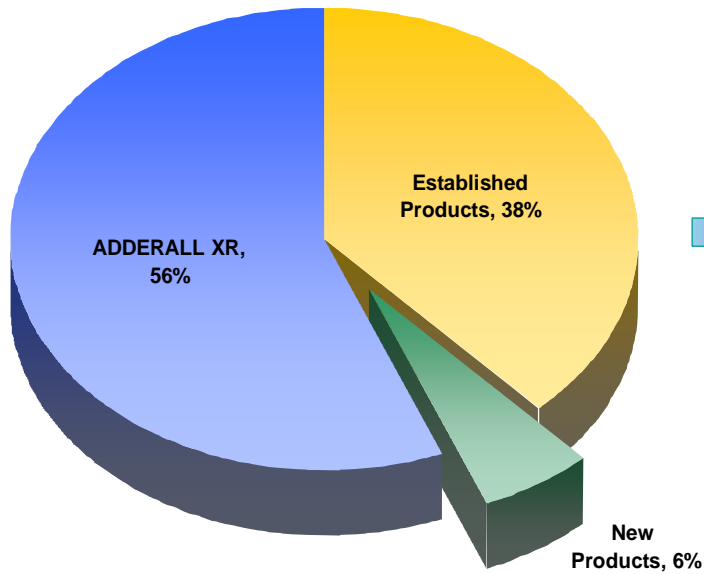
(1) These are non GAAP financial measures. See the appendix for a list of items excluded from the GAAP equivalent to calculate these measures.

(2) "Like for Like Growth" takes into account movements in average exchange rates and \$15 million of Q4 2007 revenues from products sold in 2007.

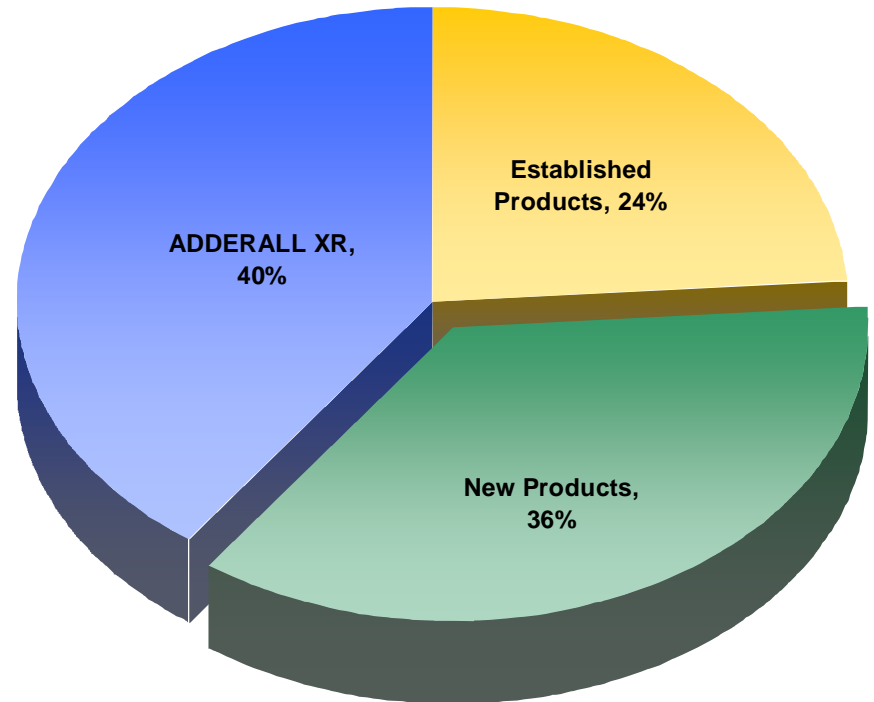
# Platform for future growth

– Product Mix (% of Total Product Sales)

2006  
\$1,536m

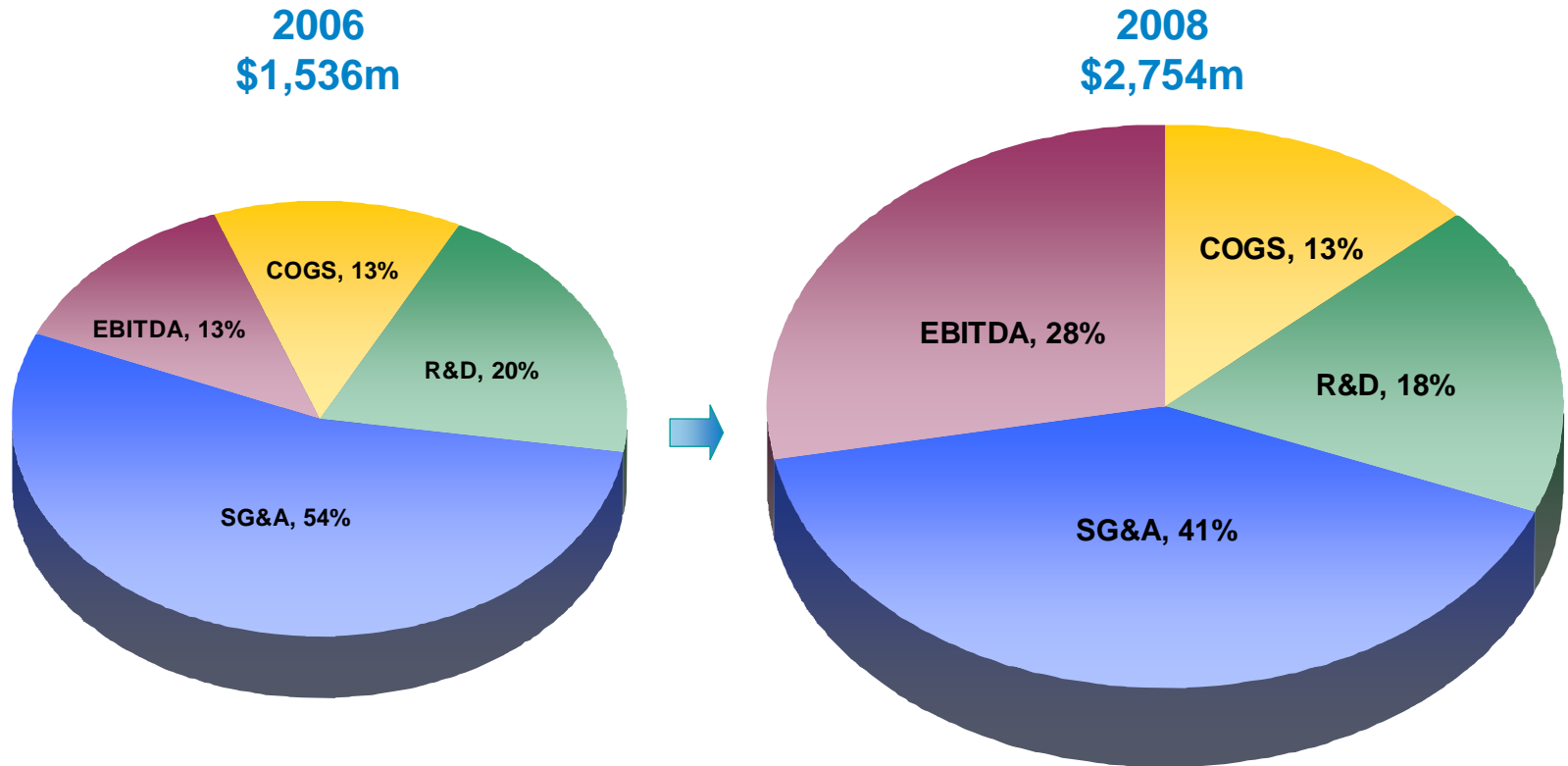


2008  
\$2,754m



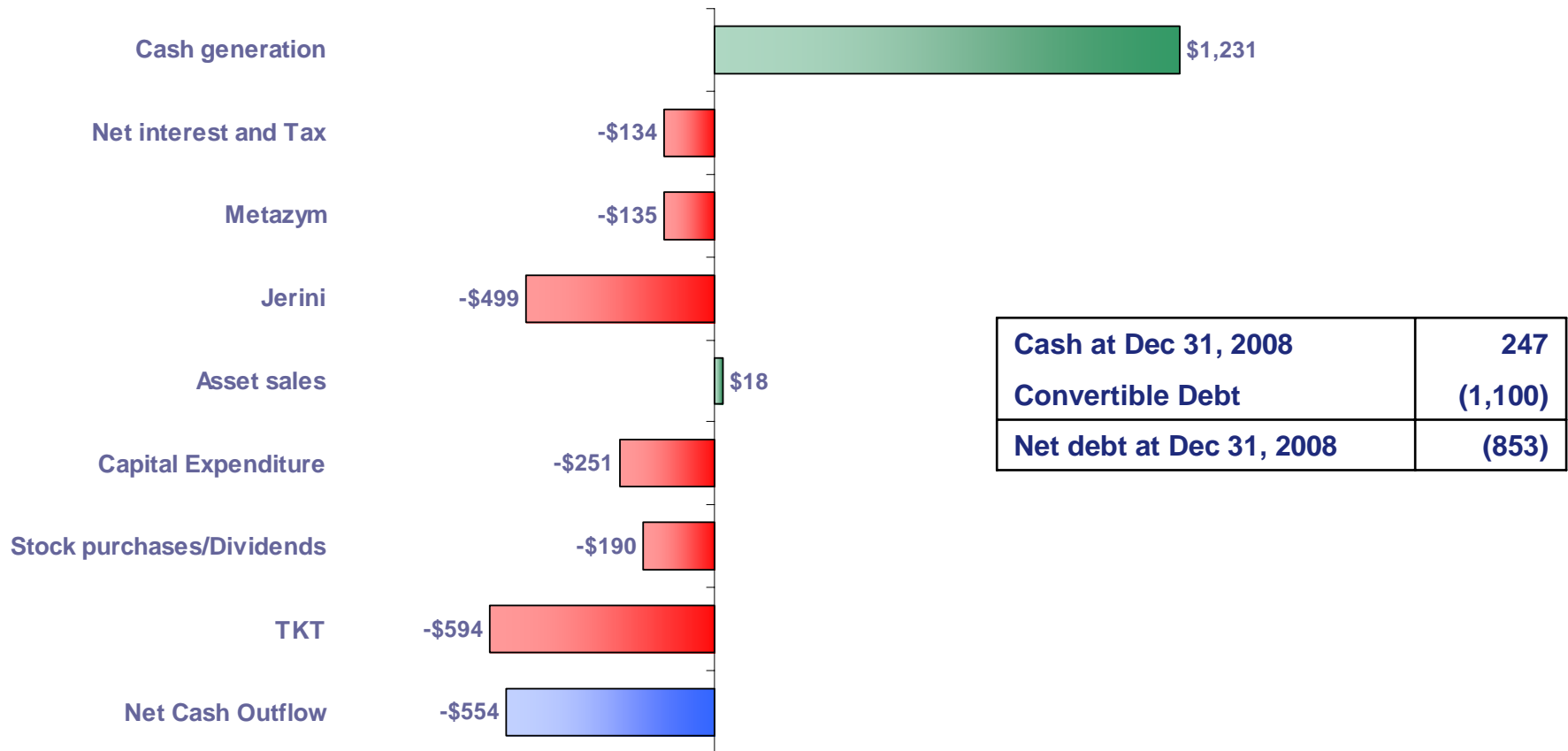
# Platform for future growth

– Operational Leverage (% of Total Product Sales)



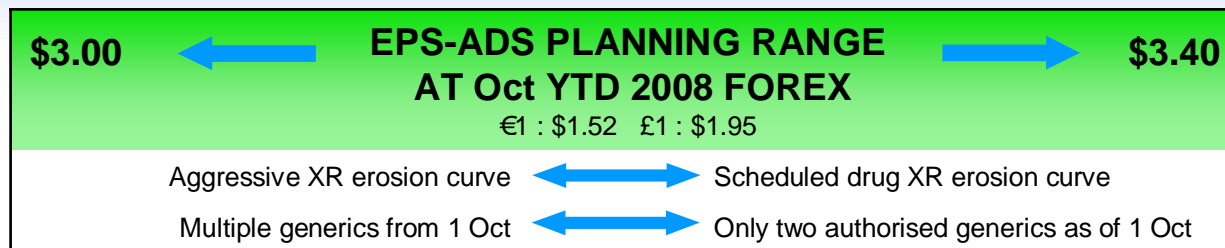
# Cashflow – Full Year 2008

Millions of USD



Cash at Dec 31, 2008	247
Convertible Debt	(1,100)
Net debt at Dec 31, 2008	(853)

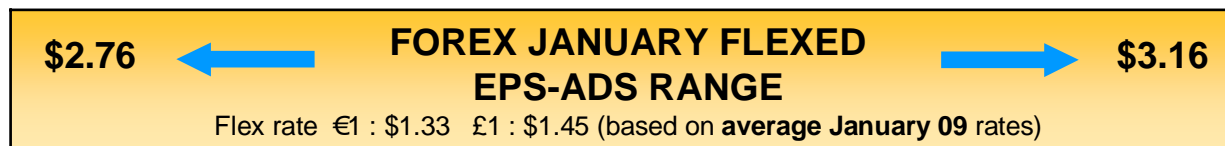
# 2009 UNCHANGED GUIDANCE FRAMEWORK



**Continued growth in new products**

**Aggressive cost base management**

**Continued investment in future growth drivers**



**EPS Sensitivity to FX rate movements**

	2009 EPS <sup>(1)</sup> Sensitivity per 10c fall	Original Guidance Rates	January Average Rates	Fall in rates	2009 EPS <sup>(1)</sup> Impact
€/\$	-10c	1.52	1.33	-19c	-19c
£/\$	-1c	1.95	1.45	-50c	-5c
					-24c

## Financial Review Summary

- Strong 2008 performance
- Platform for future growth
- Robust balance sheet and cashflows
- Reiterating 2009 guidance framework



# Specialty Pharma update

Michael Cola  
President, Specialty Pharmaceuticals



# Shire Specialty Pharma Business Model Supports Strong Growth



- Focus on diseases treated by specialist physicians
- Deep customer focus via therapeutically-aligned Business Units
- Global development / commercialization

- 4 core marketed products
- 8 potential launches by 2015 including new indications and new products

- #1 or #2 in our markets
- Growth via acquisitions and product licenses
- EU and RoW geographic expansion opportunities

## Specialty Pharma

- Continued execution of key marketed products and successfully launching new products will build a platform for growth
  - VYVANSE - US market share continues to grow and has now surpassed 11%\*
  - LIALDA - growth in the US continues with 15% monthly NRx share\*
    - GI franchise 31% share of US oral mesalamine market
    - LIALDA/MEZAVANT available in 6 countries
  - FOSRENOL - available in 31 countries
  - INTUNIV - NDA resubmission completed and now planning for launch in H2 2009

# Specialty Pharma

- New indications and geographic expansion will maximize the return on our currently marketed products
  - VYVANSE
    - clinical program to support EU regulatory submission initiated Q4 2008
    - planned submissions in Brazil and Mexico in H2 2009
  - DAYTRANA
    - MAA review ongoing and planning for EU launch in H2 2009
    - efforts progressing to support sNDA submission for use in adolescents in the US in H2 2009
  - LIALDA
    - Japan development and commercialization through agreement with Mochida
    - Phase 3 clinical trials for diverticulitis ongoing
  - FOSRENOL
    - Discussions ongoing with FDA to determine Regulatory pathway for CKD indication
    - Japan launch via partner Bayer in H1 2009

## Specialty Pharma

- Acquisition and development of new products will drive continued growth of the business
  - Earlier stage assets continue to progress through development

# HGT update

Sylvie Grégoire  
President, Shire HGT



# Shire HGT Business Model Supports Strong Growth



- Rare diseases with unmet need
- High impact Rx / high margin products
- Global development / commercialization

- 3 Marketed products
- Pipeline gaps filled
- 8 potential launches by 2015

- #1 or #2 in our markets
- Growth via internal Research and Business Development
- Strong RoW growth with minimal infrastructure

## HGT product highlights

- **ELAPRASE**

- 68% revenue growth driven by Latin America and Japan
- Approved in 43 countries
- Additional manufacturing capacity expected to come on line during 2009, for submission to regulatory authorities in Q4 2009

- **REPLAGAL**

- 22% revenue growth
- Approved in 44 countries
- Fabry market continues to grow

- **FIRAZYR**

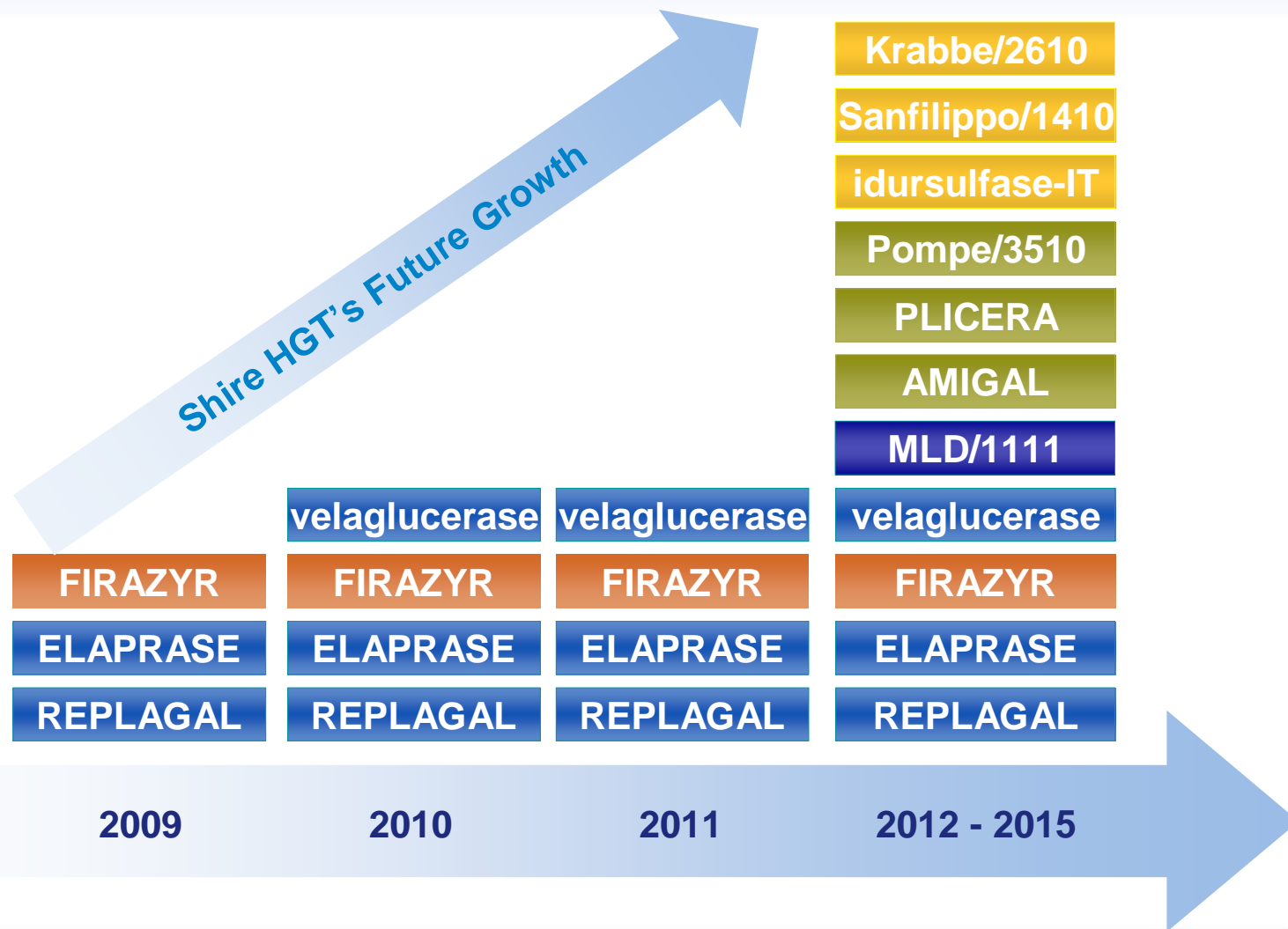
- Already launched in Germany, Austria and the UK
- Phase 3 trial to be initiated in the US in 2009



## HGT pipeline highlights

- velaglucerase alfa
  - Enrollment of Phase 3 trials complete
  - Simultaneous US/EU regulatory filings anticipated H2 2009
- HGT 1111(METAZYM) for MLD
  - Phase 2/3 targeted for H1 2009
- Chaperone therapies
  - AMIGAL for Fabry - awaiting final feedback from FDA and EMEA
  - PLICERA for Gaucher - Phase 2 results mid-2009
  - HGT 3510 for Pompe - Phase 2 trial outcome end of 2009
- idursulfase-IT for Hunter CNS
  - Phase 1 trial Q1 2009

# HGT revenue growth reflects launch of 8 new products\*



# Concluding remarks

Angus Russell  
CEO

## Solid Platform for Future Growth

- New product portfolio delivering excellent growth
  - Achieved sales of \$1 billion
  - 36% of product sales
- Continued momentum in our business
  - Drive growth in existing products
  - Launch new products
  - Develop and enhance our strong pipeline
- Aspiration to grow sales in the mid teens range on average between 2009 and 2015

# Questions and Answers

All

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



# APPENDIX

## Platform for future growth – Key product sales drivers

	FY 2008 \$m	Reported Growth <sup>(1)</sup>	Like for Like Growth <sup>(2)</sup>
VYVANSE	319	317%	
ELAPRASE	305	68%	64%
FOSRENOL	155	52%	50%
LIALDA/MEZAVANT	140	178%	
DAYTRANA	79	23%	
FIRAZYR	1	n/a	
<b>New Products</b>	<b>999</b>		
PENTASA	186	5%	
REPLAGAL	176	22%	19%
OTHERS	291	-15%	5%
<b>New and Established Products <sup>(3)</sup></b>	<b>1,652</b>		

(1) Versus full year 2007

(2) "Like for Like Growth" takes into account movements in average exchange rates and \$65 million of 2007 revenues from products sold in 2007. If blank then CER equals reported growth

(3) Excluding Adderall XR

## Royalties

	FY 2008 \$m	Reported Growth <sup>(1)</sup>	Q4 2008 \$m	Reported Growth <sup>(1)</sup>
<b>3TC</b>	140	-4%	31	-8%
<b>ZEFFIX</b>	40	-2%	10	-9%
<b>Other</b>	65	+7%	14	-20%
<b>Total</b>	<b>246</b>	<b>-1%</b>	<b>55</b>	<b>-11%</b>

Royalties in Q4 represent 7% of total revenues (Q4 07: 9%)



# Financial Ratios

## – Operational leverage

### FINANCIAL RATIOS (% of product sales)

Gross margin

R&D

SG&A

Operating EBITDA (% of product sales)<sup>(1)</sup>

Operating EBITDA (% total revenue)<sup>(2)</sup>

### YEAR ON YEAR GROWTH <sup>(3)</sup>

Product sales

R&D

SG&A

	2008		2007	
	FY	Q4	FY	Q4
Gross margin	87%	87%	86%	85%
R&D	18%	18%	19%	19%
SG&A	41%	40%	46%	42%
Operating EBITDA (% of product sales) <sup>(1)</sup>	28%	29%	21%	25%
Operating EBITDA (% total revenue) <sup>(2)</sup>	34%	35%	30%	32%
Product sales	27%	7%	41%	55%
R&D	25%	5%	35%	52%
SG&A	13%	3%	20%	14%

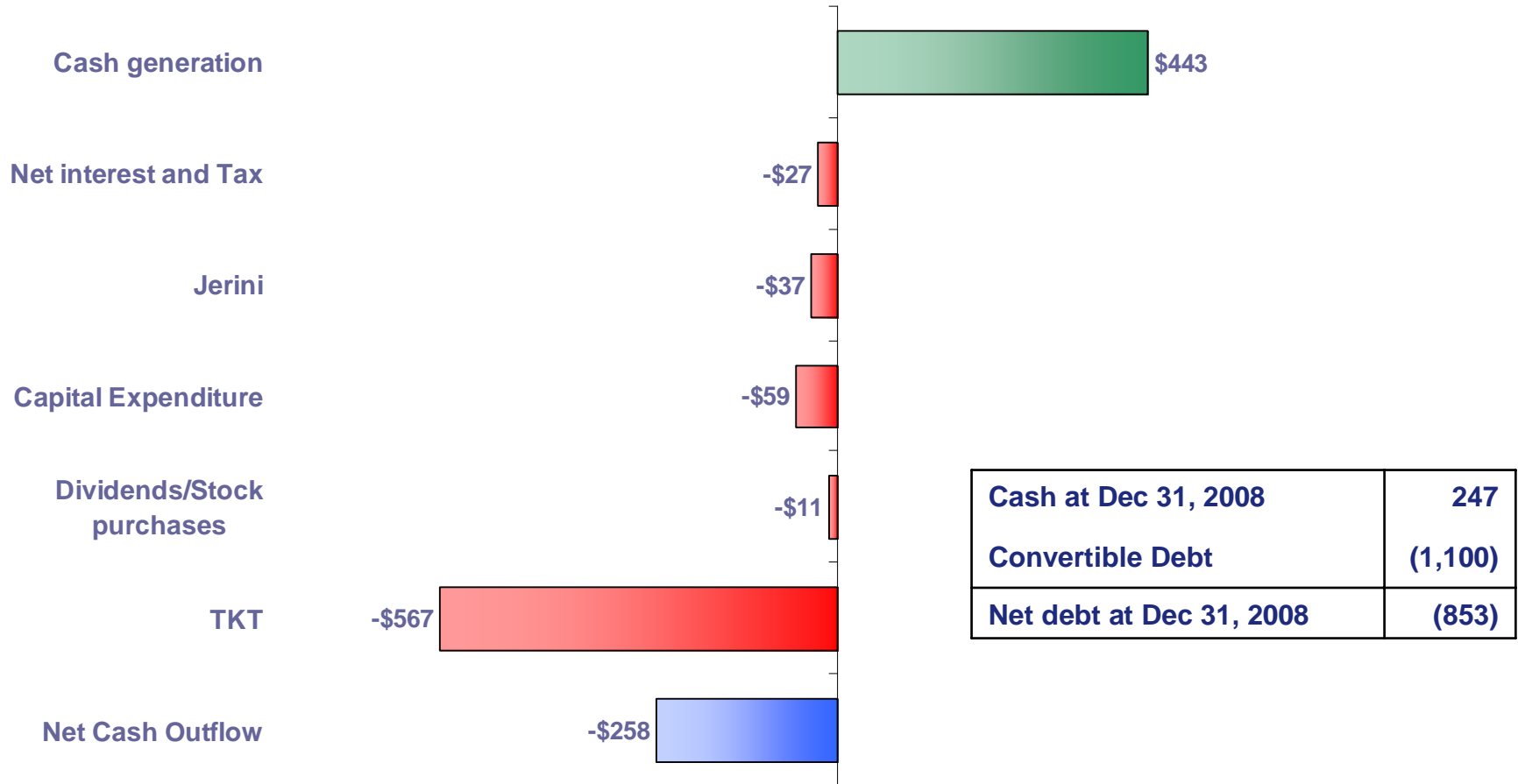
(1) Excluding royalties and other revenues

(2) Including royalties and other revenues

(3) In absolute terms

# Cashflow – Q4 2008

Millions of USD



## 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:
  - Intangible asset amortization and impairment charges;
  - Gains and losses on the sale of non-core assets;
  - Upfront payments and milestones in respect of in-licensed and acquired products (including the 2008 payment to Zymenex A/S for METAZYM™ of \$135 million);
  - Termination costs (including the 2008 intangible asset impairment charges, write downs and exit costs of \$150m associated with DYNEPO®);
  - Costs associated with the introduction of the new holding company;
  - Costs associated with the acquisition and integration of companies, and acquired in-process research and development charges (including the costs associated with the acquisition of a 98% voting interest in Jerini in 2008);
  - Other than temporary impairment of investments (including \$58 million impaired in 2008);
  - Incremental interest charges in 2008 of \$73 million arising on the settlement of litigation with the former dissenting shareholders of TKT; and
  - Taxes associated with these items.

# Full Year EPS Reconciliation

	2008 \$m	2008 cents/ADS	2007 \$m	2007 cents/ADS
<b>GAAP Net income / Diluted EPS (ADS)</b>	<b>156.0</b>	<b>85.8c</b>	<b>(1,451.8)</b>	<b>(806.1c)</b>
IPR&D charge (Jerini/Metazym/New River) <sup>(1)</sup>	263.1	139.2c	1,866.4	1,028.1c
Gain on sale of product rights	(20.7)	(10.8c)	(127.8)	(66.9c)
In-licensing and milestone payments	-	-	155.9	82.2c
New Top Co costs	14.8	7.8c	-	-
Exit costs associated with Dynepo	149.9	77.7c	-	-
Integration and transaction costs	10.3	5.4c	1.3	0.7c
Legal settlement	-	-	17.0	9.0c
Intangible asset amortization	126.2	65.4c	95.0	50.1c
Intangible asset impairment (excluding Dynepo)	2.5	1.5c	-	-
FAS 123R catch up charge	-	-	29.2	15.4c
<b>Operating Income - Non GAAP adjustments</b>	<b>546.1</b>		<b>2,037.0</b>	
Gain on disposal of minority equity investment	(9.4)	(4.8c)	-	-
Write down of investments	58.0	30.0c	-	-
Deferred finance costs write off	-	-	7.9	4.1c
Interest on TKT appraisal rights settlement	73.0	37.8c	-	-
Discontinued operations	17.6	9.0c	-	-
Taxes on above adjustments	(112.4)	(58.2c)	(61.8)	(32.5c)
<b>Non GAAP net income / Diluted EPS (ADS)</b>	<b>728.9</b>	<b>385.8c</b>	<b>531.3</b>	<b>284.1c</b>

## Q4 EPS Reconciliation

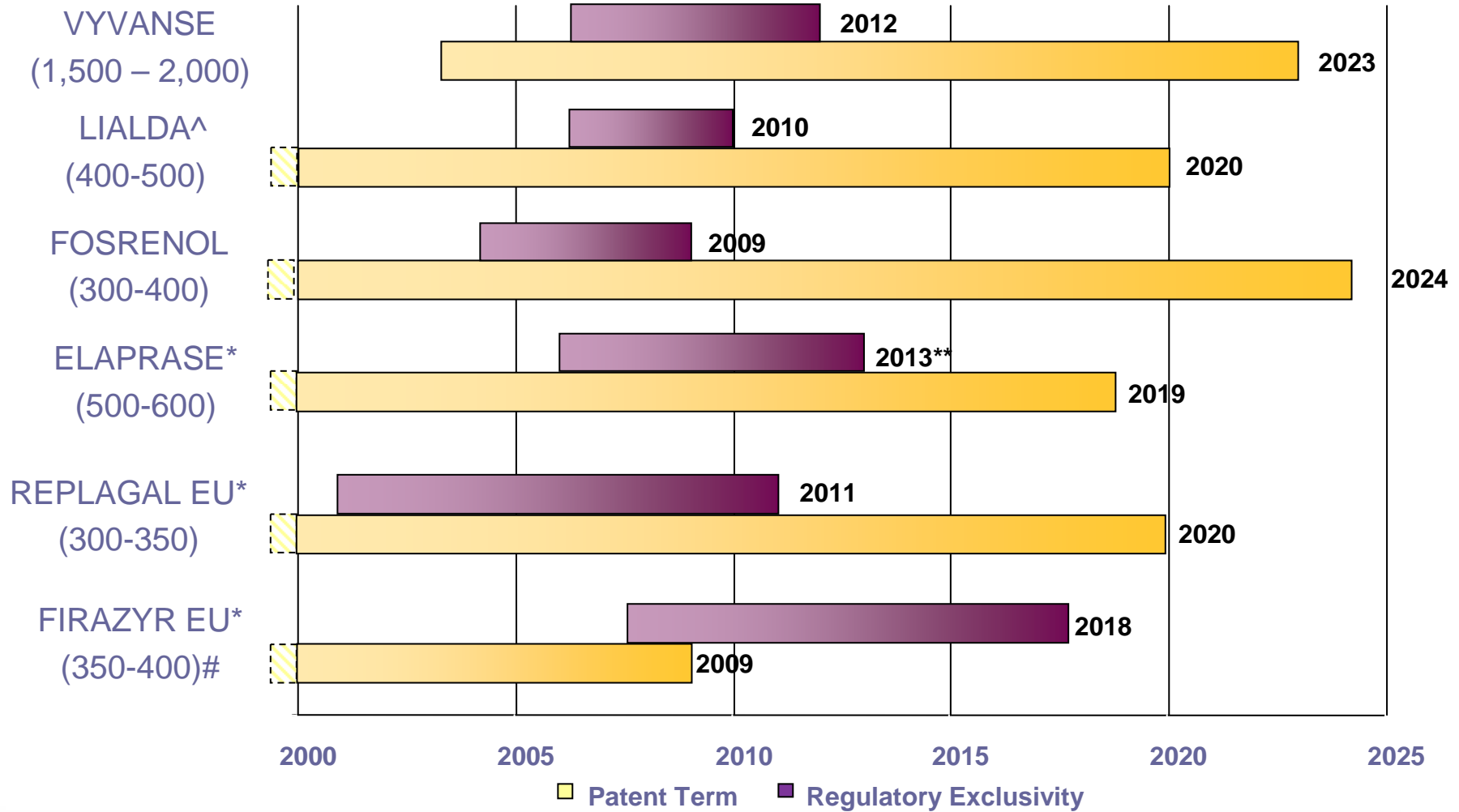
	2008 \$m	2008 cents/ADS	2007 \$m	2007 cents/ADS
<b>GAAP Net income / Diluted EPS (ADS)</b>	<b>141.3</b>	<b>78.0c</b>	<b>212.1</b>	<b>110.7c</b>
IPR&D charge (Jerini/New River)	7.6	4.0c	(29.6)	(15.3c)
Gain on sale of product rights	-	-	(115.7)	(59.4c)
In-licensing and milestone payments	-	-	75.0	38.7c
New Top Co costs	1.0	0.5c	-	-
Release of provision for exit costs associated with Dynepo	(4.7)	(2.4c)	-	-
Integration and transaction costs	2.8	1.5c	-	-
Legal settlement	-	-	(10.0)	(5.1c)
Intangible asset amortization	34.7	18.1c	31.0	15.9c
Intangible asset impairment	6.3	3.3c	-	-
FAS 123R catch up charge	-	-	29.2	15.0c
<b>Operating Income - Non GAAP adjustments</b>	<b>47.7</b>		<b>(20.1)</b>	
Write down of investments	3.8	2.0c	-	-
Discontinued operations	16.7	8.7c	-	-
Taxes on above adjustments	(24.4)	(12.6c)	(15.2)	(7.8c)
<b>Non GAAP net income / Diluted EPS (ADS)</b>	<b>185.1</b>	<b>101.1c</b>	<b>176.8</b>	<b>92.7c</b>

## Cash Generation Reconciliation

	Full Year		Q4	
	2008 \$m	2007 \$m	2008 \$m	2007 \$m
<b>Net cash provided by operating activities</b>	<b>800</b>	<b>475</b>	<b>275</b>	<b>67</b>
Payments for in-licenced products	-	156	-	81
Acquisition of METAZYM from Zymenex	135	-	-	-
Class Action escrow payment	27	-	-	-
Interest on TKT appraisal rights settlement	147	-	147	-
Tax and interest payments (net)	134	7	27	18
Foreign exchange on cash	(12)	7	(6)	-
<b>Cash Generation</b>	<b>1,231</b>	<b>645</b>	<b>443</b>	<b>166</b>

# Duration of Patent and Regulatory Exclusivity

(Peak sales range \$m)



## Potential launches from 2009-2015\*



2009	2010	2011	2012-2015
<ul style="list-style-type: none"><li>• FOSRENOL - CKD</li><li>• DAYTRANA EU</li><li>• INTUNIV**</li></ul>	<ul style="list-style-type: none"><li>• DAYTRANA ADOLESCENT</li><li>• VELAGLUCERASE ALFA</li></ul>	<ul style="list-style-type: none"><li>• VYVANSE EU</li><li>• FIRAZYR US</li></ul>	<ul style="list-style-type: none"><li>• HGT 1111 (MLD)</li><li>• PLICERA</li><li>• AMIGAL</li><li>• HGT 3510 (Pompe)</li><li>• IDURSULFASE-IT</li><li>• SANFILIPPO ERT</li><li>• HGT 2610 (Krabbe)</li><li>• JUVISTA</li><li>• LIALDA DIVERTICULITIS</li><li>• SPD550 (Celiac)</li><li>• WOMEN'S HEALTH PORTFOLIO</li></ul>