



# Building for growth

## First quarter results to March 31, 2013

Flemming Ornskov, MD  
Chief Executive Officer

Graham Hetherington  
Chief Financial Officer



**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, that:

- Shire’s products may not be a commercial success;
- revenues from ADDERALL XR® are subject to generic erosion;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payors in a timely manner for Shire’s products may impact future revenues and earnings;
- Shire relies on a single source for manufacture of certain of its products and a disruption to the supply chain for those products may result in Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis;
- Shire uses third party manufacturers to manufacture many of its products and is reliant upon third party contractors for certain goods and services, and any inability of these third party manufacturers to manufacture products, or any failure of these third party contractors to provide these goods and services, in each case in accordance with its respective contractual obligations, could adversely affect Shire’s ability to manage its manufacturing processes or to operate its business;
- the development, approval and manufacturing of Shire’s products is subject to extensive oversight by various regulatory agencies and regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- the actions of certain customers could affect Shire’s ability to sell or market products profitably and fluctuations in buying or distribution patterns by such customers could adversely impact Shire’s revenues, financial conditions or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to Shire’s activities in the highly regulated markets in which it operates may result in the distraction of senior management, significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters and other disputes, including Shire’s ability to obtain, maintain, enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on Shire’s revenues, financial condition or results of operations;

and other risks and uncertainties detailed from time to time in Shire’s filings with the U.S. Securities and Exchange Commission, including those risks outlined in “Item 1A: Risk Factors” in Shire’s Form 10-K for the years ended December 31, 2011 and 2012.

# Agenda

**Opening remarks**



**Flemming  
Ornskov, MD**

**Financial review and 2013 outlook**



**Graham  
Hetherington**

**Building for growth**



**Flemming  
Ornskov, MD**

**Q & A**

**All**

# Opening remarks

**Flemming Ornskov, MD**  
**Chief Executive Officer**



**Our purpose**

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

## A Clear Strategy

**To focus on developing and marketing innovative specialty medicines to meet significant unmet patient needs**



To be as brave as the people we help.

## Two strategic priorities

Drive **optimum performance** from our currently marketed products

Build our **future assets** through both R&D and Business Development

# Executing our strategy

**Simplify the business structure**

**Optimize the commercial execution of our portfolio**

**Drive innovation**

**Focus on the operating leverage of the business**

# Financial review and 2013 outlook

**Graham Hetherington**  
**Chief Financial Officer**



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# Double digit earnings growth while investing in our late stage pipeline

	Q1 2013 \$m	Q1 2012 \$m	Reported Growth
<b>Product sales</b>	<b>1,117</b>	<b>1,107</b>	<b>+1%</b>
<b>Royalties and other revenues</b>	<b>45</b>	<b>65</b>	<b>-30%</b>
<b>Total revenues</b>	<b>1,162</b>	<b>1,172</b>	<b>-1%</b>
<b>EBITDA<sup>(1)</sup></b>	<b>422</b>	<b>389</b>	<b>+9%</b>
<b>EBITDA % of product sales<sup>(1)(2)</sup></b>	<b>34%</b>	<b>29%</b>	<b>450bp</b>
<b>EPS - ADS<sup>(1)</sup></b>	<b>\$1.63</b>	<b>\$1.48</b>	<b>+10%</b>
<b>Cash generation<sup>(1)</sup></b>	<b>257</b>	<b>310</b>	<b>-17%</b>
<b>Note: US GAAP operating income</b>	<b>129</b>	<b>295</b>	<b>-56%</b>

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

(2) Excluding royalties and other revenues.



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## Five products delivering double digit growth

	Q1 2013	Q1 2012	Reported Growth	
	\$m	\$m	\$m	%
VYVANSE	298	260	38	+15%
ELAPRASE	114	126	(12)	-9%
REPLAGAL	114	134	(20)	-15%
LIALDA / MEZAVANT	101	90	11	+12%
VPRIV	82	72	10	+14%
INTUNIV	78	69	9	+13%
PENTASA	71	66	5	+8%
FIRAZYR	42	20	22	+112%
DERMAGRAFT	19	49	(30)	-62%
OTHER	98	110	(12)	-11%
<b>Product sales excluding ADDERALL XR</b>	<b>1,017</b>	<b>996</b>	<b>21</b>	<b>+2%</b>
ADDERALL XR	100	111	(11)	-10%
<b>PRODUCT SALES</b>	<b>1,117</b>	<b>1,107</b>	<b>10</b>	<b>+1%</b>



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# Continuing delivery of operating leverage

Year on Year:	Q1 2013	Q1 2012
<b>Product sales</b>	+1%	+24%
<b>R&amp;D<sup>(1)</sup></b>	+15%	+10%
<b>SG&amp;A<sup>(1)</sup></b>	-16%	+25%
<b>Combined R&amp;D and SG&amp;A<sup>(1)</sup></b>	-6%	+20%

## Ratios:

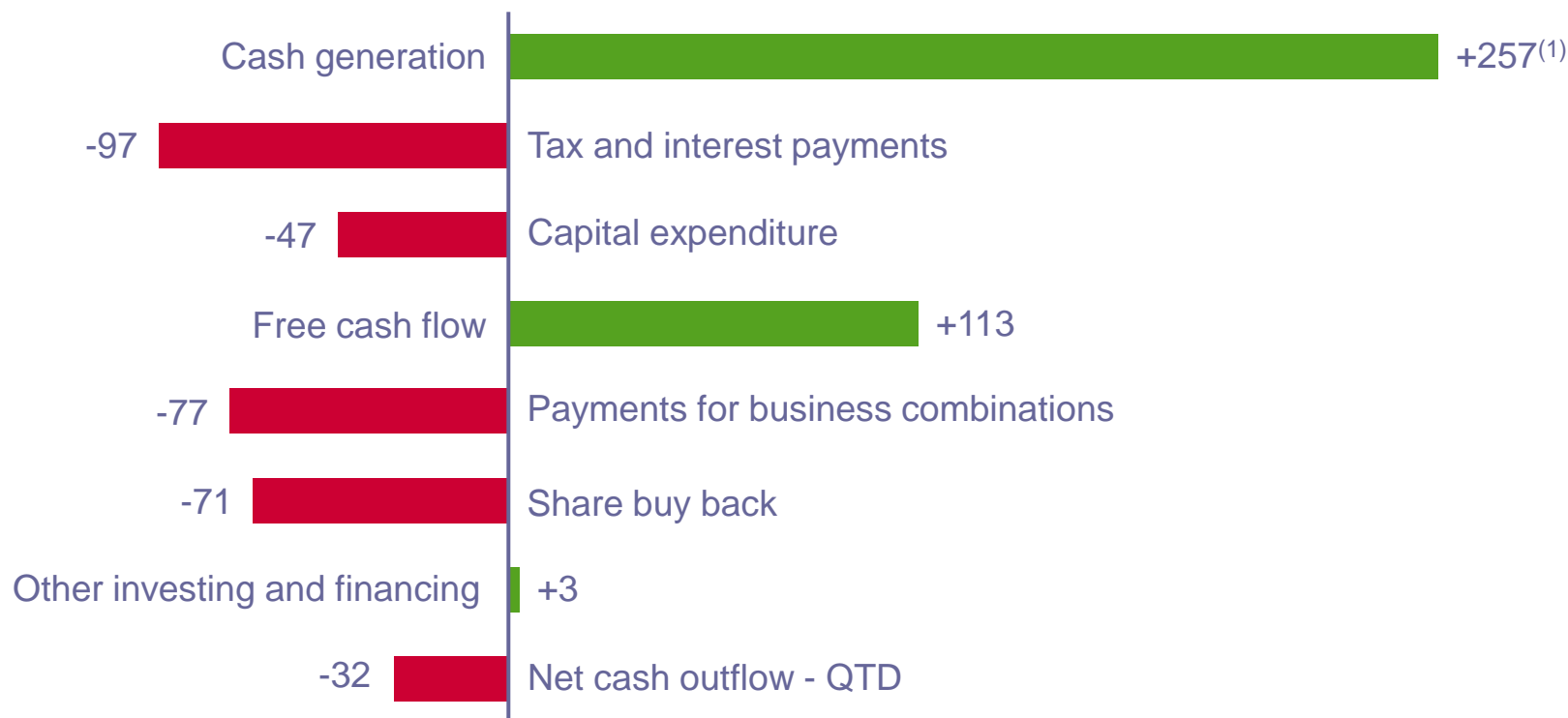
% of product sales		
<b>Gross margin<sup>(1)</sup></b>	86.7%	◀ ..... 86.3%
<b>R&amp;D<sup>(1)</sup></b>	20%	▶ ..... 17%
<b>SG&amp;A<sup>(1)</sup></b>	33%	◀ ..... 40%
<b>EBITDA<sup>(1) (2)</sup></b>	34%	◀ ..... 29%

(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.

# Solid cash generation in Q1 2013

Millions of USD



Note: Shire has a revolving 5 year credit facility of \$1.2bn signed in November 2010 which remained undrawn as at March 31, 2013.

(1) Cash generation excluding payment of Impax settlement (\$48m) was \$305m.



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# Confidence in delivering earnings growth in line with current consensus expectations

## Full year 2013 dynamics

Direction  
versus FY 2012

<b>Product sales</b>	↑	Growth in the mid-to-high single digits
<b>Royalties and Other revenues</b>	↓	Combined royalties & other revenues down 30-40%
<b>Gross margins</b>	≈	At a similar level to 2012
<b>R&amp;D</b>	↑	Low-to-mid teens growth
<b>SG&amp;A</b>	↓	Marginally lower than 2012
<b>Combined R&amp;D and SG&amp;A</b>	↑	Low single digits growth
<b>Tax rate</b>	≈	Core effective tax rate of 18-20%
<b>Reported EPS-ADS</b>	↑	In line with current consensus earnings expectations <sup>(1)</sup>

(1) Based on the most recent consensus estimates compiled by Consensus Forecast Ltd, as of the date of this presentation, of \$6.67 Non GAAP diluted earnings per ADS for the year ended December 31, 2013, available on Shire's website (<http://www.shire.com/shireplc/en/investors/forecasts>).



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# Building for growth

**Flemming Ornskov, MD**  
**Chief Executive Officer**



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# To focus on developing and marketing innovative specialty medicines to meet significant unmet patient needs



Focus

Marketing

Innovative

## Two strategic priorities

Drive **optimum performance** from our currently marketed products

Build our **future assets** through both R&D and Business Development



# Simplifying our business structure

## In-line products

Drive optimum performance from our currently marketed products

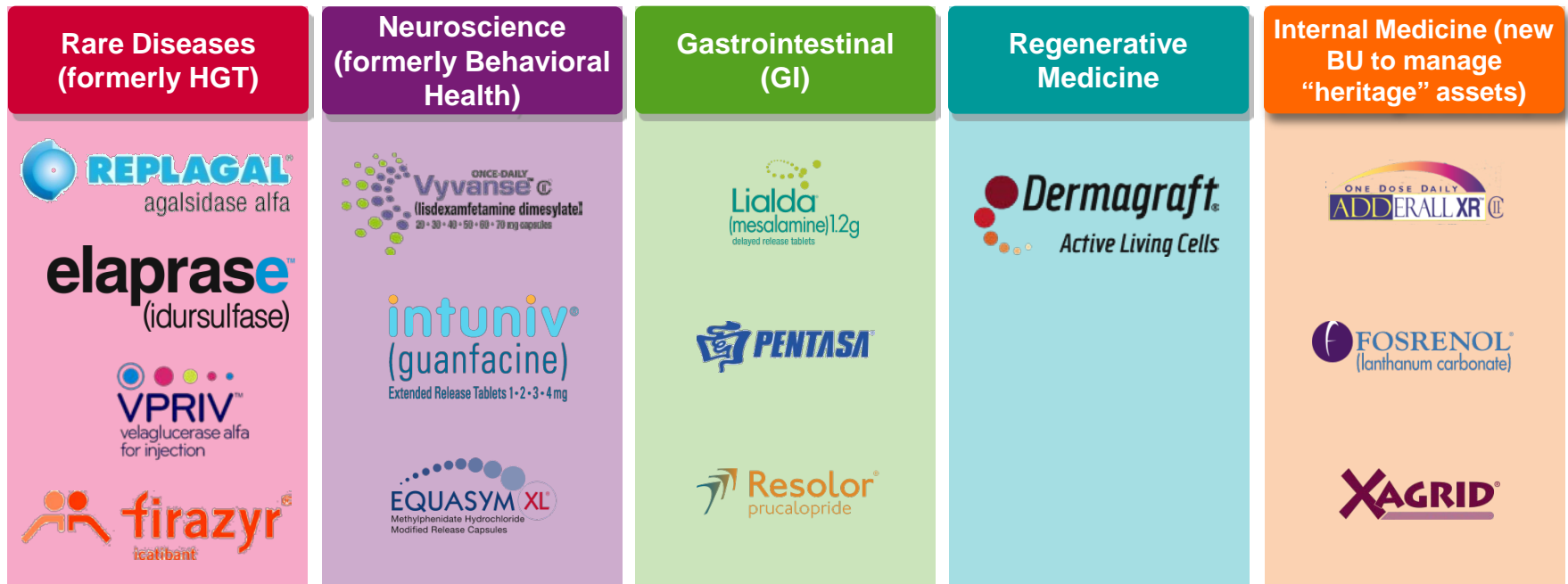


## Pipeline

Build our future assets through both R&D and Business Development

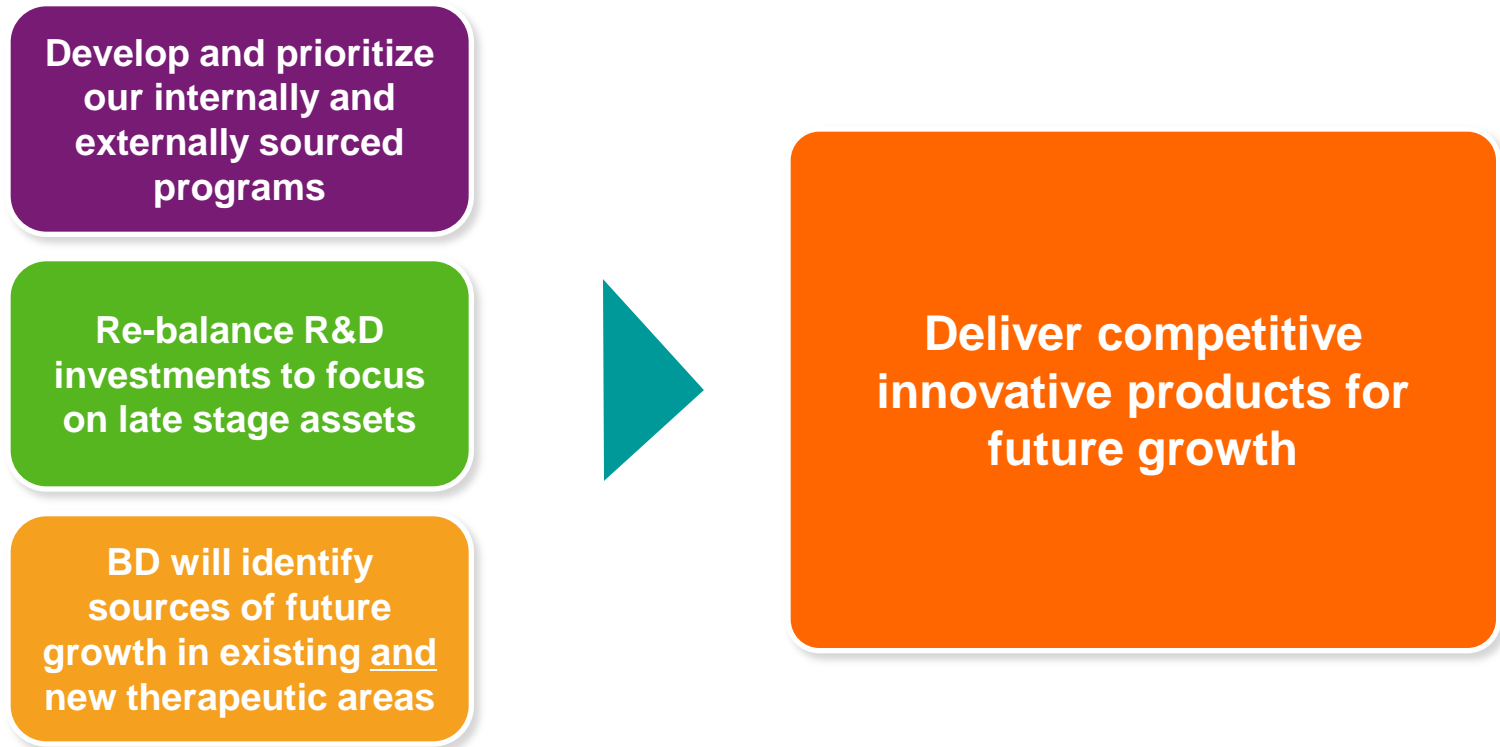


# In-line – commercial execution and optimization



- Commercially focused business units (BU) accountable for product sales and marketing strategy
- Scalability and flexibility to grow
- Ability to add new business units
- Optimize revenue and cash generation

## Pipeline – *delivering innovation and value for the future*



## In-line priorities – *drive optimum performance*



Focus on sales and marketing growth for rare disease treatments



Market expansion initiatives in ADHD



Flawless launch of Elvanse in Europe

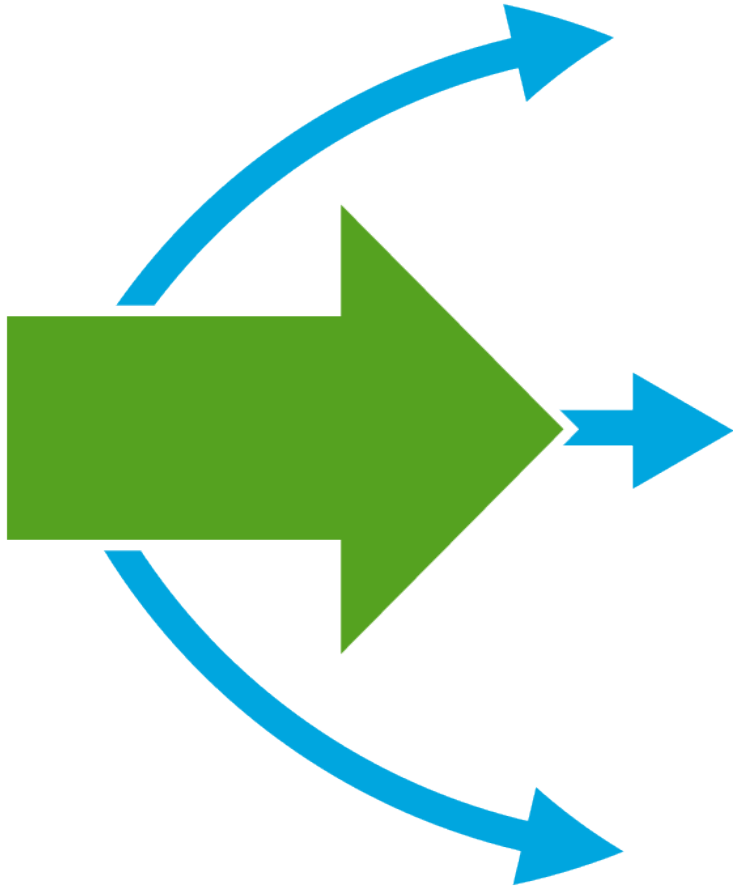


GI and Internal Medicine: optimize sales and profitability performance



Return Dermagraft to significant growth

## Pipeline priorities – *build our future assets*



- Bring additional rigor to the prioritization of our pipeline investments
- Execute smart Business Development deals to increase the proportion of late stage assets in our portfolio
- Identify new specialist therapy areas, which leverage our strengths and where we can compete and win

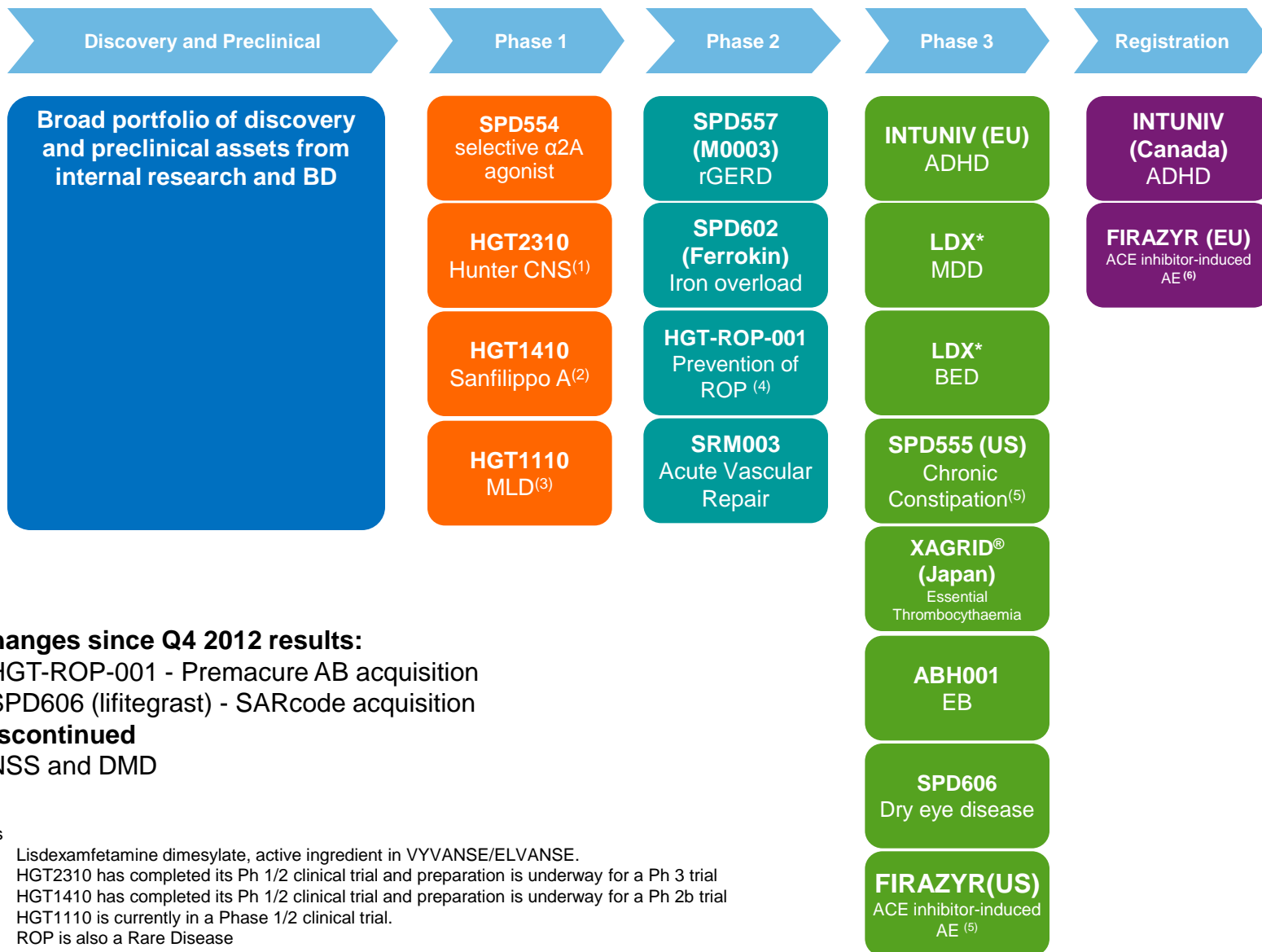
# SARcode and Premacure – *exciting assets in ophthalmology*



## premacure

- Phase 3 compound lifitegrast
    - For signs and symptoms of dry eye disease
    - Possible US launch 2016
  - 25m patients in US suffer from dry eye disease
  - 9m candidates (moderate-severe) for therapy
  - Global dry eye disease market ~\$1.5 billion in 2012
  - No currently approved competition for symptoms of dry eye disease
- Rare condition retinopathy of prematurity
  - Routinely screened for in babies younger than 30 weeks gestation
  - Can result in ocular scarring and blindness
  - ~30K-40K addressable patients worldwide per year
  - Phase 2 data available H2 2014

# Building an innovative pipeline to deliver future growth



## Changes since Q4 2012 results:

- HGT-ROP-001 - Premacure AB acquisition
- SPD606 (lifitegrast) - SARcode acquisition

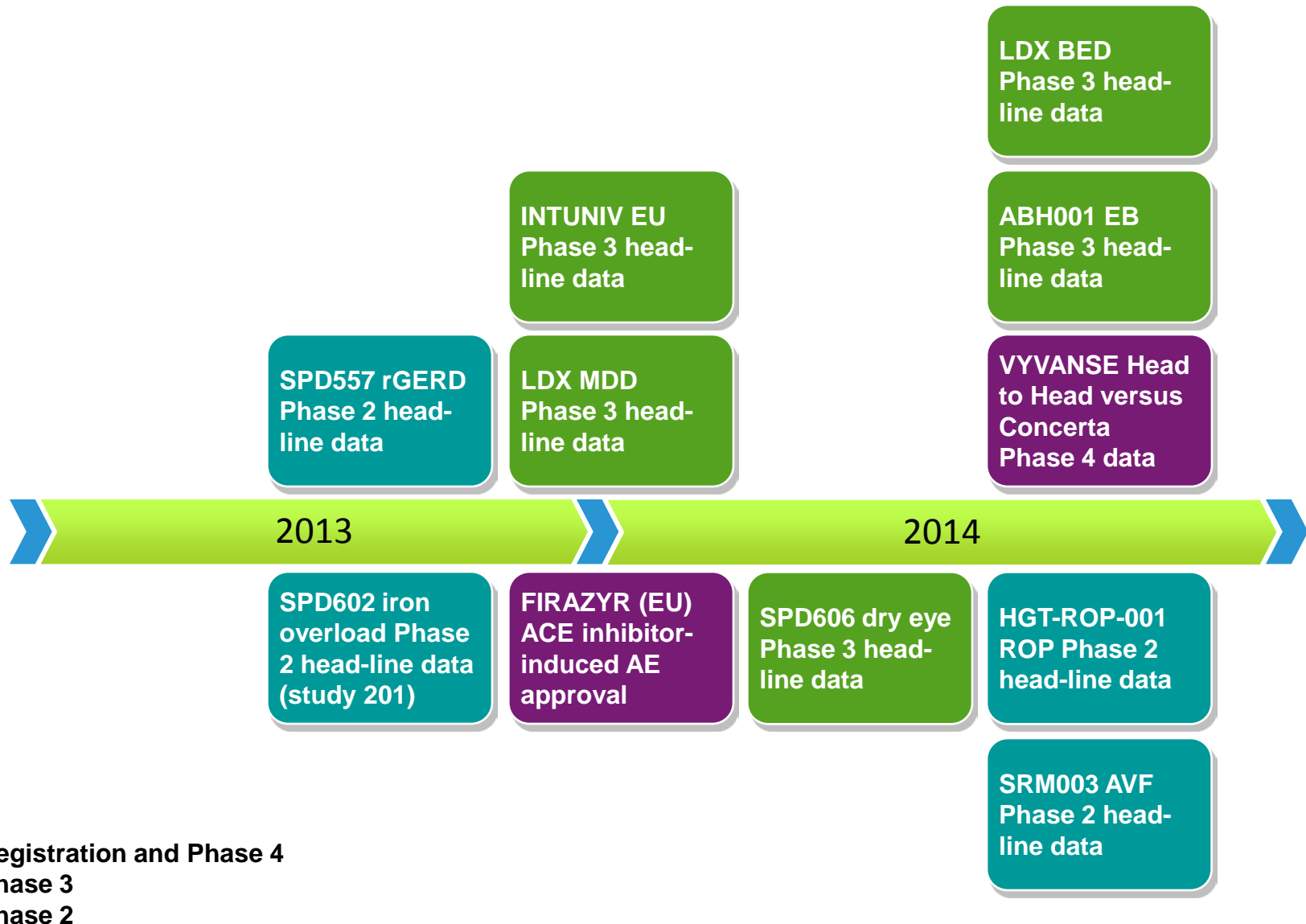
## Discontinued

- NSS and DMD

## Notes

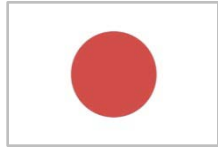
- \* Lisdexamfetamine dimesylate, active ingredient in VYVANSE/ELVANSE.
- (1) HGT2310 has completed its Ph 1/2 clinical trial and preparation is underway for a Ph 3 trial
- (2) HGT1410 has completed its Ph 1/2 clinical trial and preparation is underway for a Ph 2b trial
- (3) HGT1110 is currently in a Phase 1/2 clinical trial.
- (4) ROP is also a Rare Disease
- (5) Phase 3 ready.
- (6) Application for EU label change filed in December 2012.

# Significant clinical milestones





# Geographic expansion



## Japan

- Significant growth potential



## China

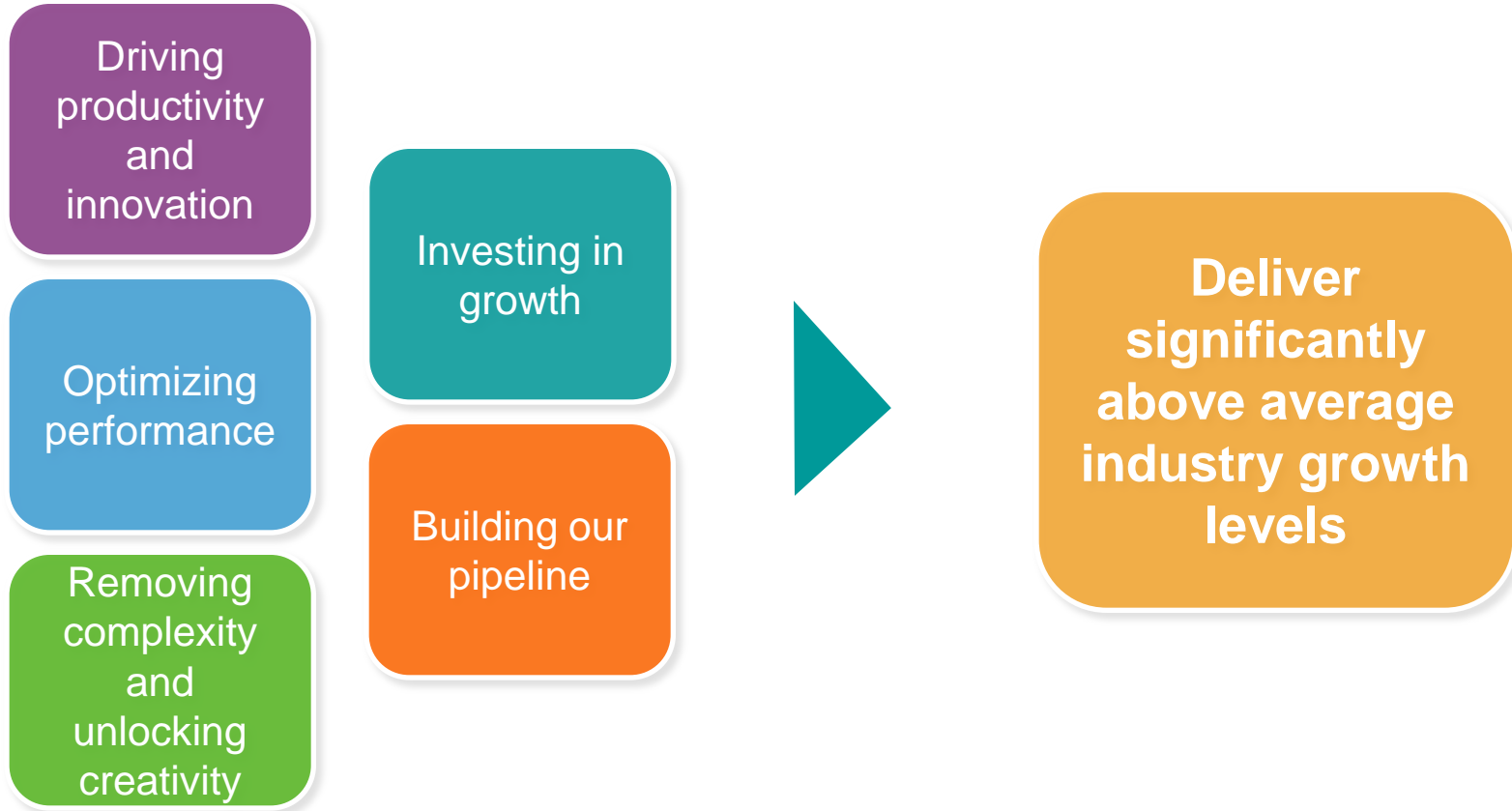
- Promising opportunity



## Brazil

- Continued strong performance in a rapidly growing market

# Delivering future growth



# Questions and Answers



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# Appendix



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## Product sales – regional analysis

	US \$m	Europe \$m	LATAM \$m	Other \$m	Total \$m
<b>Q1 2013 product sales</b>	<b>760</b>	<b>241</b>	<b>32</b>	<b>84</b>	<b>1,117</b>
% of Product sales	68%	22%	3%	7%	
YoY growth	3%	-1%	-40% <sup>(1)</sup>	12%	1%
<b>FY 2012 product sales</b>	<b>2,929</b>	<b>983</b>	<b>171</b>	<b>324</b>	<b>4,407</b>
% of Product sales	67%	22%	4%	7%	
YoY growth	14%	0%	33%	19%	12%

<sup>(1)</sup> YoY growth was adversely affected by the impact of ordering patterns for REPLAGAL and ELAPRASE.



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## Royalties & Other revenues

	Q1 2013 \$m	Q1 2012 \$m	Reported Growth
3TC and ZEFFIX	12	14	-8%
FOSRENOL	9	10	-10%
ADDERALL XR	8	25	-68%
REMINYL & Other	9	7	+20%
<b>Royalties</b>	<b>38</b>	<b>56</b>	<b>-32%</b>
<b>Other revenues</b>	<b>7</b>	<b>9</b>	<b>-22%</b>
<b>Royalties &amp; Other revenues</b>	<b>45</b>	<b>65</b>	<b>-30%</b>

# Shire income statement growth analysis

	2012 Q1	2012 Q2	2012 Q3	2012 Q4	2012 FY	2013 Q1	Direction v. FY 12	FY 2013 Dynamics Explanations
<b>Total Product Sales</b>	\$1,107m	\$1,148m	\$1,055m	\$1,097m	\$4,407m	\$1,117m	↑	<b>Growth in mid-to-high single digits</b>
<b>versus prior year</b>	+24%	+16%	+4%	+5%	+12%	+1%		
<b>Royalties &amp; Other revenues</b>	\$65m	\$60m	\$45m	\$104m	\$274m	\$45m	↓	<b>Combined royalties &amp; other revenues down 30-40%</b>
<b>versus prior year</b>	-22%	-14%	-32%	+11%	-12%	-30%		
<b>Total Revenues</b>	\$1,172m	\$1,208m	\$1,100m	\$1,201m	\$4,681m	\$1,162m		
<b>versus prior year</b>	+21%	+14%	+1%	+5%	+10%	-1%		
<b>Gross Margin <sup>(1) (2)</sup></b>	86%	87%	85%	86%	86%	87%	≈	<b>At a similar level to 2012</b>
<b>R&amp;D <sup>(2)</sup></b>	191	205	219	234	849	220	↑	<b>Low-to-mid teens growth</b>
<b>versus prior year</b>	+10%	+20%	+22%	+14%	+16%	+15%		
<b>SG&amp;A <sup>(2)</sup></b>	441	410	369	411	1,631	372	↓	<b>Marginally lower than 2012</b>
<b>versus prior year</b>	+25%	+5%	-5%	+5%	+7%	-16%		
<b>Combined R&amp;D and SG&amp;A <sup>(2)</sup></b>	\$632m	\$615m	\$588m	\$645m	\$2,480m	\$592m	↑	<b>Low single digits growth</b>
<b>versus prior year</b>	+20%	+10%	+3%	+8%	+10%	-6%		
<b>Tax Rate <sup>(2)</sup></b>	20%	20%	18%	15%	18%	19%	≈	<b>Core effective tax rate of 18-20%</b>
<b>EPS – ADS <sup>(2)</sup></b>	\$1.48	\$1.68	\$1.36	\$1.58	\$6.10	\$1.63	↑	<b>In line with current consensus earnings expectations<sup>(3)</sup></b>
<b>versus prior year</b>	+20%	+26%	+6%	+4%	+14%	+10%		

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

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

(3) Based on the most recent consensus estimates compiled by Consensus Forecast Ltd, as of the date of this presentation, of \$6.67 Non GAAP diluted earnings per ADS for the year ended December 31, 2013, available on Shire's website (<http://www.shire.com/shireplc/en/investors/forecasts>).

# Non GAAP cash flow measures

Non GAAP cash generation and free cash flow reconciliation	Q1 2013 \$m	Q1 2012 \$m
<b>Non GAAP cash generation<sup>(1)</sup></b>	<b>257</b>	<b>310</b>
Tax and interest payments, net	(97)	(30)
Up-front payments in respect of in-licensed and acquired products	-	(23)
<b>US GAAP net cash provided by operating activities</b>	<b>160</b>	<b>257</b>
Capital expenditure	(47)	(32)
Up-front payments in respect of in-licensed and acquired products	-	23
<b>Non GAAP free cash flow<sup>(2)</sup></b>	<b>113</b>	<b>248</b>

(1) Non GAAP cash generation represents net cash provided by operating activities, excluding up-front and milestone payments for in-licensed and acquired products, tax and interest payments.

(2) Non GAAP free cash flow represents net cash provided by operating activities, excluding up-front and milestone payments for in-licensed and acquired products, but including capital expenditure in the ordinary course of business.



## Non GAAP net cash

	March 31, 2013 \$m	December 31, 2012 \$m
Cash and cash equivalents	1,451	1,482
Convertible bonds	(1,100)	(1,100)
Other	(9)	(9)
<b>Net cash</b>	<b>342</b>	<b>373</b>

## Non GAAP to US GAAP reconciliation

	Q1 2013 \$m	Q1 2012 \$m	Reported Growth
<b>Non GAAP Operating income</b>	<b>393</b>	<b>362</b>	<b>+9%</b>
Intangible asset amortisation	(46)	(46)	
Impairment of RM goodwill	(199)	-	
Other legal and litigation costs	(4)	-	
Up-front payments in respect of in-licensed and acquired products	-	(23)	
Integration and acquisition costs	(4)	(5)	
Gains on sale of non-core assets	7	7	
Reorganisation costs	(18)	-	
Other	-	-	
<b>US GAAP Operating income</b>	<b>129</b>	<b>295</b>	<b>-56%</b>



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# 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:**
    - Up-front 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.
  - Legal and litigation costs:**
    - Net legal costs related to the settlement of litigation, government investigations and other disputes (excluding internal legal team costs).