# Strategy delivering strong results

## Third quarter results to September 30, 2013


**Flemming Ornskov, MD**
Chief Executive Officer

**Graham Hetherington**
Chief Financial Officer


Shire

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

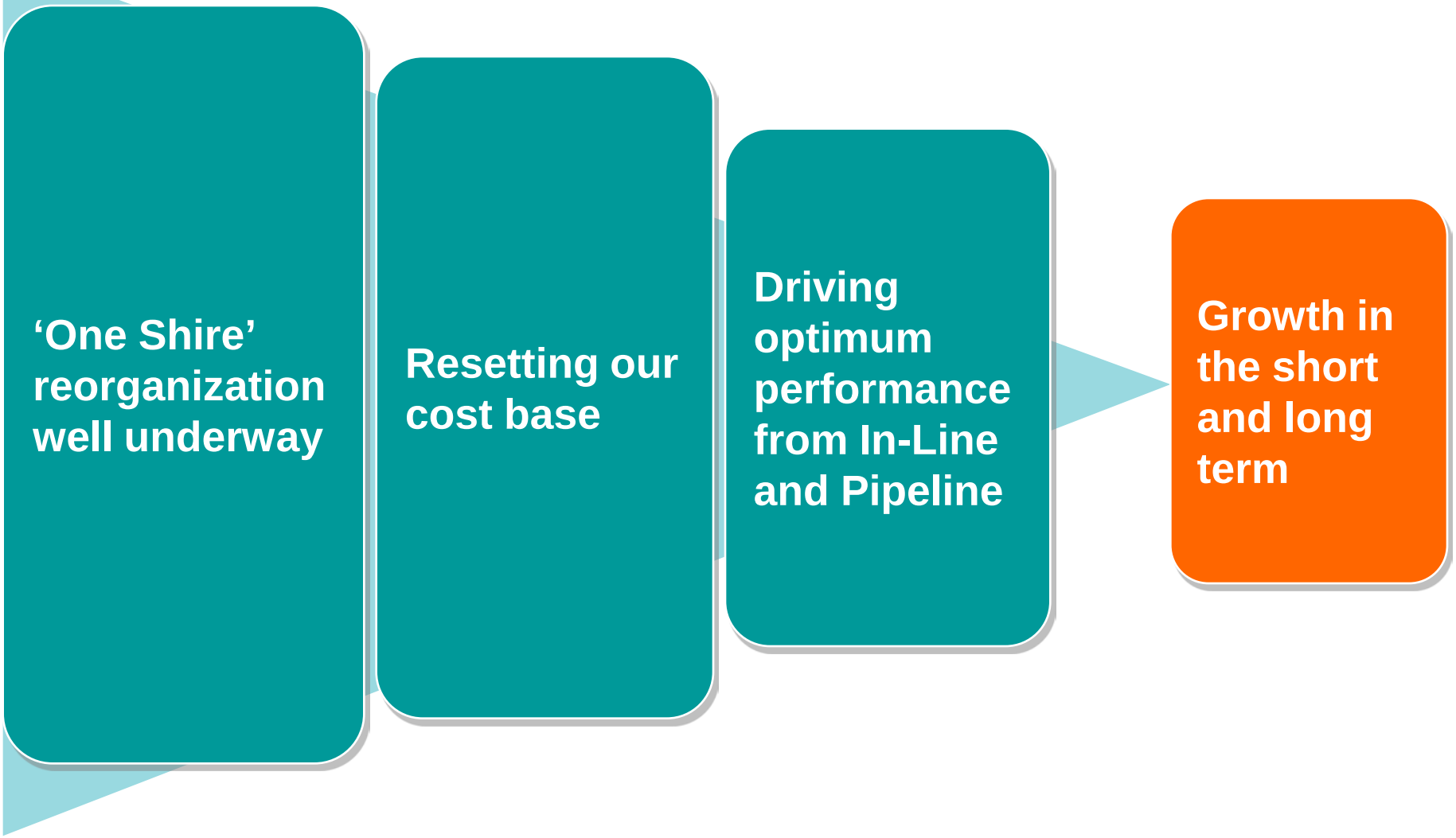
# THE "SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

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 year ended December 31, 2012.

# Strategy delivering strong results



# Strong results demonstrate good progress

**Q1**
**+1%**

**Q2**
**+7%**

**Q3**
**+13%**

**Product sales forecast**

**Q4 double digit growth**

driven by


**FY 2013**

**mid-to-high single digit product sales growth**

**Increased guidance:**
**We anticipate delivering full year mid-to-high teens Non GAAP earnings growth**

# One Shire: reorganization well underway

**Specialty Pharma**

**Human Genetic Therapies**

**Regenerative Medicine**

**"One Shire" transition**

## In-line


## Pipeline

**Single R&D organization and business development**

- Simplifying our business structure
- Greater commercial focus
- Holistic pipeline assessment

- More efficient operations
- Reduction in overlap
- Cost reduction and margin expansion

# Sustaining earnings growth

**Product sales and revenue growth**

**+**

**One Shire transition**

**More efficient ways of working**

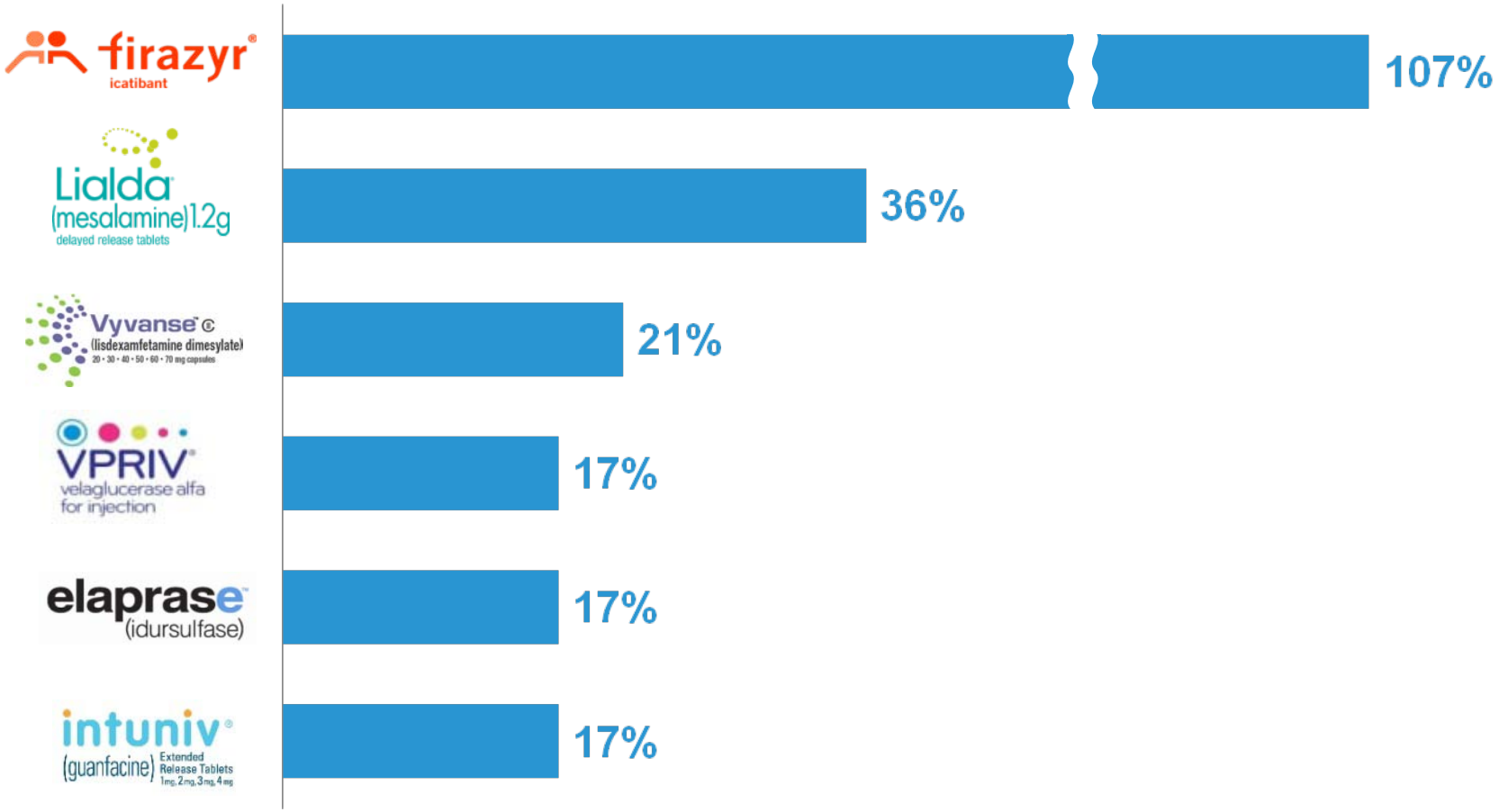
**Pipeline prioritization**

**Combined Non GAAP R&D and SG&A for 2013 1-3% lower than in 2012**

**=**

**Significant operating leverage in 2013**

# In-Line focus driving commercial excellence



# Firazyr: strong revenue growth driven by US success


| | |
|---|---|
| **Patients** | • Estimated 7,000-8,000 US HAE sufferers<br>• Only around half of sufferers currently treated |
| **Product** | • Firazyr has benefited from its portable, on-demand, subcutaneous self – administered presentation<br>• Average patient on Firazyr is treating 12 – 18 attacks per year |
| **Progress** | • Firazyr has the leading market share in US of HAE attacks treated acutely*<br>• >1,500 patients in US have received Firazyr commercial therapy to date |
| **Potential** | • Potential for significant growth in the future with only 50% of the market treated |

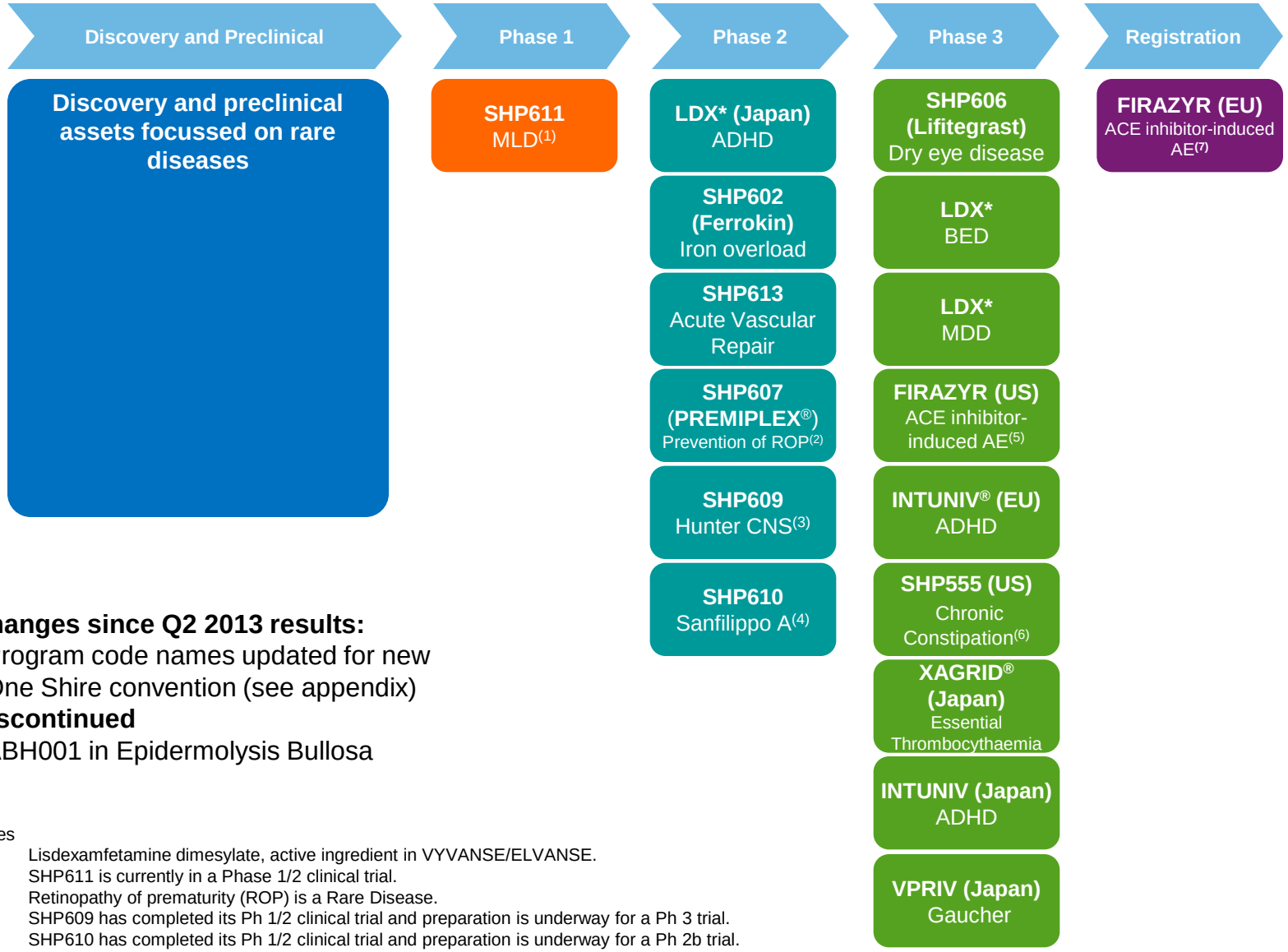
Shire To be as brave as the people we help.

*based on Shire's market research

# Vyvanse ‘Back to School’ campaign gains traction in US

- **Positive trends in Rx growth along with good Q3 sales results**
  - Specific tactics stabilizing downward trend seen earlier in the year
- **Sales and Marketing Execution**
  - Focused efforts for key physician groups
  - Removing barriers to patient access (i.e., formulary position, patient economics)
- **Current Rx growth rates in line with overall market**
  - Share growth higher than achieved during the same “Back to School” period in 2012

# Building an innovative pipeline to deliver future growth




**Changes since Q2 2013 results:**

- Program code names updated for new One Shire convention (see appendix)

**Discontinued**

- ABH001 in Epidermolysis Bullosa

Notes

* Lisdexamfetamine dimesylate, active ingredient in VYVANSE/ELVANSE.

(1) SHP611 is currently in a Phase 1/2 clinical trial.

(2) Retinopathy of prematurity (ROP) is a Rare Disease.

(3) SHP609 has completed its Ph 1/2 clinical trial and preparation is underway for a Ph 3 trial.

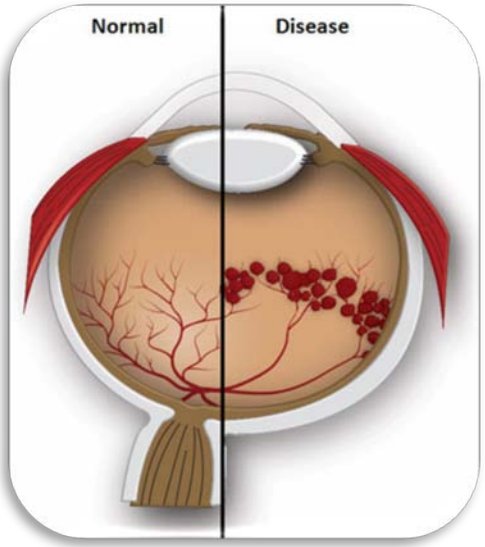
(4) SHP610 has completed its Ph 1/2 clinical trial and preparation is underway for a Ph 2b trial.

(5) Phase 3 study expected to commence in Q4 2013.

(6) Discussions are planned with the FDA to determine potential clinical development pathways.

(7) Application for EU label change, based on an investigator sponsored trial was filed in December 2012.

# SHP607 – Prevention of ROP is a significant commercial opportunity

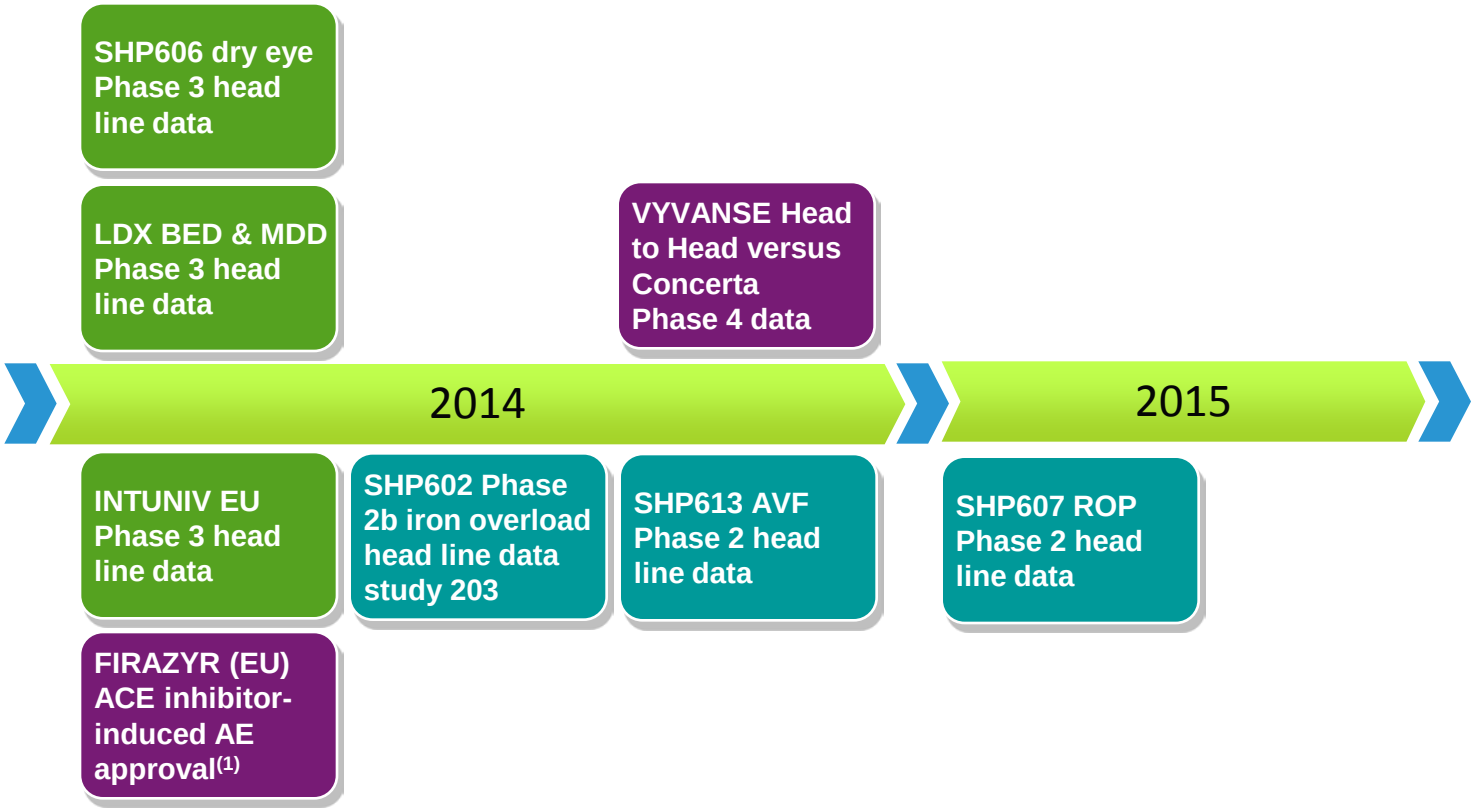



| | |
|---|---|
| **Patients** | • ~30-40K addressable patients in the US and EU per year<br>• Surgery is currently the only widely recognized treatment option |
| **Product** | • IGF-1 protein replacement therapy administered preventatively by continuous IV infusion in first 24-48 hours of life<br>• Delivered until endogenous production of IGF-1 begins at ~30-32 weeks gestational age |
| **Progress** | • Phase 2 studies ongoing, with headline data expected 1H 2015<br>• Dose optimization completed |
| **Potential** | • Significant commercial opportunity to treat a serious unmet need |

## SHP607 – Clinical progress

- Phase 2 multi-centre trial ongoing in Sweden
- Completed dose optimization
  - Single dose without need for frequent IGF-1 monitoring
  - Allows for scalability across multiple sites and effective commercialization
- Endpoints
  - $1^{o}$ – Maximum severity of ROP
  - $2^{o}$ – Time to discharge from NICU, Development of bronchopulmonary dysplasia (BPD), Growth / weight gain, Head circumference / brain volume
  - Continued safety analysis
- Headline line data in H1 2015

# Significant clinical milestones




**Registration and Phase 4**
**Phase 3**
**Phase 2**

(1) Application for EU label change, based on an investigator sponsored trial was, filed in December 2012.

# Financial review and 2013 outlook

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

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# Significant third quarter earnings growth

| | Q3 2013 $m | Q3 2012 $m | Reported Growth |
|---|---|---|---|
| **Product sales** | **1,195** | **1,055** | **+13%** |
| **Product sales excluding ADDERALL XR** | **1,114** | **952** | **+17%** |
| **Royalties and other revenues** | **42** | **45** | **-9%** |
| **Total revenues** | **1,237** | **1,100** | **+12%** |
| **EBITDA[(1)]** | **456** | **354** | **+29%** |
| **EBITDA % of product sales[(1)(2)]** | **35%** | **29%** | **545bp** |
| **EPS - ADS[(1)]** | **$1.77** | **$1.36** | **+30%** |
| **Cash generation[(1)]** | **482** | **355** | **+36%** |

(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.

# Portfolio delivering broad based growth

| | Q3 2013 $m | Q3 2012 $m | Reported Growth $m | Reported Growth % |
|---|---|---|---|---|
| VYVANSE | 299 | 247 | 52 | +21% |
| LIALDA / MEZAVANT | 142 | 104 | 38 | +36% |
| ELAPRASE | 129 | 111 | 18 | +17% |
| REPLAGAL | 109 | 122 | (13) | -11% |
| VPRIV | 88 | 75 | 13 | +17% |
| INTUNIV | 81 | 69 | 12 | +17% |
| PENTASA | 71 | 67 | 4 | +5% |
| FIRAZYR | 63 | 30 | 33 | +107% |
| DERMAGRAFT | 24 | 34 | (10) | -29% |
| OTHER | 108 | 93 | 15 | +16% |
| Product sales excluding ADDERALL XR | 1,114 | 952 | 162 | +17% |
| ADDERALL XR | 81 | 103 | (22) | -20% |
| Product sales | 1,195 | 1,055 | 140 | +13% |

# Significant operating leverage in 2013

| Year on Year: | 2013 YTD | 2012 YTD |
|---|---|---|
| **Product sales** | +7% | +14% |
| **R&D**(1) | +10% | +17% |
| **SG&A**(1) | -7% | +8% |
| **Combined R&D and SG&A**(1) | -1% | +11% |

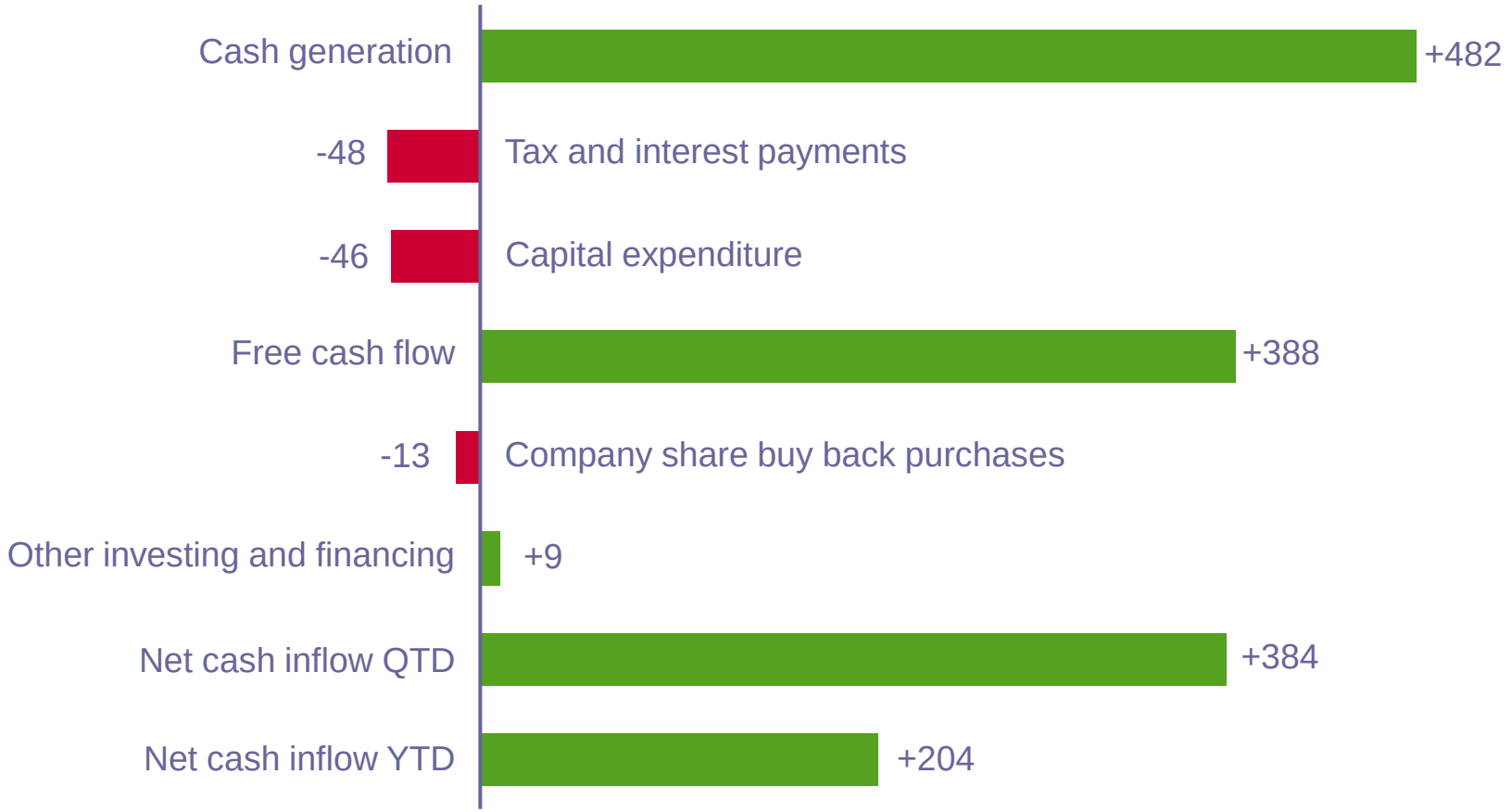
**Ratios:**

| % of product sales | | |
|---|---|---|
| **Gross margin**(1) | 85.9% | 86.2% |
| **R&D**(1) | 19% | 19% |
| **SG&A**(1) | 32% | 37% |
| **EBITDA**(1) (2) | 35% | 31% |

(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.

# Strong third quarter cash generation

Millions of USD




Note: Shire has a revolving 5 year credit facility of $1.2bn signed in November 2010 which remains undrawn at September 30, 2013.

# Increasing guidance to mid-to-high teens earnings growth in 2013

| Full year 2013 dynamics | Direction v. FY 2012 | Latest guidance | Previous guidance where changed |
|---|---|---|---|
| **Product sales** | ↑ | Growth in the mid-to-high single digits(1) | |
| **Royalties and Other revenues** | ↓ | Combined royalties & other revenues 35-40% lower than 2012 | |
| **Gross margins** | ≈ | At a similar level to 2012 | |
| R&D | ↑ | 5-7% higher than 2012 | Low double digit growth |
| SG&A | ↓ | 5-7% lower than 2012 | 2-4% lower than 2012 |
| **Combined R&D and SG&A** | ↓ | 1-3% lower than 2012 | Only marginally higher than 2012 |
| **Tax rate** | ≈ | Core effective tax rate of 18-20% | |
| **Reported EPS-ADS** | ↑ | **Mid-to-high teens Non GAAP earnings growth for the full year** | Anticipate delivering full year double digit Non GAAP earnings growth |

**Expectations for 2014-2015**

- Continuing operating leverage in both 2014 and 2015.
- Combined R&D and SG&A approximately $250 million lower in 2014 and $300 million lower in 2015 (compared to current consensus expectations(2)).

(1) Similar level of product sales growth expected in the fourth quarter as delivered in the third quarter.

(2) Based on the most recent consensus estimates compiled by Consensus Forecast Ltd, as of the date of this release, of combined Non GAAP R&D and SG&A of $2,662 million and $2,683 million for the years ending December 31, 2014 and 2015 respectively, available on Shire's website (http://www.shire.com/shireplc/en/investors/forecasts).

# Summary

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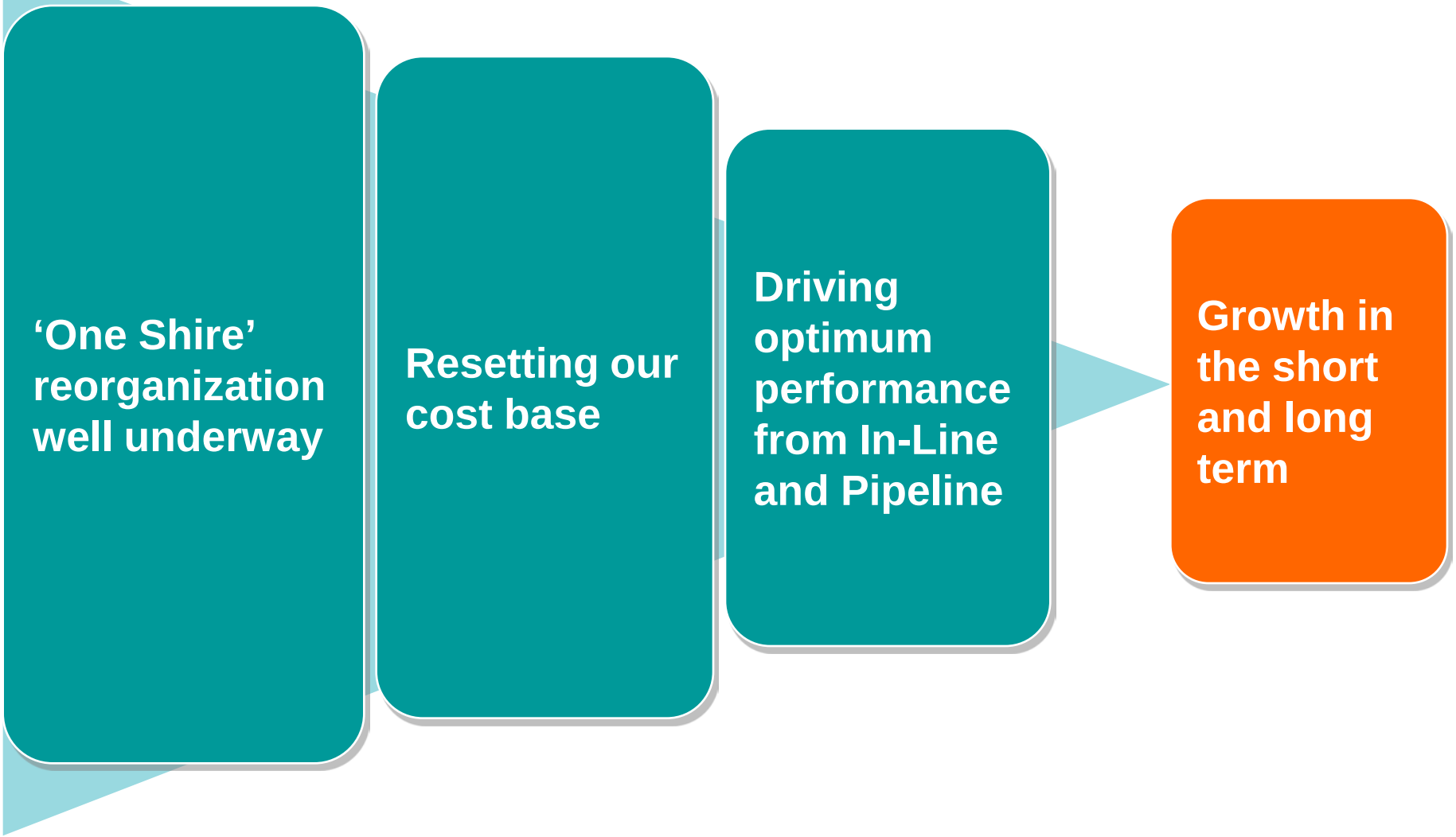
# Strategy delivering good results



# Questions and Answers

# Appendix

# Program Code Renaming Index for new One Shire convention

| New Code | Old Code | Indication |
|---|---|---|
| SHP555 | SPD555 | Chronic Constipation |
| SHP602 | SPD602 | Iron Overload |
| SHP606 | SPD606 | Dry Eye Disease |
| SHP607 | HGT-ROP-001 | Retinopathy of Prematurity |
| SHP609 | HGT2310 | Hunter CNS |
| SHP610 | HGT1410 | Sanfilippo Syndrome Type A |
| SHP611 | HGT1110 | Metachromatic Leukodystrophy (MLD) |
| SHP613 | SRM003 | Acute Vascular Repair |

# Operating leverage – Key financial ratios

| Year on Year: | Q3 2013 | Q3 2012 |
|---|---|---|
| **Product sales** | +13% | +4% |
| **R&D**(1) | +2% | +22% |
| **SG&A**(1) | +1% | -5% |
| **Combined R&D and SG&A**(1) | +1% | +3% |

**Ratios:**

| % of product sales | | |
|---|---|---|
| **Gross margin**(1) | 84.4% | 85.0% |
| **R&D**(1) | 19% | 21% |
| **SG&A**(1) | 31% | 35% |
| **EBITDA**(1) (2) | 35% | 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.

# Product sales – regional analysis

| | US $m | Europe $m | LATAM $m | Other $m | Total $m |
|---|---|---|---|---|---|
| **Q3 2013 product sales** | **815** | **248** | **44** | **88** | **1,195** |
| % of Product sales | 68% | 21% | 4% | 7% | |
| YoY growth | +15% | +6% | +37% | +10% | +13% |
| **YTD 2013 product sales** | **2,403** | **737** | **145** | **257** | **3,542** |
| % of Product sales | 68% | 21% | 4% | 7% | |
| YoY growth | +8% | +1% | +19% | +9% | +7% |
| **FY 2012 product sales** | **2,929** | **983** | **171** | **324** | **4,407** |
| % of Product sales | 67% | 22% | 4% | 7% | |
| YoY growth | +14% | 0% | +33% | +19% | +12% |

# Royalties & Other revenues

| | Q3 2013 $m | Q3 2012 $m | Reported Growth |
|---|---|---|---|
| **FOSRENOL** | 14 | 14 | -1% |
| **3TC and ZEFFIX** | 10 | 11 | -5% |
| **ADDERALL XR** | 6 | 11 | -45% |
| **REMINYL & Other** | 8 | 6 | +25% |
| **Royalties** | **38** | **42** | **-10%** |
| **Other revenues** | 4 | 3 | - |
| **Royalties & Other revenues** | **42** | **45** | **-9%** |

# Shire income statement growth analysis

| | 2012 Q1 | 2012 Q2 | 2012 Q3 | 2012 Q4 | 2012 FY | 2013 Q1 | 2013 Q2 | 2013 Q3 | FY 2013 Dynamics: Direction V. FY 12 | FY 2013 Dynamics: Explanations |
|---|---|---|---|---|---|---|---|---|---|---|
| **Total Product Sales** | $1,107m | $1,148m | $1,055m | $1,097m | $4,407m | $1,117m | $1,230m | $1,195m | ↑ | Growth in the mid-to-high single digits [3] |
| **versus prior year** | +24% | +16% | +4% | +5% | +12% | +1% | +7% | +13% | | |
| **Royalties & Other revenues** | $65m | $60m | $45m | $104m | $274m | $45m | $45m | $42m | ↓ | 35 - 40% lower than 2012 |
| **versus prior year** | -22% | -14% | -32% | +11% | -12% | -31% | -26% | -9% | | |
| **Total Revenues** | $1,172m | $1,208m | $1,100m | $1,201m | $4,681m | $1,162m | $1,275m | $1,237m | | |
| **versus prior year** | +21% | +14% | +1% | +5% | +10% | -1% | +6% | +12% | | |
| **Gross Margin [1] [2]** | 86% | 87% | 85% | 86% | 86% | 87% | 87% | 84% | ≈ | At a similar level to 2012 |
| **Combined R&D and SG&A [2]** | $632m | $615m | $588m | $645m | $2,480m | $592m | $626m | $595m | ↓ | 1-3% lower than 2012 |
| **versus prior year** | +20% | +10% | +3% | +8% | +10% | -6% | +2% | +1% | | |
| **Tax Rate [2]** | +20% | +20% | +18% | +15% | +18% | +19% | +23% | +19% | ≈ | Core effective tax rate of 18-20% |
| **EPS – ADS [2]** | $1.48 | $1.68 | $1.36 | $1.58 | $6.10 | $1.63 | $1.79 | $1.77 | ↑ | Mid-to-high teens Non GAAP earnings growth for the full year |
| **versus prior year** | +20% | +26% | +6% | +4% | +14% | +10% | +6% | +30% | | |

(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) Similar level of product sales growth expected in the fourth quarter as delivered in the third quarter.

# Non GAAP cash flow measures

| Non GAAP cash generation and free cash flow reconciliation | Q3 2013 $m | Q3 2012 $m |
|---|---|---|
| **Non GAAP cash generation[1]** | **482** | **355** |
| Tax and interest payments, net | (48) | (67) |
| **US GAAP net cash provided by operating activities** | **434** | **288** |
| Capital expenditure | (46) | (27) |
| **Non GAAP free cash flow[2]** | **388** | **261** |

(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

| | September 30, 2013 $m | December 31, 2012 $m |
|---|---|---|
| Cash and cash equivalents | 1,686 | 1,482 |
| Convertible bonds | (1,100) | (1,100) |
| Other | (9) | (9) |
| **Net cash** | **577** | **373** |

# 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
- Non-controlling 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).

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