

# Cowen Healthcare Conference

Shire plc  
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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, 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.

# 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)



	% Growth	CAGR
Revenues	190%	16%
EBITDA	169%	15%

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  $\alpha 2A$  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**

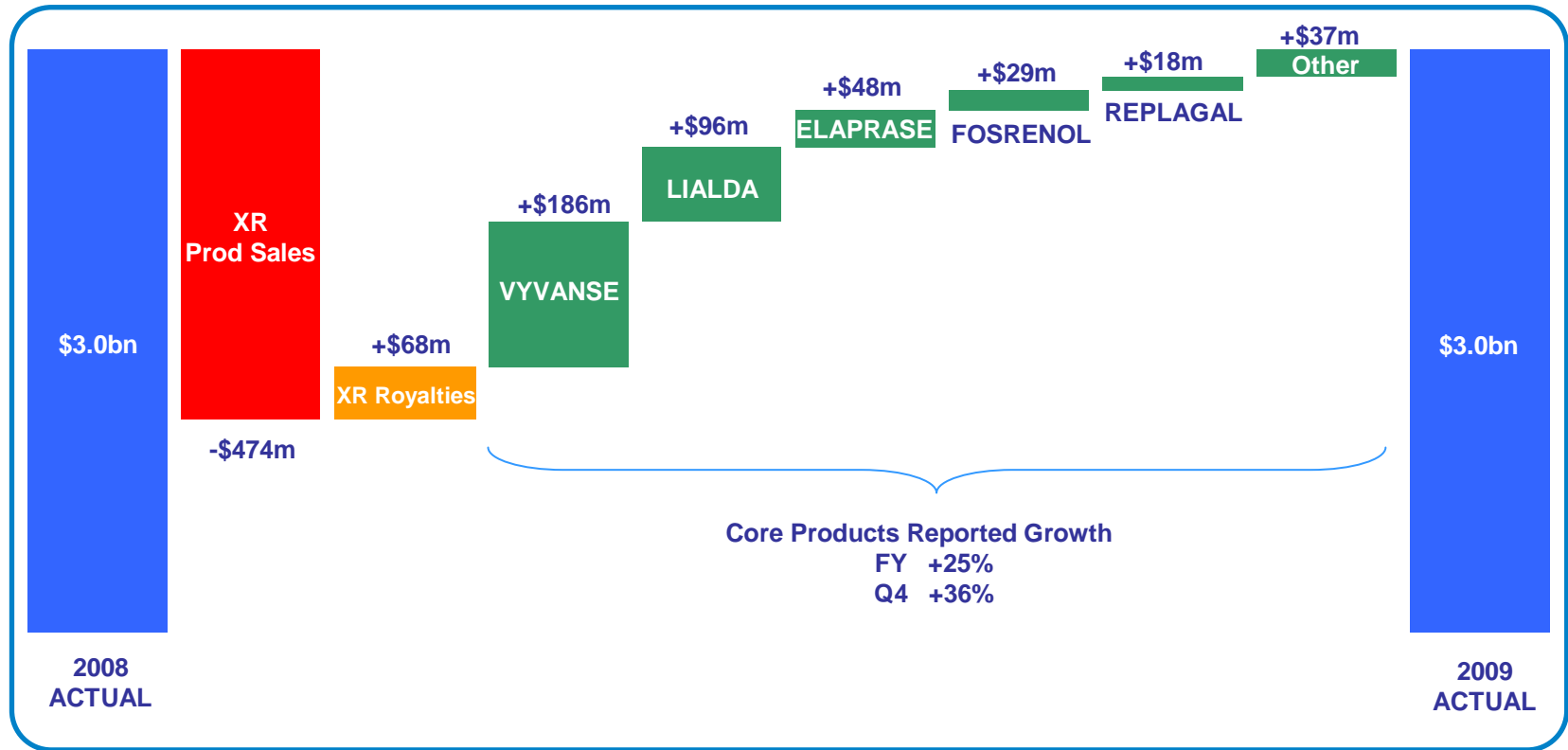
**Pipeline opportunities for long term growth**

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

**Sustaining our financial performance**

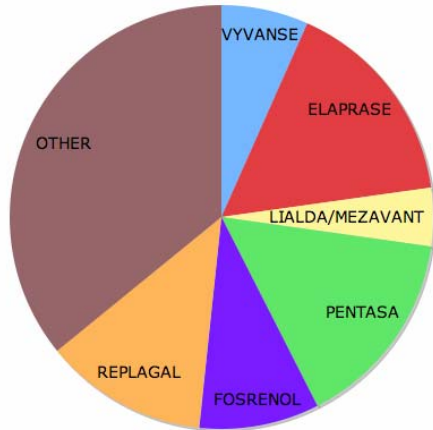
**Aspiration to grow sales in the mid-teens range year-on-year on average over the course of 2009 through 2015**

# 2009 Total revenues in-line with 2008

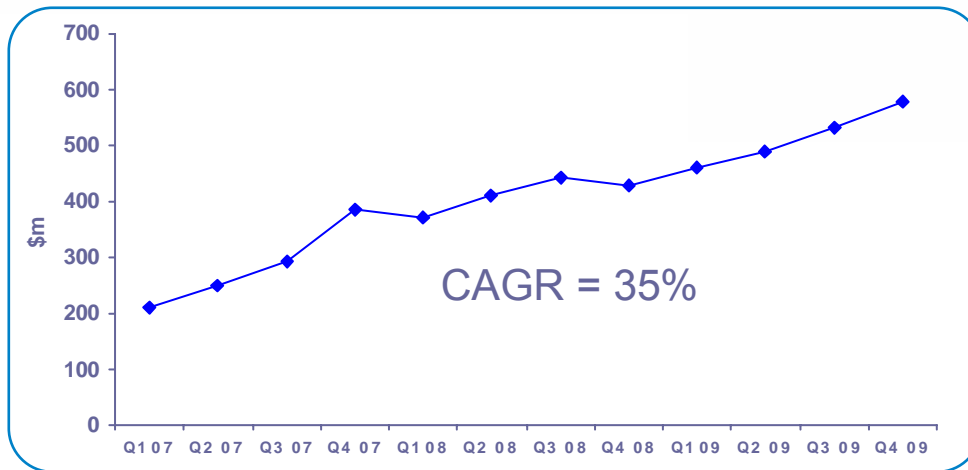
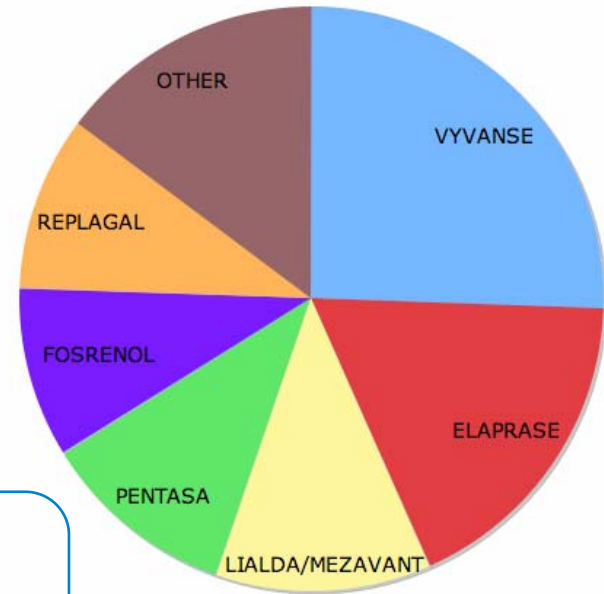


# Core product sales growth

FY 2007  
\$1.1bn



FY 2009  
\$2.1bn



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

## 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)

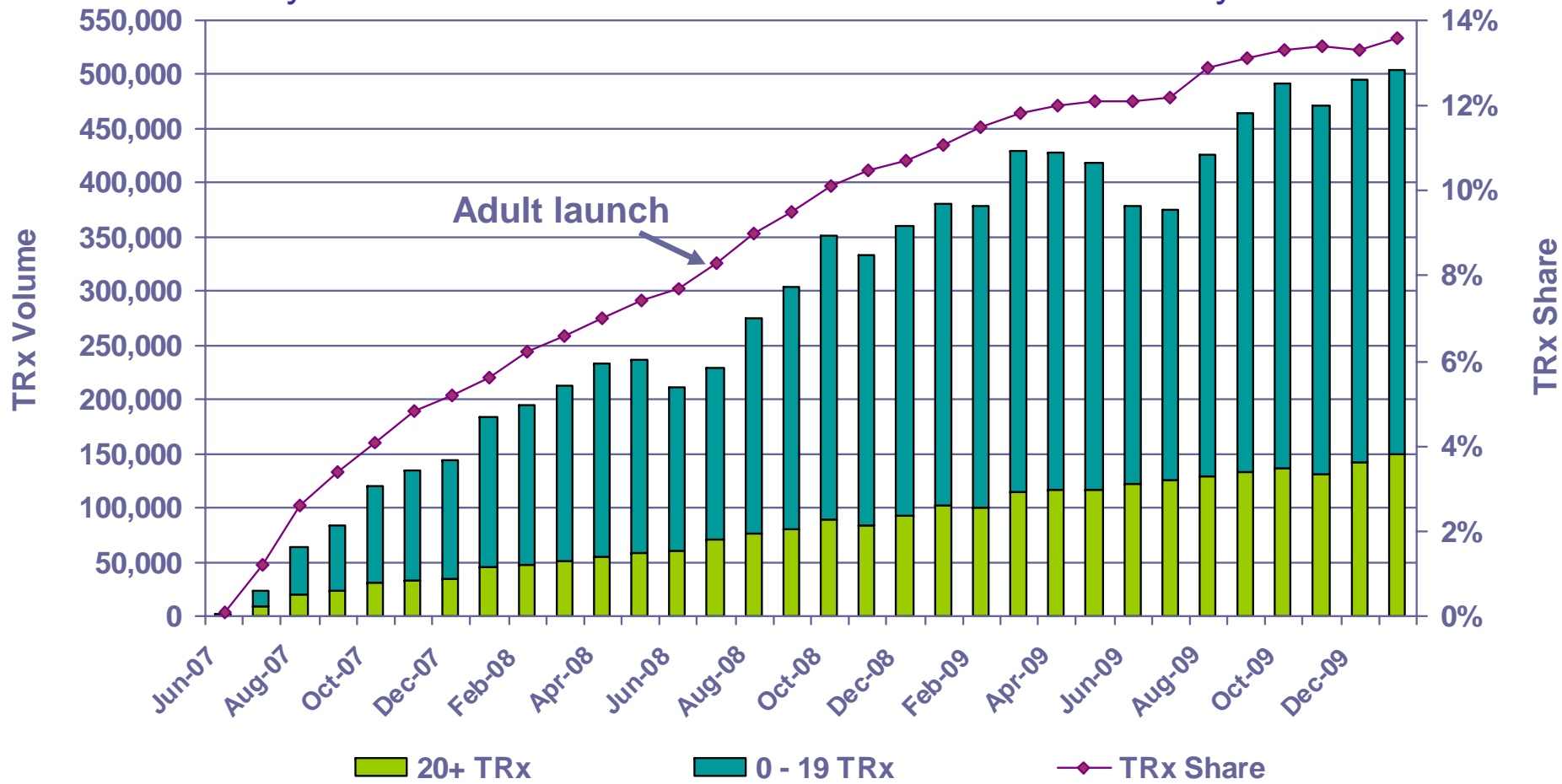
## VYVANSE demonstrated outstanding growth in 2009 in the face of ADDERALL XR going generic

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

# Vyvanse continues to grow share and volume

Vyvanse TRx Volume and Share June 2007 – January 2010

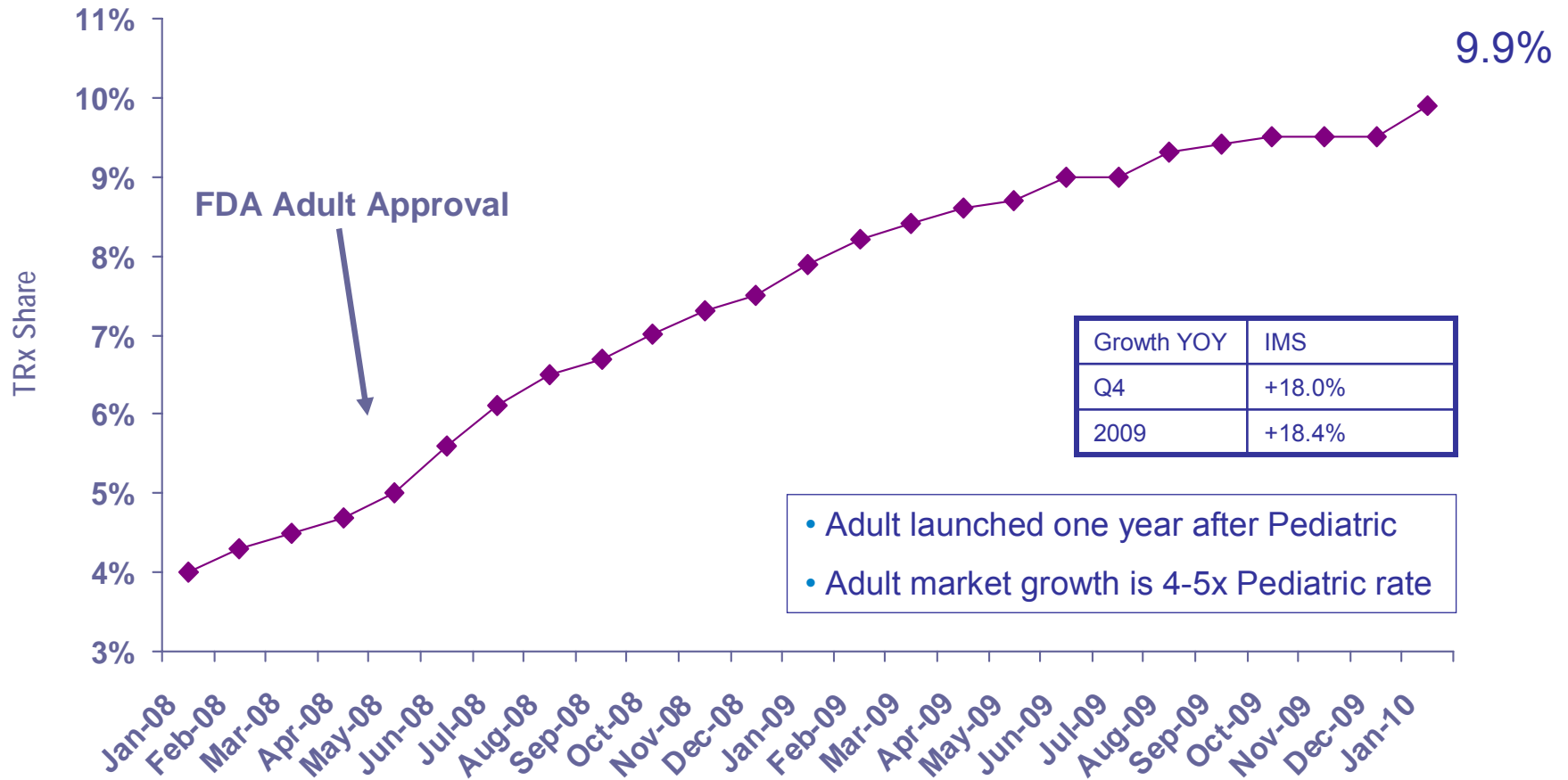


To be as brave as the people we help

Source: IMS NPA Monthly

# VYVANSE Adult share continues to grow

## Adult Market Share

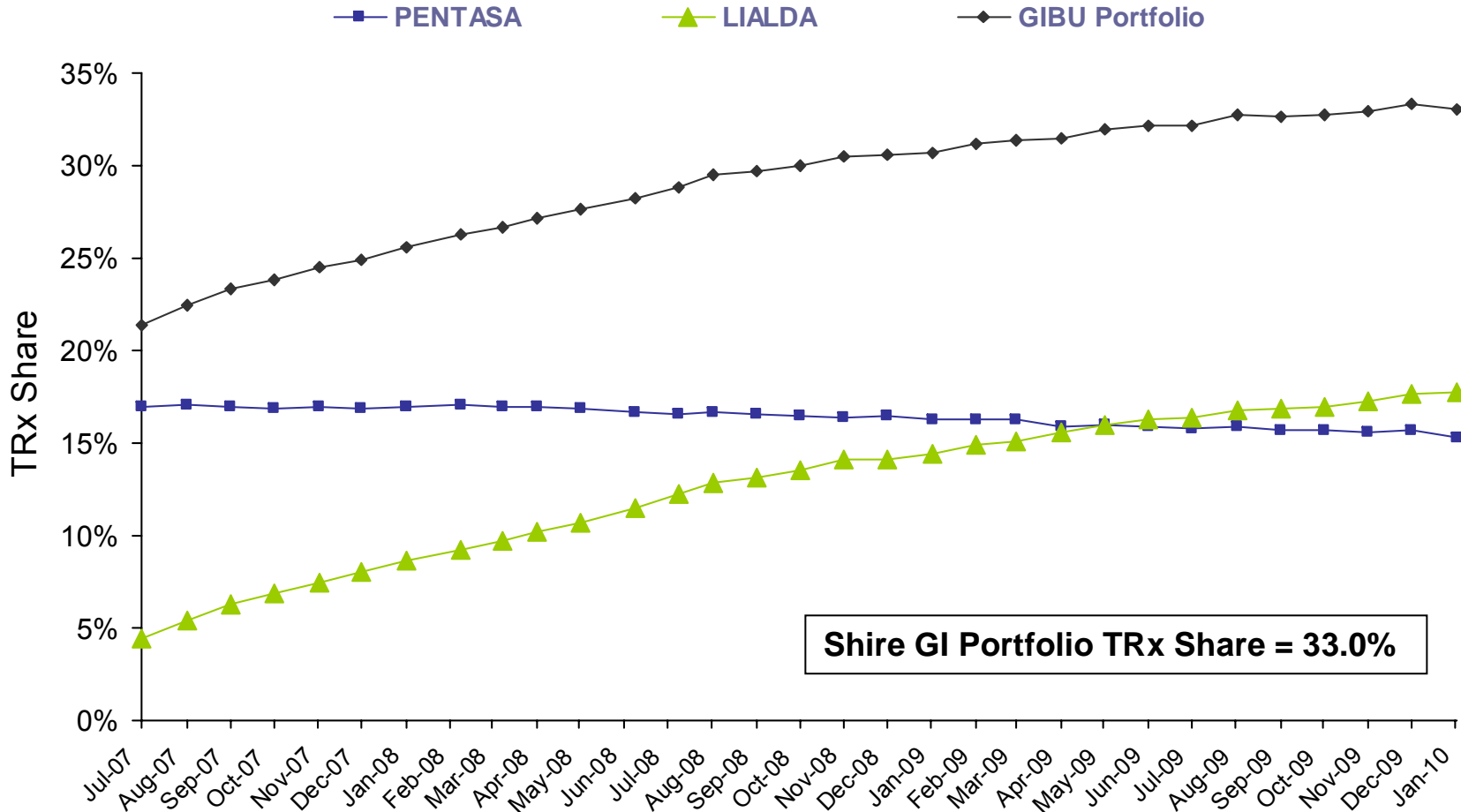


## INTUNIV Launch update

- Although it is still early post launch for INTUNIV, we are very encouraged by the early indicators
  - For the week ending February 26<sup>th</sup>, 2010, the overall national market share was 1.4%, 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

# Shire GI Portfolio – Monthly TRx Share of Oral 5-ASA

## Shire GI Portfolio Oral 5-ASA Monthly TRx Share



Source: IMS NPA Monthly

## 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

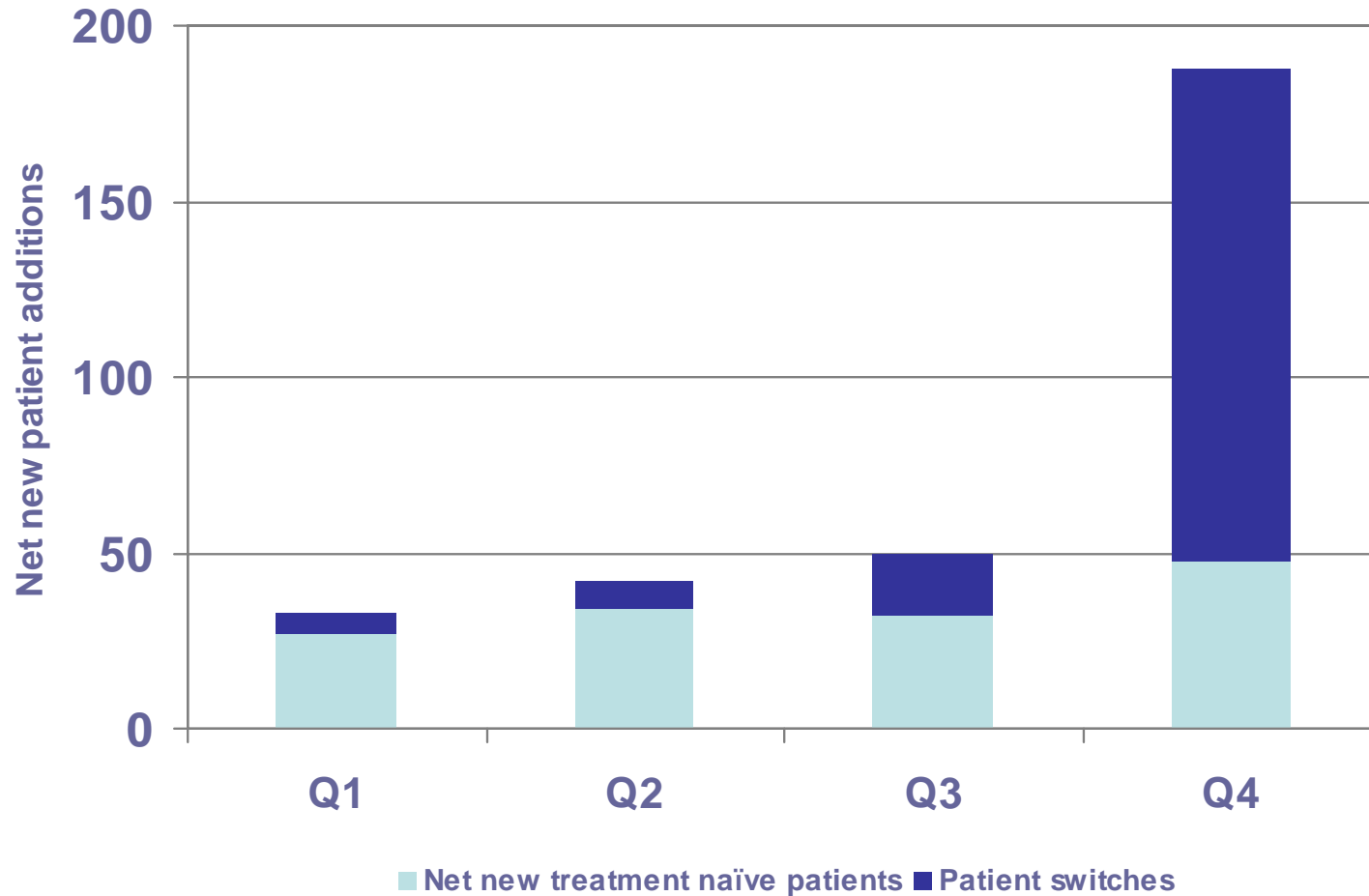
## Efforts continue to progress early pipeline products

- 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 Product launch preparations for 2010 and beyond

- VPRIV
  - Approved by FDA and launched in the US
  - 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
  - Over 400 patients have received VPRIV globally
- REPLAGAL
  - Focus on market growth and switch
  - Continue to address unmet need in the US
  - Fast track designation granted by FDA / rolling submission initiated

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



# 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

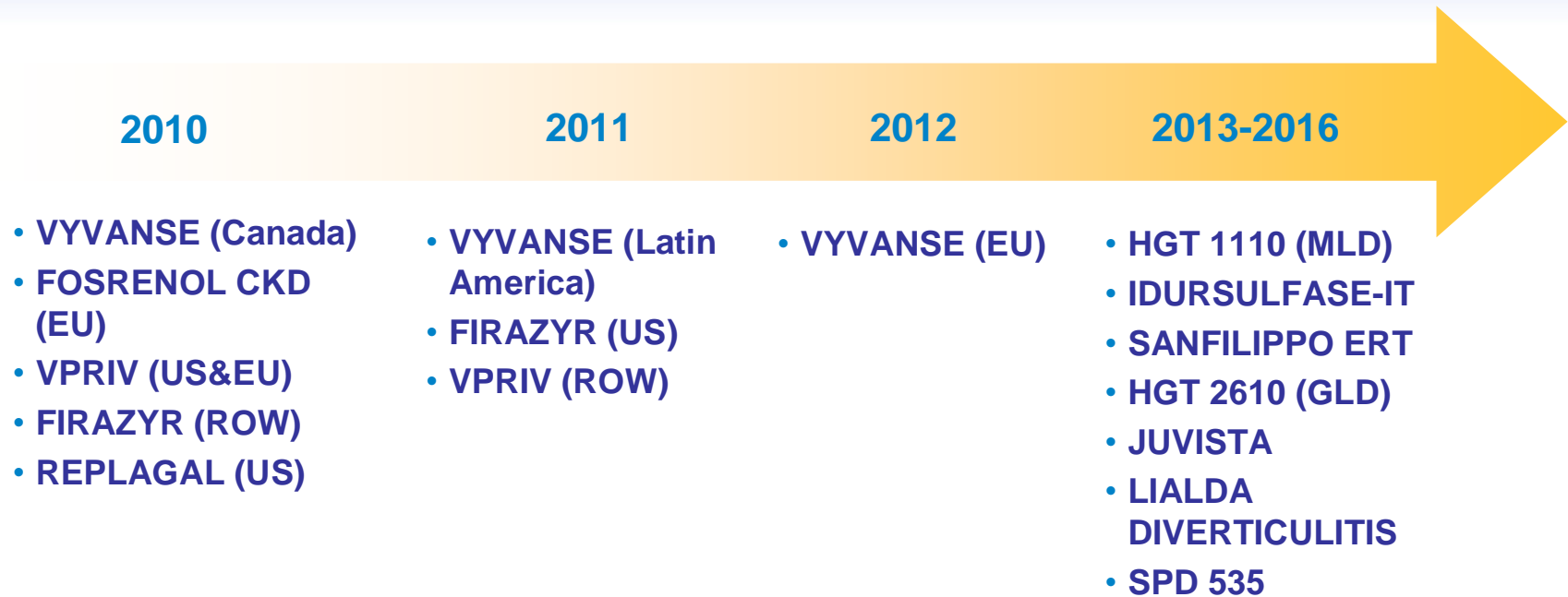
### LEVERAGE INFRASTRUCTURE INVESTMENT

- 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

# Potential launches from 2010-2016\*



\*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 approved by FDA and available pre-approval ex-US
  - REPLAGAL received Fast Track designation
  - 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



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# APPENDIX



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## 2009 Key financial ratios

<b>FINANCIAL RATIOS (% of product sales)</b>	<b>FY 09</b>	<b>y-o-y Growth</b>	<b>FY 08</b>	<b>y-o-y Growth</b>
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%	
<b>FINANCIAL RATIOS (% of core product sales)</b>				
Core product sales	2,067	25%	1,653	45%
R&D - Core product sales	25%		29%	
SG&A - Core product sales	55%		71%	

(1) Excluding royalties and other revenues.

(2) 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.

# Emerging shape of Shire 2010 Income Statement

## 2010 Dynamics

Direction  
Versus FY 09

(see Appendix for more analysis)

Core Product Sales



2009 growth continues, with potential to accelerate

Total Product Sales



Core product growth > AXR decline

Royalties



Growth in AXR royalty offset by lower other royalty income

Gross Margins



R&D and SG&A



- 5-10% growth in R&D and SG&A investment
- Operating leverage on Core Product Sales

Tax rate



Reported EPS-ADS



Note: Sensitivity to Forex Movements:	EPS-ADS \$
A 10 cent strengthening of the \$ against the €	-0.08
A 10 cent strengthening of the \$ against the £	0.03
	<u>-0.05</u>

Interest on convertible = \$34m pa