

# J.P. Morgan Healthcare Conference

## January 12, 2010

Shire plc

**Angus Russell**  
Chief Executive Officer



Our purpose

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

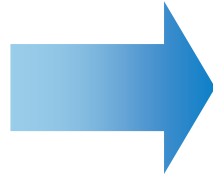
## THE “SAFE HARBOR” STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

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, 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.

# Transformation continues

**2004**

- ADDERALL XR and ADHD the prime focus
- Small molecules
- Oral drug delivery (SLI)
- Hatch Waxman dependent
- US the dominant market
- Presence in Canada and 6 EU markets



**2010**

- Leading Specialty Biopharmaceutical Company
- Business based on:
  - Small molecules
  - Peptides
  - Biologics
- Technology platforms
  - Human cell line biologics
  - Carrierwave
  - Locked Nucleic Acid Technology
- ADHD, GI and Human Genetic Therapies
  - Balanced product portfolio
- 8 growth-driving products
- Products with global rights
- Strong pipeline
- Robust Intellectual property
- Presence in over 25 countries and growing

## 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



### Impact Since 2003

	% Growth	CAGR
Revenues	191%	20%
EBITDA	171%	18%
Shire Share Price	132%	15%
Nasdaq	18%	3%
FTSE 100	14%	2%

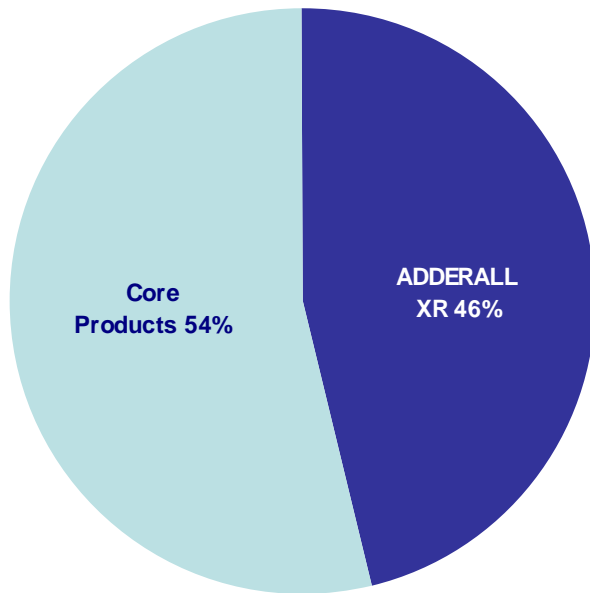
Note: data covers timeframe of 1/1/2003 through 12/31/2008

## Strategy is delivering

- Focused on the needs of patients and physicians
  - velaglucerase alfa available in US and EU pre-approval
  - REPLAGAL
    - increased demand in the EU
    - pre-approval access available for US patients
- Launching new products
  - INTUNIV
- Expanding the business through acquisition, progression of the R&D pipeline and targeted geographic expansion
- Aspiration to grow sales in the mid-teens range year-on-year on average over the course of 2009 through 2015

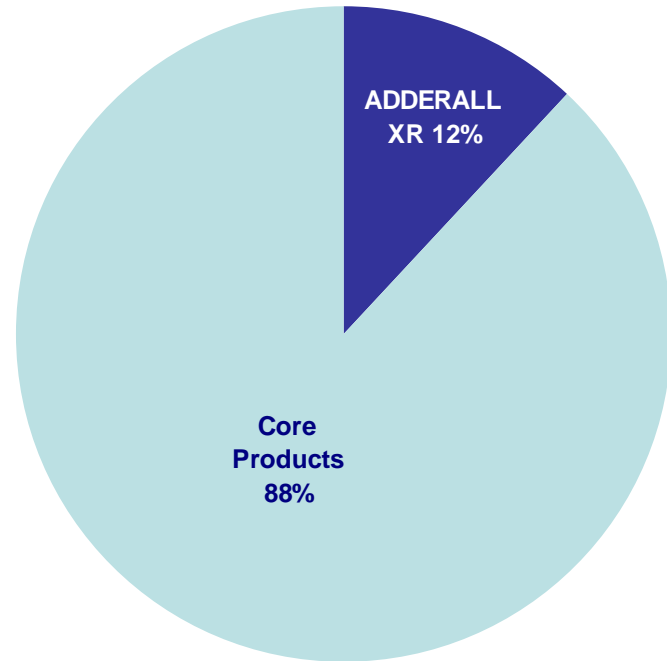
# New phase for Shire

Q3 2007



Product sales \$543m

Q3 2009



\$603m

# Product updates



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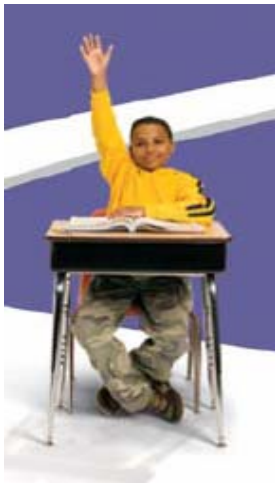
## INTUNIV is a significant opportunity for Shire in ADHD

- 0.9%\* market share after 7 weeks of promotion
- Payor access is on target – numerous recent state Medicaid and commercial wins
- INTUNIV is positioned to complement, not compete, with our existing ADHD portfolio
  - VYVANSE remains the cornerstone of our ADHD franchise
- Opportunity to capture patients not previously available to Shire

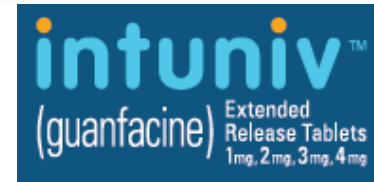
# Clear Positioning allows physicians to differentiate VYVANSE and INTUNIV on the basis of patient symptoms



- For the **majority** of ADHD patients exhibiting core symptoms of ADHD:



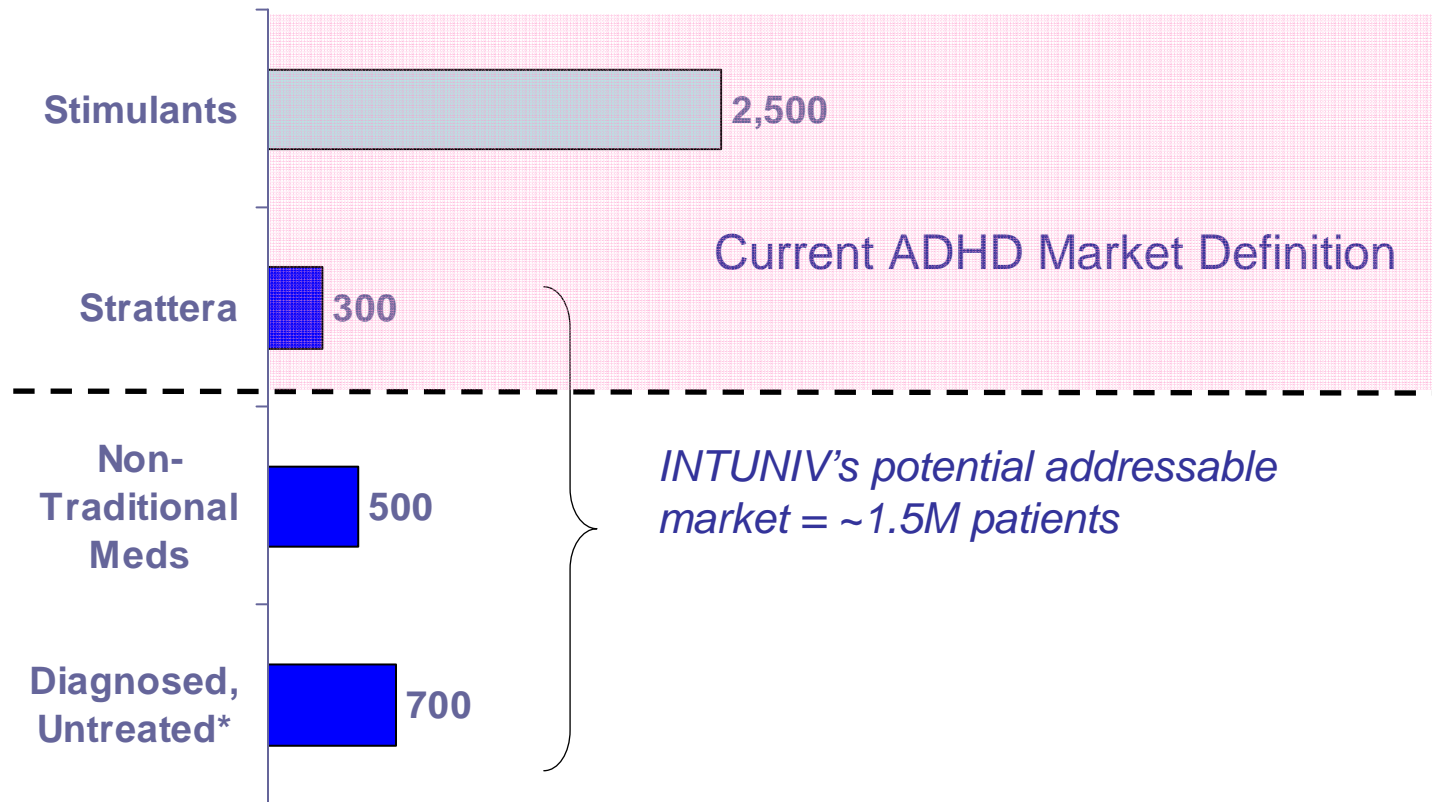
- inattention
- hyperactivity
- impulsivity
- lack of focus or distractibility



- ADHD patients whose symptoms are not limited to inattention, hyperactivity and impulsivity, and may include disruptive behaviors:
  - arguing
  - losing temper
  - deliberately annoying others

# Opportunity to capture patients not previously available to Shire

Treatment Patterns for Pediatric ADHD Patients (000's)



\*60% of MDs indicate that they have diagnosed, untreated pediatric patients in their practice who are candidates for Intuniv

## VYVANSE's Growth

- Strong Back-to-School season
- Continued steady performance in the adult segment
- NO impact on VYVANSE from generic AXR
- Over \$1 Billion in cumulative gross sales since launch

## Other Specialty Pharma news

- FOSRENOL - Approval for new CKD indication received across EU through mutual recognition process (MRP)
  - EU launches anticipated from H1 2010
  - Continue assessment of path forward in US
- LIALDA global Phase 3 trials in diverticulitis are ongoing
- VYVANSE non-ADHD: Phase 2 clinical trials planned or underway with data anticipated H2 2010
  - Adjunctive therapy in depression
  - Cognitive impairment in depression
  - Negative symptoms and cognitive impairment in schizophrenia

## Shire HGT - Swift response to evolving market demands

- Key achievements, 2H 2009 in response to supply restrictions of two currently approved ERTs
  - velaglucerase alfa (Gaucher disease)
    - Manufacturing timelines accelerated by 18 months
    - Early access programs for patients implemented US and EU
    - Reported positive results from all phase III trials
    - NDA submitted, priority review granted
    - MAA submitted, accelerated assessment granted
  - REPLAGAL (Fabry disease)
    - Early access for patients through FDA-approved treatment protocol and emergency IND
    - Increase in demand/volume seen in the EU from switches
    - Sufficient supply on hand to manage through extended supply shortage
    - BLA filed December 2009

## Preparations for 2010 and beyond

- velaglucerase alfa – US Launch Preparations
  - Manufacturing and clinical site inspections complete
  - Sales force training and readiness efforts complete
  - Pricing/ reimbursement initiatives underway
  - Phase 3 data to be presented at LDN meeting in February
- Replagal
  - Continue to meet increased demand/volume in the EU
  - Continue to address unmet need in the US
  - Ongoing discussions with FDA regarding BLA submission

## HGT Key growth drivers

- HGT core products
  - Continued growth of ELAPRASE
    - Lexington roller bottle facility - Positive opinion from EMEA in December 2009 and on track for H1 2010 approval in the US
  - FIRAZYR
    - Now launched in eleven countries, including the five largest European countries
    - Hospital product – reimbursement / formulary listing
    - Well received by patients and treating physicians
    - US Phase 3 trial ongoing
  - International expansion continuing

## Future of Shire HGT: *ATLAS Manufacturing Plant*



- Manufacturing to begin July 2010
- Additional capacity up to four 2000L bioreactors
- Adds level of redundancy
- Single use bioreactor technology further reduces manufacturing risk
- Long-term gross margin improvement

## Solid foundation for future growth

- Strong financial performance
  - Excellent growth from core products
  - Proactive cost management
  - Strong cashflow
- Strategy is delivering
  - Driving growth from balanced portfolio of 8 core products
  - INTUNIV – launch off to a strong start
  - velaglucerase alfa now available pre-approval
  - REPLAGAL BLA filed in December 2009
  - 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

## Borgia Room



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# Shire acquisition/in-licensing history

Year	Company <small>*company acquired</small>	Product(s) marketed or in clinical pipeline	Small molecules	Peptides	Biologics	Technology platform	Geographic expansion
1997	*Pharmavene	CARBATROL	✓			✓	
1997	*Richwood	ADDERALL (XR)	✓				✓
1999	*Roberts *Fuisz	XAGRID, PENTASA N/A	✓				✓ ✓
2001	*BioChem	Royalty products	✓				✓
2002	Noven Giuliani	DAYTRANA LIALDA / MEZAVANT	✓ ✓				
2005	*TKT	ELAPRASE, REPLAGAL, velaglucerase alfa			✓	✓	✓
2007	*New River	VYVANSE	✓			✓	
2007	Renovo	JUVISTA			✓		
2008	Zymenex	HGT 1111 (Metazym)			✓		
2008	*Jerini AG	FIRAZYR		✓		✓	
2009	UCB	EQUASYM	✓				✓
2009	Santaris	Three pre-defined targets				✓	