

**Interim Results Presentation  
London**

**November 2012**

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 **Overview & Corporate Update**

**Chris Blackwell**

 **Financial Results**

**Anne Hyland**

 **Summary**

**Chris Blackwell**



**Overview and Corporate Update**  
**Chris Blackwell**

## ✔ **Leader in the development of novel inhaled pharmaceuticals**

- Approved product for COPD in EU & Japan/RoW
  - NVA237 (Seebri<sup>®</sup> Breezhaler<sup>®</sup>) marketed by Novartis
- Two partnered, late-stage products in development for COPD
  - NVA237 (US) & QVA149 (EU/Japan/RoW/US) – fully funded by Novartis

## ✔ **Three generic respiratory programmes**

- VR315 - Licensed in EU/RoW (Sandoz) and in US (undisclosed partner)
- VR506 - Development ongoing to generate licensing package
- VR632 - Licensed in EU (Sandoz)

## ✔ **Technology platforms, validated by deals, underpin product focus**

- Number two globally in respiratory patent filings (DPI technology & formulation)
- “Big Pharma” validation e.g. current deals with GSK, Novartis and Sandoz

## ✔ **Strong balance sheet with £72.1m in cash**

- Supported by existing royalty streams (Baxter products) and a disciplined approach to cost control

## Operational Highlights

- ✓ **First launch of Seebri<sup>®</sup> Breezhaler<sup>®</sup> (NVA237) in Europe**
  - Also approved in Japan, Canada and Australia
- ✓ **QVA149 filed in Europe and Japan**
- ✓ **VR315, VR506 & VR632 all made solid progress**
  - First milestone on VR315 (US)
  - Demonstrates progress with new partner

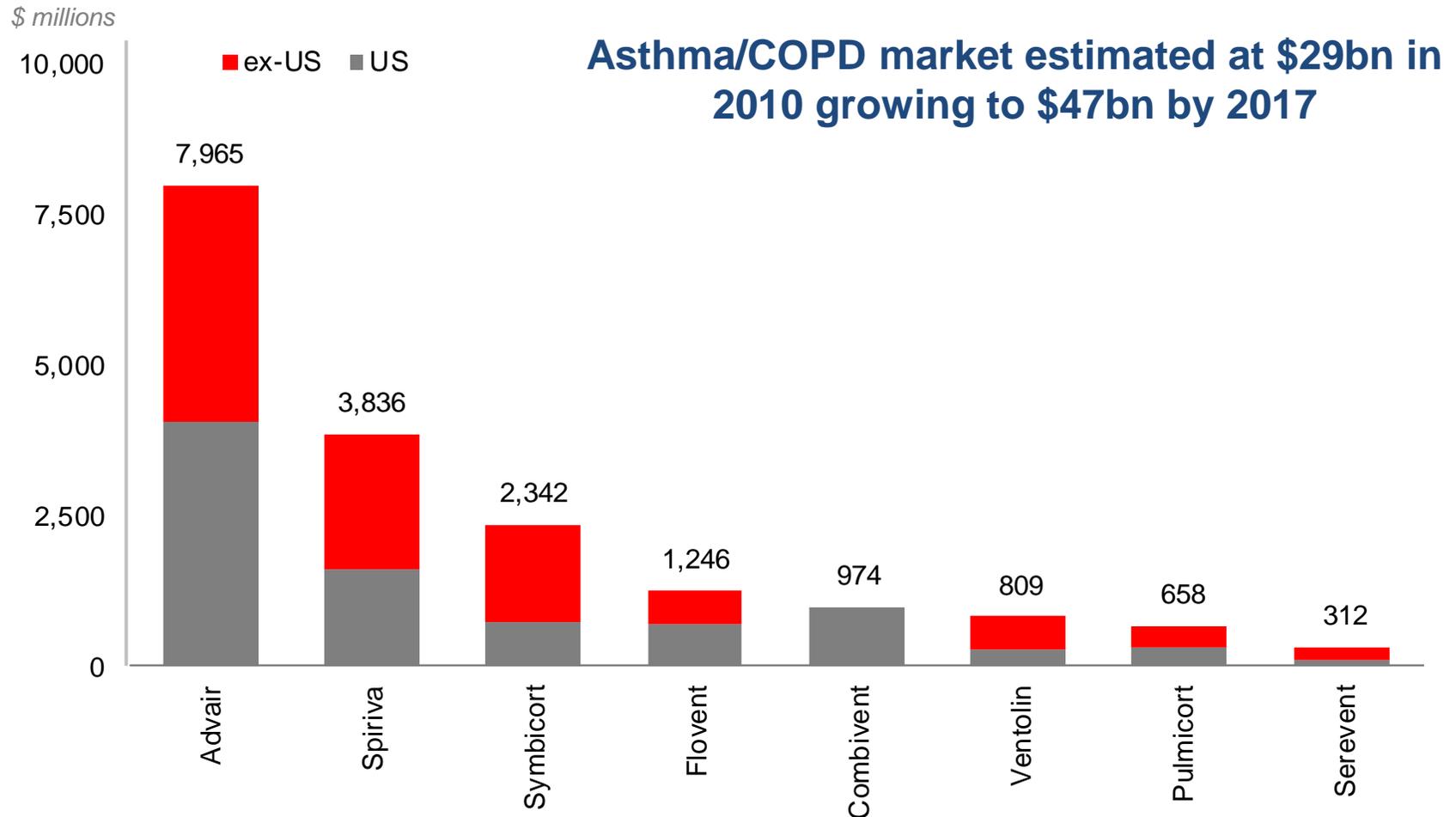
## Financial Highlights

- ✓ **Revenues £17.0m (H1 2011/12: £21.1m)**
  - Ahead of market expectations
  - Decline due to timing of milestones
- ✓ **Profit after tax £0.9m (H1 2011/12: £2.6m)**
  - Ahead of market expectations
- ✓ **EPS of 0.3p (H1 2011/12: 0.8p)**
- ✓ **Robust balance sheet with cash and cash equivalents £72.1m**
  - (£75.5m at 31 March 2012)



## Branded Programmes

# Significant Respiratory Market Opportunity



Source: Sell side analyst reports; BCC Research (2012)

## ✔ Treated according to GOLD guidelines

- 2011 update classifies patients according to two key attributes:
  - Symptoms
  - Exacerbation risk

## ✔ Inhaled therapy

- Bronchodilators
  - Long acting muscarinic antagonists (LAMA)
  - Short/long acting beta agonists (SABA/LABA)
- Inhaled corticosteroids (ICS)

## ✔ Three major COPD drugs drive current sales of ca. \$10bn

- Advair<sup>®</sup>/Seretide<sup>®</sup> (ICS/LABA combination) \$3.5bn COPD sales in 2011
- Symbicort<sup>®</sup> (ICS/LABA combination) \$1.2bn COPD sales in 2011
- Spiriva<sup>®</sup> (LAMA) \$4.4bn COPD sales in 2011

- ❖ **Single LAMA products to remain an important product class (NVA237)**
  - ~ 30% volume share within 7 years
  - Upside opportunity from use of LAMAs in asthma
    - Encouraging exacerbation data in severe asthmatics using Spiriva (ERS 2012)
- ❖ **LAMA/LABA combinations will redefine the standard of care in COPD (QVA149)**
  - The combination is synergistic over its components
- ❖ **Combination products expected to refine market dynamics<sup>1</sup>**
- ❖ **Conclusion: Vectura is poised to capture significant value**
  - Seebri® Breezhaler®
  - QVA149
  - Generic products

<sup>1</sup>Source: Sell-side analyst research

- ✔ **Once-daily maintenance bronchodilator treatment for COPD licensed to Novartis**
- ✔ **Seebri<sup>®</sup> Breezhaler<sup>®</sup> approved in EU, Japan & Canada**
  - US filing expected Q1 2014
- ✔ **Comprehensive phase III clinical trial programme (GLOW)**
  - GLOW1: Lung function (trough FEV1) improvements over placebo at 12 weeks (primary endpoint;  $p < 0.01$ )
  - GLOW2: Similar benefit to open-label tiotropium bromide over 52 weeks, measured by improvements in trough FEV1 compared with placebo
  - GLOW3: A 21% improvement in exercise endurance compared with placebo at the end of the study (Day 21), with a significant 10% increase from Day 1 (both  $p < 0.001$ )
  - GLOW4: The data from this Japanese study showed that glycopyrronium bromide had a similar safety profile to open-label tiotropium bromide and a safety profile similar to placebo
- ✔ **Market roll out is underway**
  - Launched in Germany & UK by Novartis

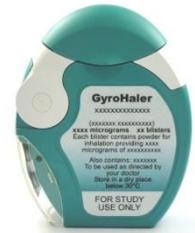
- ✔ **Significantly derisked: component drugs and device already approved for COPD**
  - Indacaterol maleate - Onbrez<sup>®</sup> Breezhaler<sup>®</sup>
  - Glycopyrronium bromide - Seebri<sup>®</sup> Breezhaler<sup>®</sup>
  
- ✔ **Regulatory filing recently submitted in EU (Oct. 2012)**
  - Japan regulatory filing submitted in November 2012
  
- ✔ **US filing expected end 2014**
  
- ✔ **IGNITE COPD registration trial programme comprises 10 studies in total**
  - > 7,000 patients across 42 countries
  - Significant improvements over
    - Placebo
    - Tiotropium bromide
    - Salmeterol/fluticasone
    - Individual components



## Generic Programmes

## GyroHaler® - competitive product design

- Performance engineered to match brand-leaders
- Easy to use
- Inexpensive, minimalist design
- Accurate, reproducible dosing through excellent protection of the powder formulation



## Focus on promising, high value products

- VR315 - Licensed in EU/RoW (Sandoz) and in US (undisclosed partner)
- VR632 - Licensed in EU (Sandoz)
- VR506 - Development ongoing, strong out-licensing candidate

## Comprehensive understanding of complex regulatory requirements

- Significant experience of interaction with regulators, particularly the EMA and FDA

## ✔ **EU rights licensed to Sandoz in 2006**

- Sandoz responsible for clinical development, manufacturing and marketing
- Significant investment (ca. €50m) in commercial manufacturing facility

## ✔ **US agreement signed with an undisclosed pharmaceutical company in 2011**

- US division of a major pharmaceutical company
- Partner responsible for clinical development, manufacturing and commercialisation
- First development milestone (\$3m) earned

## ✔ **Agreement with Sandoz extended in 2011 to include the Rest of World (ex US)**

- €7m milestones and pre-launch royalties and royalties on product sales

## ✔ **Next key milestone for VR315 is European approval**

- Pragmatic approach from EMA
- Development risk is mitigated: (known entities) – question is more about timing
- Vectura is restricted in the information it can give on regulatory timing

## Rationale to develop is two-fold

- Strong stand alone commercial opportunity
- Active ingredient is a component in one of our combination products
  - Regulators require individual components to be characterised

## Clinical programme initiated

- Evaluate the dose-response relationship and efficacy of VR506 using a new inhaler for the treatment of asthma
- Programme requires approximately 500 randomised patients
- Sites in US, EU and Far East

## Continued investment by Vectura in this programme

- Characterisation of the asset
- Generating sufficient data to maximise the licensing opportunity

## ✔ **EU rights licensed to Sandoz in 2007**

- Further collaboration with an established partner

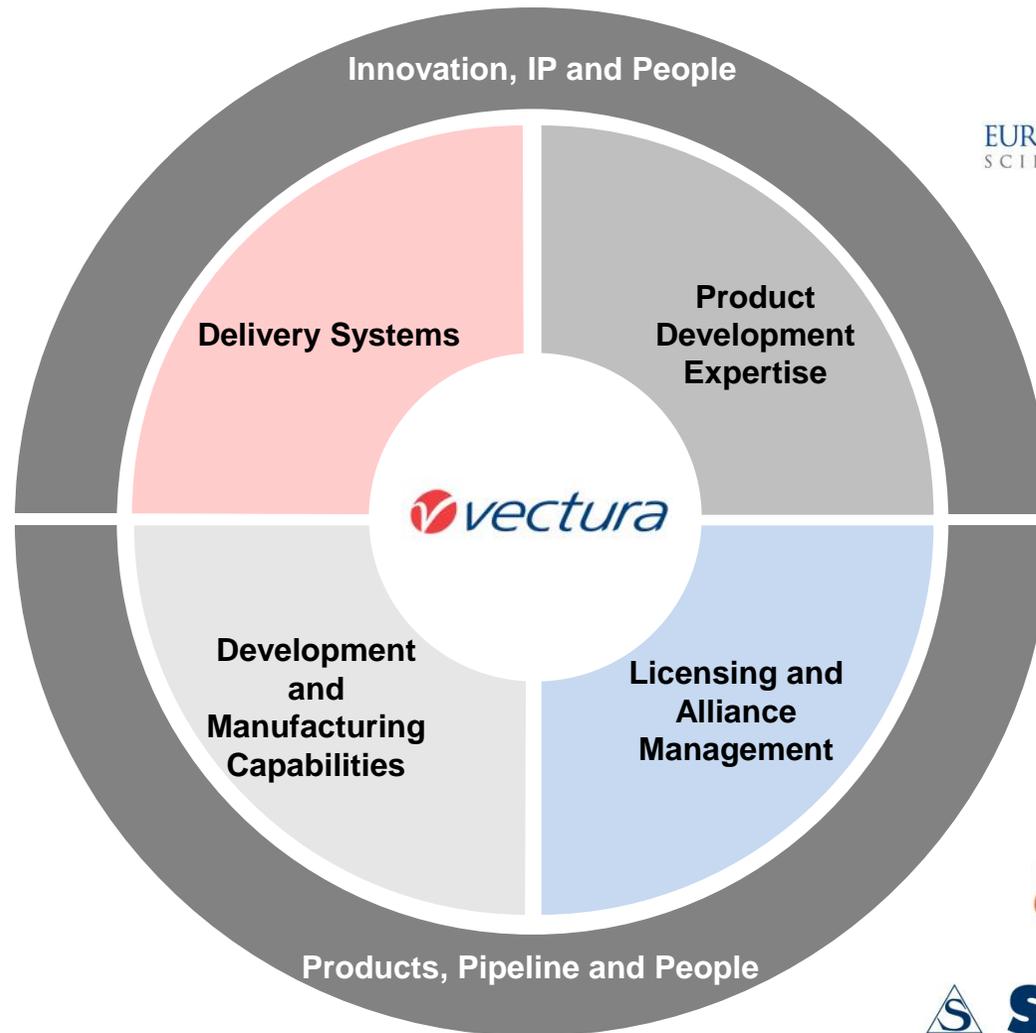
## ✔ **Recent development milestone received in March 2012**

## ✔ **Potential for future licensing**

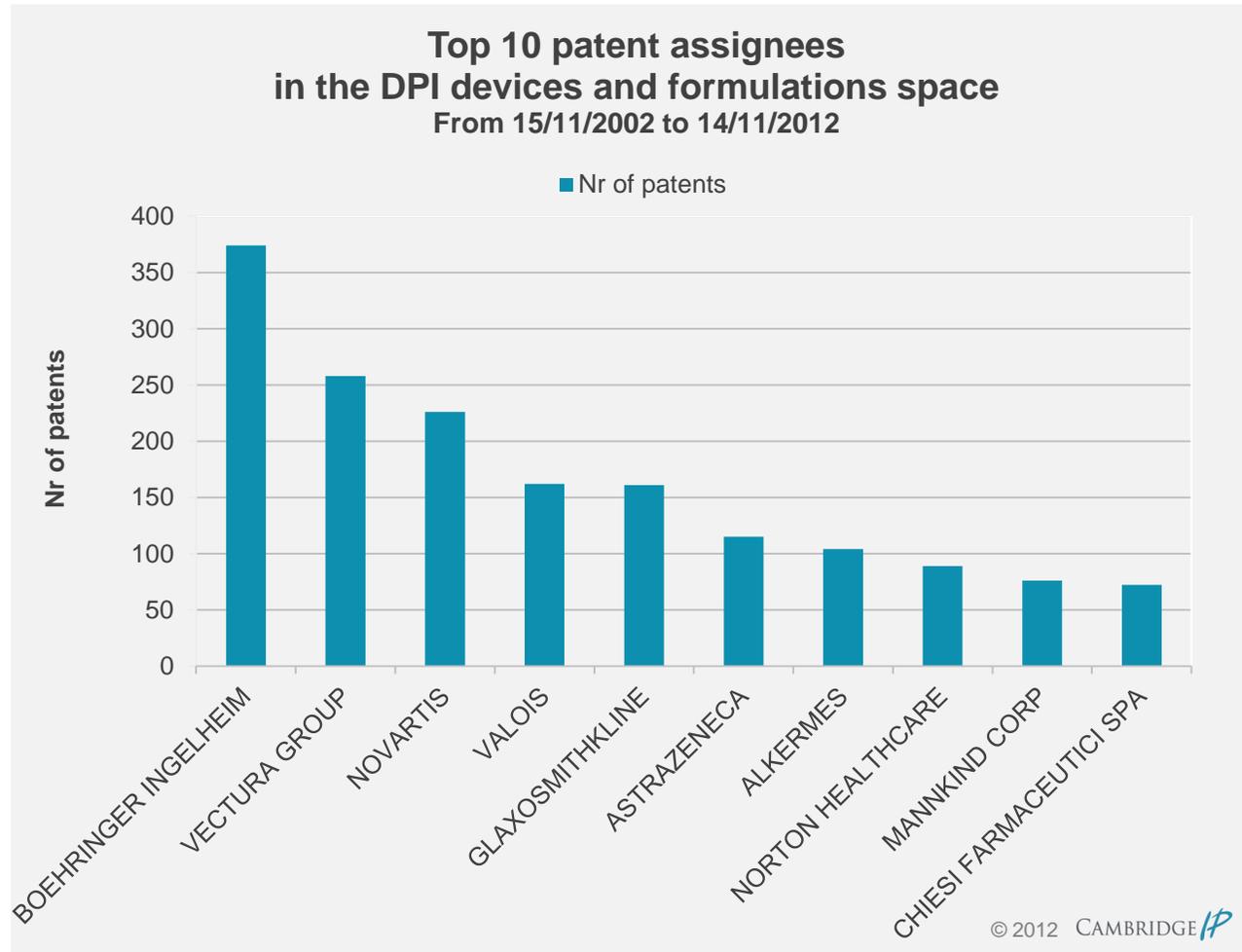
- Vectura retains all rights ex-Europe
- European data useful to support partnering initiatives

## **Vectura's Platform Technology**

# Success Factors in Respiratory Development



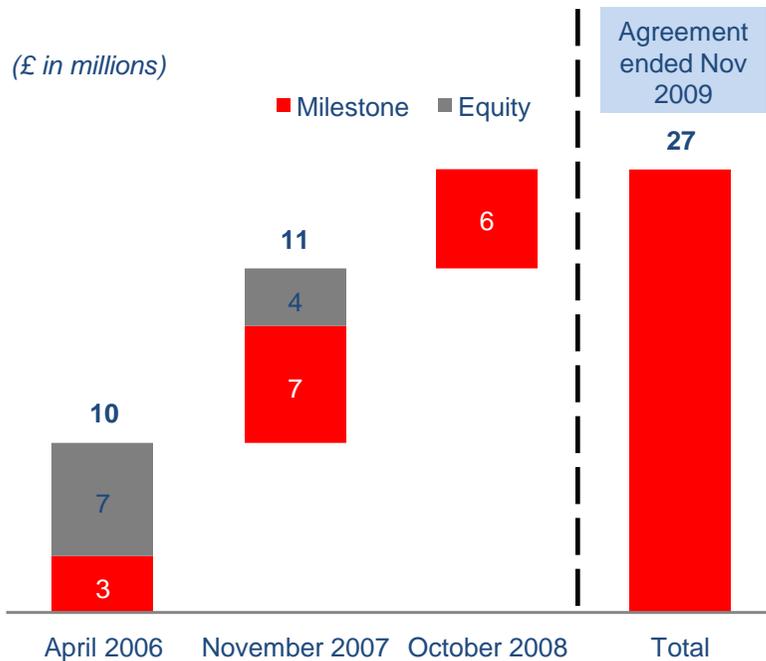
# Significant IP Generation within DPI Space



## Examples of Vectura IP deals

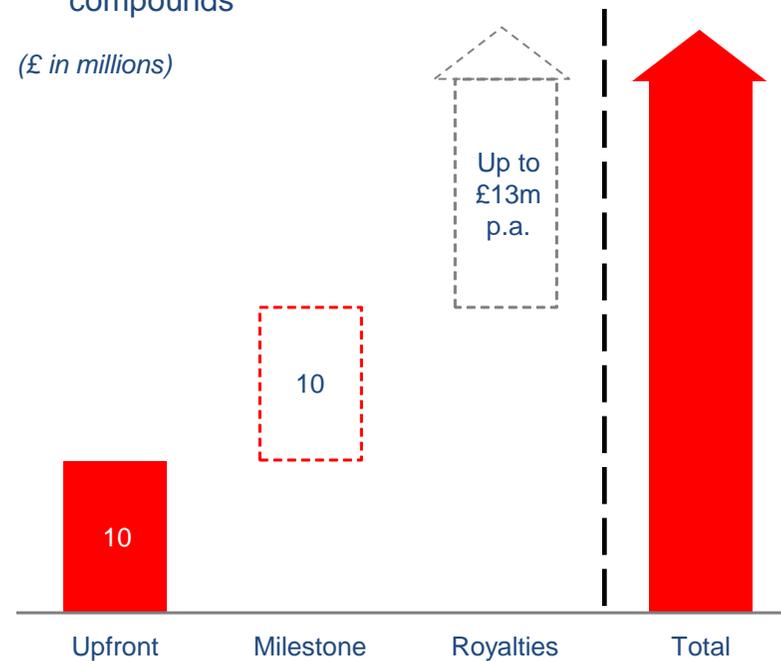
### Boehringer Ingelheim (April 2006)

- Worldwide collaboration, development and licence agreement



### GSK (August 2010)

- Licensing of Vectura's drug formulation patents in relation to two late stage development compounds



No additional investment required to generate these returns

Vectura invests approx. £3m per annum on its patent portfolio

## Attractive returns from IP portfolio and know-how



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## **Financial Results Anne Hyland**

✔ Strong cash balance of £72.1m

✔ Profit after tax of £0.9m

£m	H1 2012/13	H1 2011/12	FY 2011/12
Revenues	17.0	21.1	33.0
Gross profit	16.9	19.7	30.8
EBITDA	2.6	4.9	(4.2)
Profit/(loss) after tax	0.9	2.6	(4.4)
<b>Cash</b>	<b>72.1</b>	<b>80.2</b>	<b>75.5</b>

# Revenue Breakdown

£m	H1 2012/13	H1 2011/12	FY 2011/12	Comments
Royalties	6.1	6.0	13.5	
Product licensing	9.6	10.8	12.1	
Technology licensing	1.1	1.2	2.3	
Pharmaceutical development services	-	1.1	2.8	Work has been successfully completed on partnered projects
Device sales	0.2	2.0	2.3	Stock is now at the required level
<b>Total revenues</b>	17.0	21.1	33.0	

# Income Statement H1 2012/13

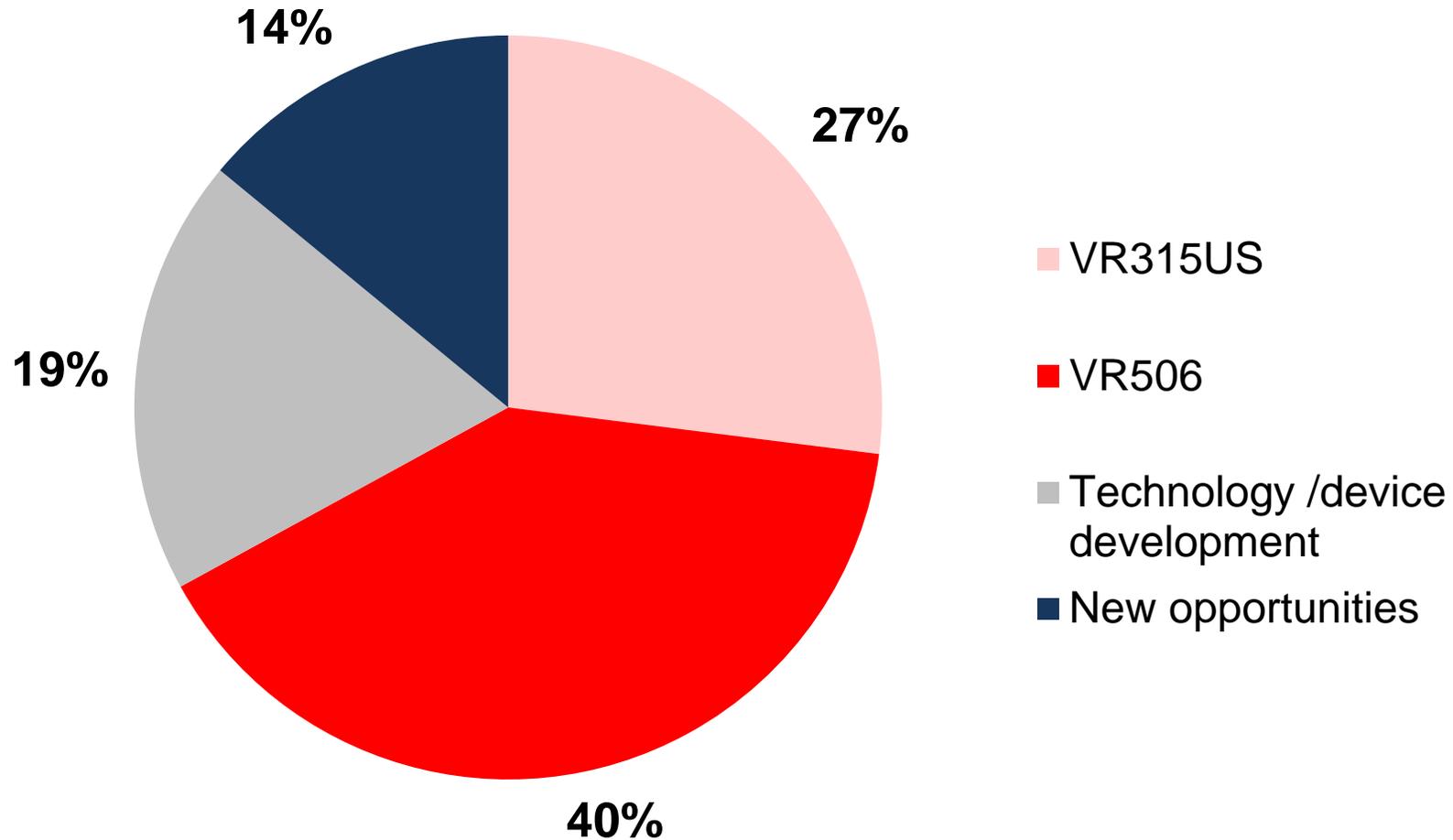


£m	H1 2012/13	H1 2011/12	FY 2011/12	Comments
<b>Revenue</b>	<b>17.0</b>	<b>21.1</b>	<b>33.0</b>	
Gross profit	16.9	19.7	30.8	
R&D costs	(12.8)	(13.3)	(31.7)	Spend weighted towards H2
Administrative costs	(1.5)	(1.5)	(3.3)	
<b>EBITDA</b>	<b>2.6</b>	<b>4.9</b>	<b>(4.2)</b>	
Amortisation	(3.2)	(3.4)	(7.5)	
Depreciation	(0.5)	(0.5)	(1.1)	
Share based-compensation	(0.2)	(0.5)	(1.1)	
<b>Operating (loss)/profit</b>	<b>(1.3)</b>	<b>0.5</b>	<b>(13.9)</b>	
Net finance income	0.2	0.6	0.7	
<b>Pre-tax (loss)/profit</b>	<b>(1.1)</b>	<b>1.1</b>	<b>(13.2)</b>	
Taxation	2.0	1.5	8.8	
<b>Profit/(loss) after tax</b>	<b>0.9</b>	<b>2.6</b>	<b>(4.4)</b>	
<b>Profit/(loss) per share</b>	<b>0.3p</b>	<b>0.8p</b>	<b>(1.3)p</b>	

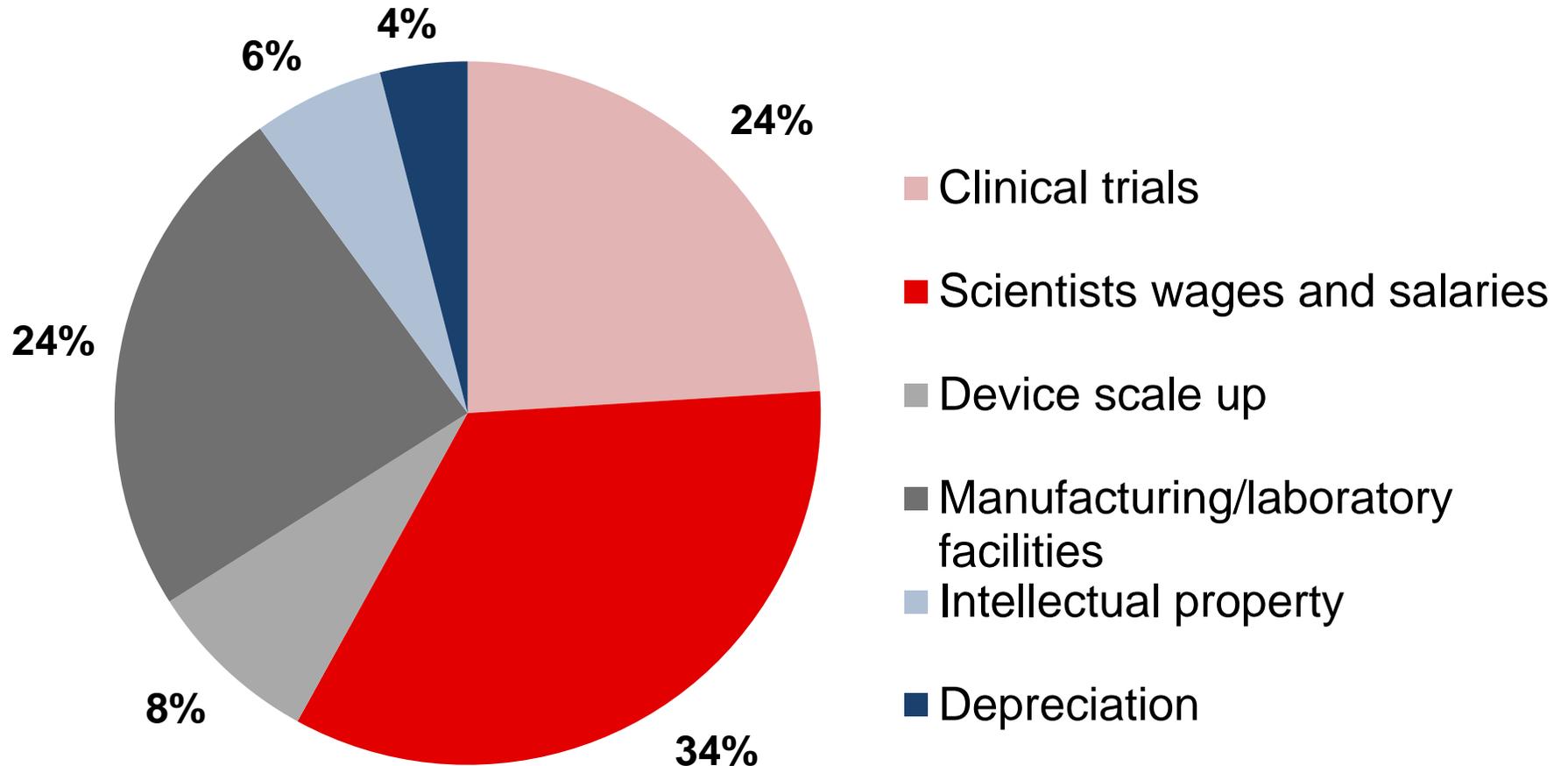
# Cash Flow

£m	H1 2012/13	H1 2011/12	FY 2011/12	Comments
<b>EBITDA</b>	<b>2.6</b>	<b>4.9</b>	<b>(4.2)</b>	
Deferred income	(3.0)	(1.0)	(0.7)	
Working capital	(7.3)	(0.8)	2.4	
Exchange gains	-	0.2	-	
Net taxes received	4.4	-	4.6	11/12 tax credit received early
<b>Operating cash (outflow)/inflow</b>	<b>(3.3)</b>	<b>3.3</b>	<b>2.1</b>	
Investing activities				
▪ Net capital expenditure	(0.7)	(0.3)	(4.2)	Cap Ex will increase in H2 12/13
▪ Interest received	0.2	0.4	0.7	
<b>Cash (outflow)/inflow before financing</b>	<b>(3.8)</b>	<b>3.4</b>	<b>(1.4)</b>	
Financing activities				
▪ Issue of shares	0.4	2.4	2.5	
<b>(Decrease)/increase in cash</b>	<b>(3.4)</b>	<b>5.8</b>	<b>1.1</b>	

# Expected R&D Investment by Project FY12/13



## Expected R&D Investment by Type FY12/13



## Revenue

- Milestone receipts will depend on product filings and approvals
- Royalties expected to increase as Seebri<sup>®</sup> launch rolls out

## R&D investment

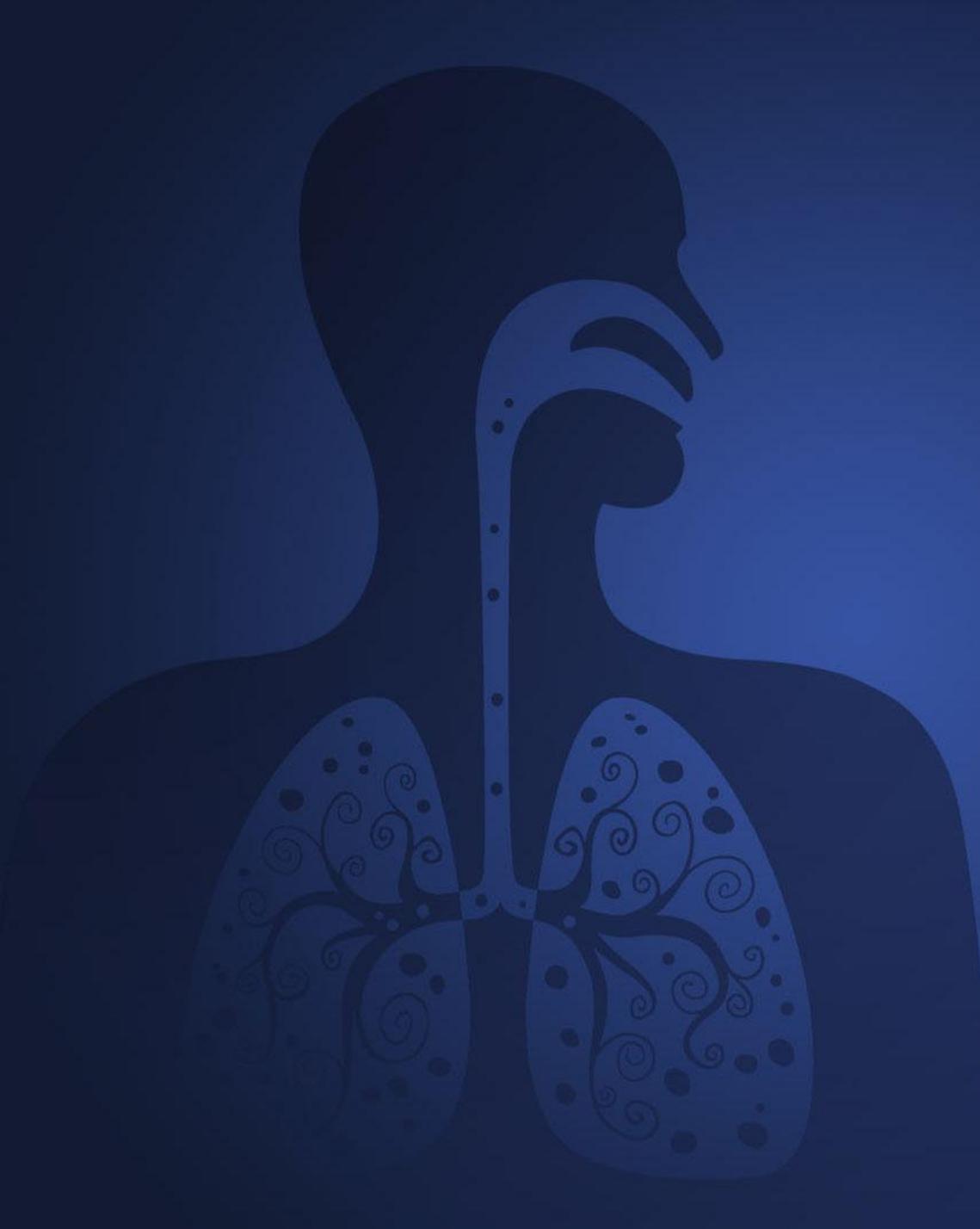
- Main investment is on VR506, VR315 US and device technology
- Ca. 5% reduction in R&D FY 12/13 expected versus FY 11/12

## Administration

- FY 12/13 in line with 11/12 excluding amortisation, share based compensation and any exceptional items

## Cash flows

- Cash inflows/outflows will depend on milestones, royalties and one-off receipts



**Summary**  
**Chris Blackwell**

# Anticipated Near-term Catalysts

	NVA237	QVA149	VR315	VR632	VR506
<b>Short-term</b>	<ul style="list-style-type: none"><li>EU &amp; Japan approval &amp; launch</li></ul> 	<ul style="list-style-type: none"><li>EU &amp; Japan filing</li></ul> 	<ul style="list-style-type: none"><li>US development milestones</li></ul> 	<ul style="list-style-type: none"><li>Final development milestone</li></ul>	<ul style="list-style-type: none"><li>Clinical progress</li></ul>
<b>To follow</b>	<ul style="list-style-type: none"><li>Filing in US</li><li>Approval in US</li></ul>	<ul style="list-style-type: none"><li>Approvals in Europe &amp; RoW</li><li>Approval in Japan</li><li>Filing &amp; approval in US</li></ul>	<ul style="list-style-type: none"><li>Further development milestones</li><li>Approvals in Europe &amp; RoW</li><li>Approval in US</li></ul>	<ul style="list-style-type: none"><li>Approval in Europe</li><li>Licensing for other territories</li></ul>	<ul style="list-style-type: none"><li>Out-licensing and approval</li></ul>

- ❖ **Significant clinical and regulatory success with its key branded programmes, partnered with Novartis**
  - The first launches of Seebri<sup>®</sup> Breezhaler<sup>®</sup> are now underway
  - QVA149 filed for approval in Europe and Japan
  
- ❖ **Generic programmes continue to make progress**
  - Difficult to provide guidance but we believe its a matter of “when, not if”
  
- ❖ **Robust financial position will be supplemented by royalties from Seebri<sup>®</sup> Breezhaler**
  - Additional milestones from Seebri<sup>®</sup> and other pipeline drugs
  - Manage cash spend through product development prioritisation and tight cash control
  
- ❖ **Future strategy will continue to focus on value creation in a prudent manner**
  - We evaluate products to assess suitability for our platform to add value
    - But our model does not encompass spend on highly attritional discovery projects
  - We are evaluating emerging market opportunities to assess our “value brand” offering
    - Local strategies with local players are key