



2011/12 Preliminary Results

26 April 2012



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 **Overview & Corporate update**

Chris Blackwell

 **Financial Results**

Anne Hyland

 **Summary**

Chris Blackwell

Overview & Corporate update

Dr Chris Blackwell

- ✔ A leading developer of respiratory medicines with a range of proprietary technologies
- ✔ Significant validation of technologies and capabilities demonstrated by a history of partnerships and licensing deals
- ✔ Exposure to large and fast growing respiratory markets (>\$25bn) with high barriers to entry but with a well balanced risk profile through:
 - *Limited exposure to new chemical entities*
 - *Diversification across branded and generic products and geographies*
 - *Partnered products, proprietary products; a broad and advanced pipeline*
- ✔ Strong balance sheet supported by existing royalty streams and disciplined R&D investment
- ✔ Step-change in revenues projected as key value driving products reach market, providing a clear route to self sustainability

Vision - self-sustainable cash-generative company focused on the development and commercialisation of products for the treatment of broncho-pulmonary diseases



Strong financial performance

- Revenues ahead of expectations at £33m (2010/11: £42.9m)
- Loss before tax in line with previous year at £13.2m (2010/11 £13.3m)
- Loss after tax reduced by 50% to £4.4m (2010/11: £8.8m)
- Cash and cash equivalents increased by £1.1m to £75.5m at 31 March 2012

NVA237 on track for first launch in 2012

- European Marketing Authorisation Application filed, August 2011 (\$5m milestone receipt)
- European decision expected mid-2012
- New Drug Application (NDA) for Japan filed in November 2011
- Positive Phase III data presented at ERS in September 2011
- US NDA filing expected early in 2014

QVA149 first regulatory submissions expected 2012; first launch expected 2013

- QVA149 (COPD): Positive Phase III data, April 2012 - ILLUMINATE, SHINE, BRIGHT, and ENLIGHTEN all met their respective primary endpoints
- US NDA filing is expected at the end of 2014

VR315 – two major licensing deals

- Agreement signed with Sandoz for Rest of World (RoW) development
- Agreement with the US division of an international pharma company for development and commercialisation in the US - \$10m upfront payment received

New milestone payments demonstrate progress of generic products

- VR315 - \$2m payment from our US partner relating to development progress - March 2012
- VR632 - €0.4m milestone received – March 2012

Leading Development Projects

Innovative

NVA237
(COPD)

QVA149
(COPD)

Respiratory Generics

VR315
(Asthma/COPD)

VR632
(Asthma/COPD)

VR506
(Asthma)

Product & License Revenue

Baxter

Royalties from Advate,
Extraneal, Adept

GSK

Licensed technology
to GSK for key
respiratory products

Device Sales

Revenues from
Vectura devices used
in licensed &
marketed products

Vectura Technologies



ILLUMINATE

- Superior lung function of once-daily QVA149 compared with twice-daily Seretide® in >500 patients

SHINE

- Superior lung function compared with once-daily indacaterol, once-daily NVA237 and open-label tiotropium in 2,144 patients

BRIGHT

- Significantly better exercise endurance versus placebo in 85 patients

ENLIGHTEN

- Well tolerated with a safety and tolerability profile similar to placebo in 339 patients

Leading Development Projects

Innovative

NVA237
(COPD)

QVA149
(COPD)

Respiratory Generics

VR315
(Asthma/COPD)

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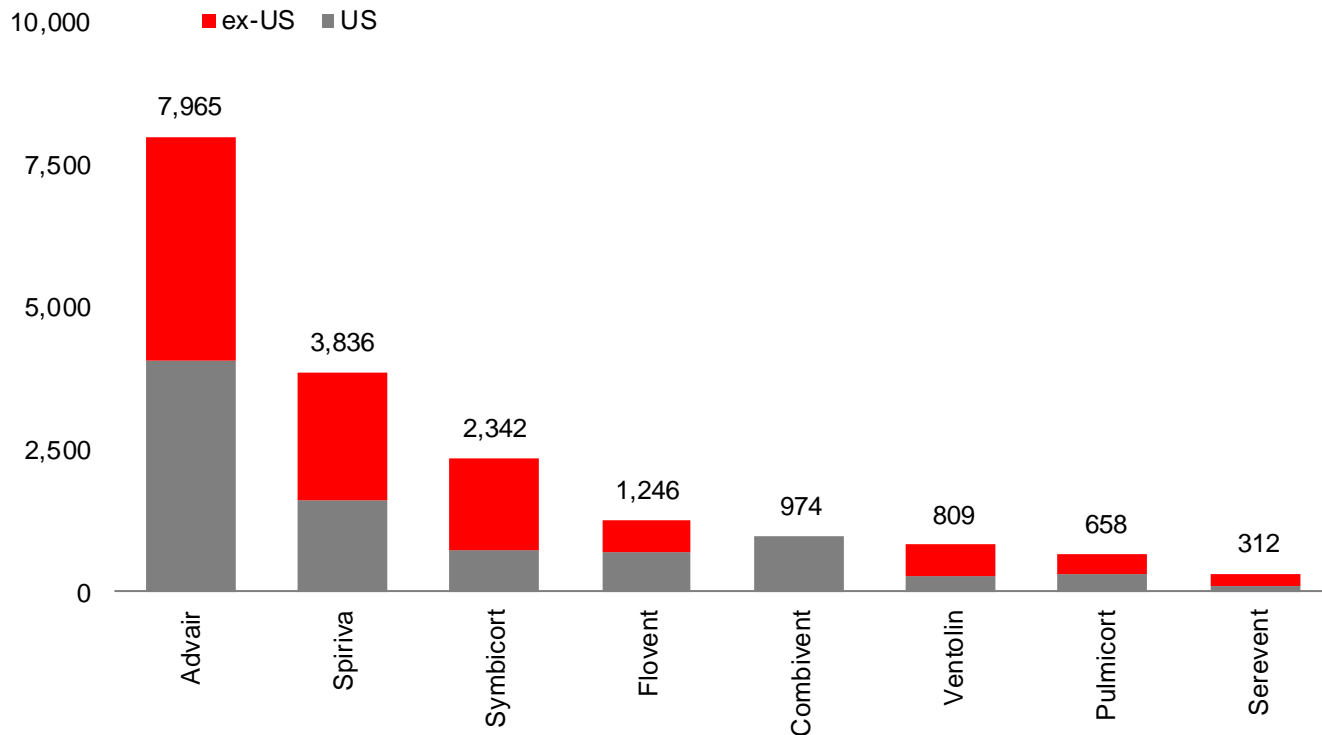
Vectura Technologies



The respiratory market

2010 Reported Worldwide Sales of Key Asthma / COPD drugs

(\$ in millions)



Respiratory market estimated at \$29bn in 2010¹

Commentary

- Respiratory is the 2nd largest global therapeutic category
- Asthma is the largest market within respiratory with further increase in global prevalence forecasted
- Significant proportion of asthma sufferers require long-term treatment
- COPD is a significant cause of mortality (3rd in US, 4th globally to rise to 3rd by 2030²)

Source: Company annual filings

1: Cowen (March 2011)

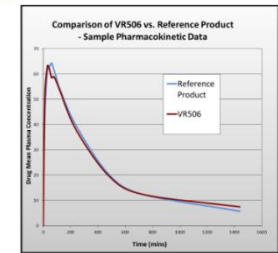
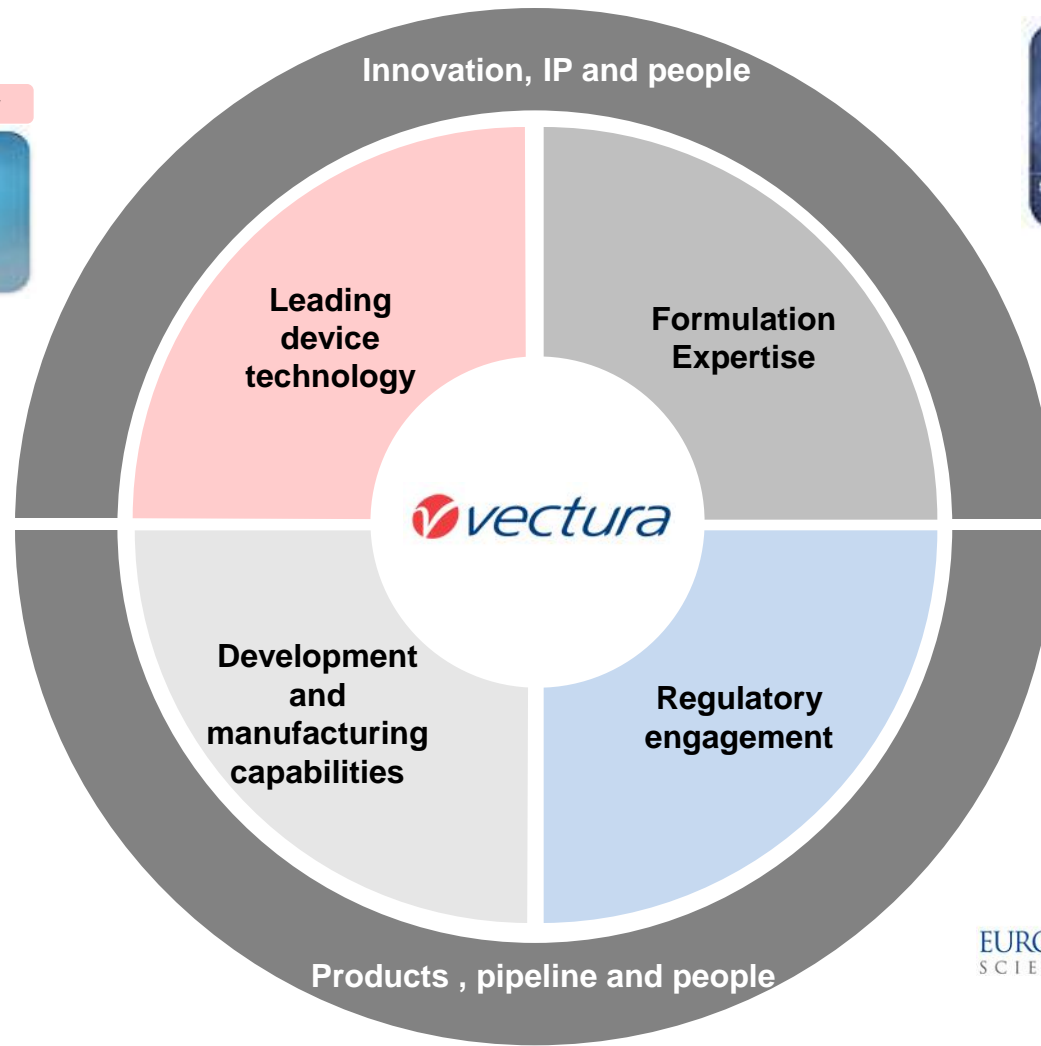
2: WHO

Large market with limited competition

- ❖ Limited competition in respiratory space – barriers to entry restrict number of players, even for generics
- ❖ Difficult to manufacture and develop due to the technical expertise needed
- ❖ Vectura has the capability to compete in a space that is normally restricted to the largest of players
- ❖ Significant need for novel therapies and generics



Success factors in respiratory development



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Grow revenues from high value out-licensing and commercialisation of branded and generic products:

High value out-licensing

- ✓ High value products requiring broad promotional efforts to be licensed to partners
- ✓ Technology to be licensed to partners
- ✓ Downside is capped – cost of large scale Phase III trials borne by partners
- ✓ Vectura avoids the speculative risk of pre-clinical research – focused on adding value to promising molecules and in-licensing at later stage

Generics

- ✓ Focus on large generic opportunities with high technical barriers to entry
 - ✓ Areas where Vectura can add value rather than compete in commodity generics
- ✓ Out-license to partners
- ✓ Leverage partners' commercial infrastructure
- ✓ Use of technology to gain a competitive advantage where possible

Commercialisation

- ✓ Third party commercialisation whilst retaining product ownership
- ✓ Additional commercialisation of products with an attractive risk-reward profile
 - ✓ Capture a large share of the of the value chain in selected territories

To deliver significant value and benefit to shareholders and patients

High value out-licensing

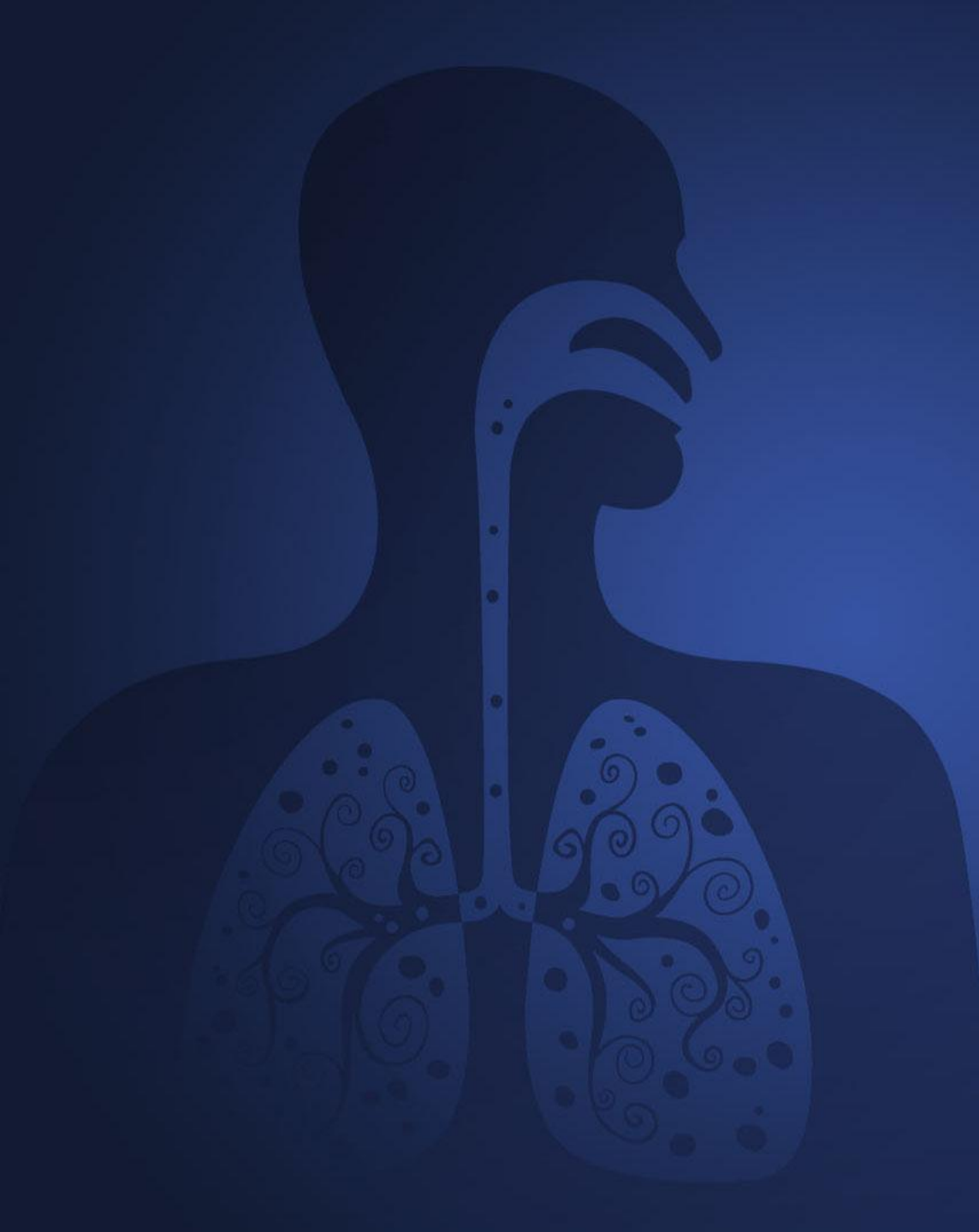
- ✔ Expected NVA237 approval in Europe and RoW
- ✔ QVA149 milestones following regulatory submission in initial territories
- ✔ VR506 clinical package to provide attractive licensing opportunity

Generics

- ✔ VR315
- ✔ VR632
- ✔ VR506

Portfolio development and commercialisation

- ✔ Leverage current assets for low risk exploitation of emerging market opportunities
- ✔ Identify new pipeline opportunities to build on near-term revenues and strengthen self-sustainability
- ✔ In the future, capture opportunities that facilitate direct revenue generation



Financial Results

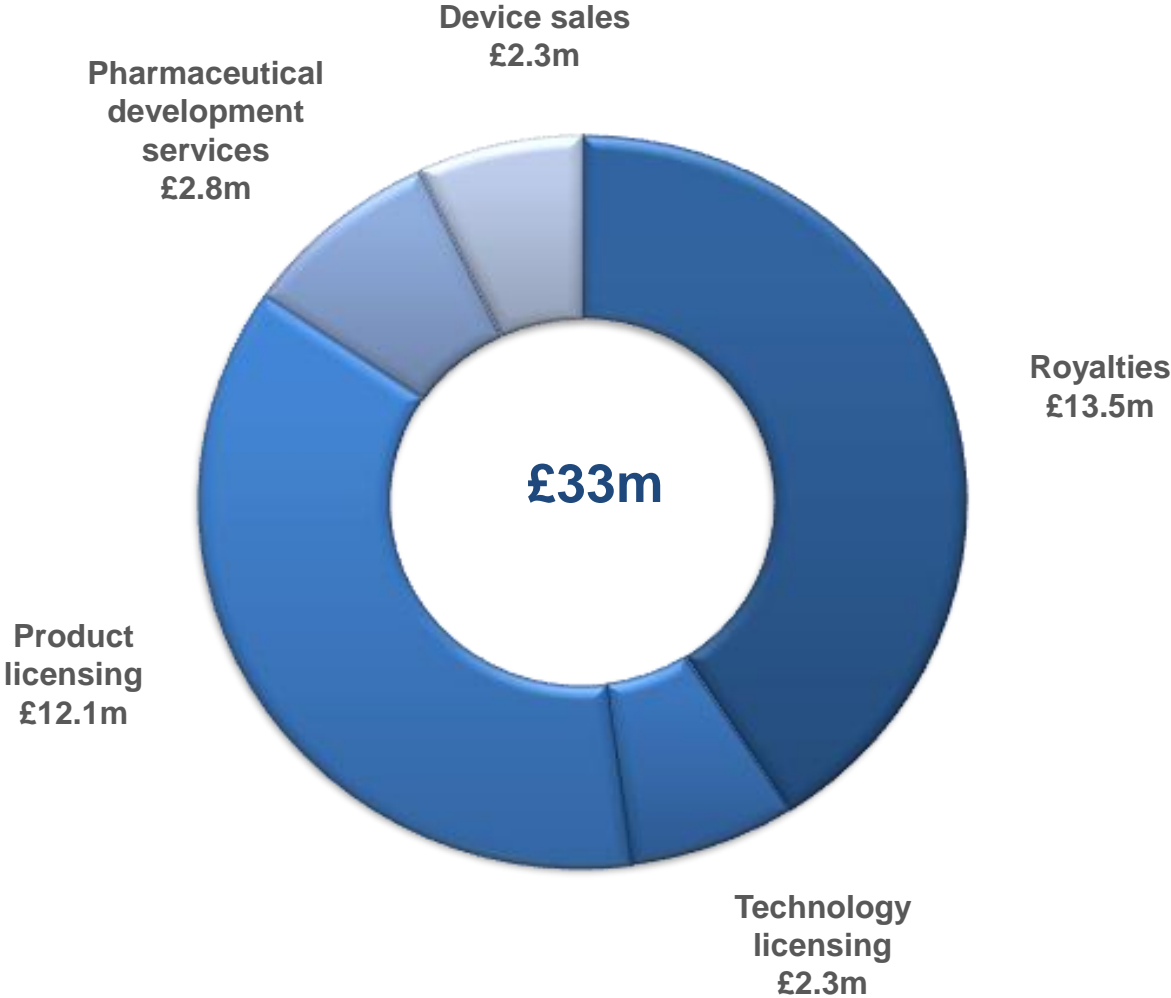
Anne Hyland

Financial highlights

- ✔ Revenues ahead of expectations
- ✔ Operating loss in line with previous year despite fall in revenues
- ✔ Continued disciplined investment in R&D

£m	2011/12	2010/11
Revenues	33.0	42.9
<i>Gross profit margin</i>	93%	94%
R&D investment	(32.8)	(37.7)
Operating Loss	(13.2)	(13.3)
Loss after tax	(4.4)	(8.8)
Cash and cash equivalents	75.5	74.4

Diversified revenue streams



Revenue breakdown



£m	2011/12	2010/11	Increase/ (decrease)	Comments
Royalties	13.5	13.6	(1%)	
Product licensing	12.1	10.6	14%	Two new VR315 deals in 11/12
Technology licensing	2.3	12.9	(82%)	GSK £10m included in 10/11
Pharmaceutical development services	2.8	4.2	(33%)	Work completed on partnered EU generic programmes
Device sales	2.3	1.6	44%	Inventory build
Total revenues	33.0	42.9	(23%)	

Income statement



- ✔ Revenues in excess of R&D costs
- ✔ Loss per share decreased to 1.3p (2010/11: 2.7p)

£m	2011/12	2010/11	Increase/ (decrease)	Comments
Revenue	33.0	42.9	(23%)	GSK £10m receipt 10/11
Gross profit	30.8	40.2		
Gross profit margin	93%	94%		
R&D costs	(31.7)	(36.4)	(13%)	Disciplined R&D investment
Administrative costs	(3.3)	(3.3)		
EBITDA	(4.2)	0.5		
Amortisation	(7.5)	(10.7)	(30%)	Extraneal amortisation charge decrease
Depreciation	(1.1)	(1.3)		
Share based-compensation	(1.1)	(1.8)		
Operating loss	(13.2)	(13.3)		
Investment income	0.7	0.8		
Finance costs	-	(0.8)		
Pre-tax loss	(13.2)	(13.3)		

Cash flow

£m	2011/12	2010/11	Comments
EBITDA	(4.2)	0.5	
Deferred income	(0.7)	2.8	
Working capital	2.4	0.2	Favorable supplier payment schedules
Exchange (losses)	-	(0.8)	
Net taxes received	4.6	8.1	Two years tax receipts in 10/11
Operating cash inflow	2.1	10.8	
Investing activities			
▪ Net capital expenditure	(4.2)	(1.4)	Manufacturing facilities
▪ Interest received	0.7	0.7	
Cash (outflow)/inflow before financing	(1.4)	10.1	
Financing activities			
▪ Issue of shares	2.5	0.2	
Increase in cash	1.1	10.3	

Revenue

- Milestone receipts will depend on product filings and approvals
- Royalties may increase if a new product launches

R&D investment

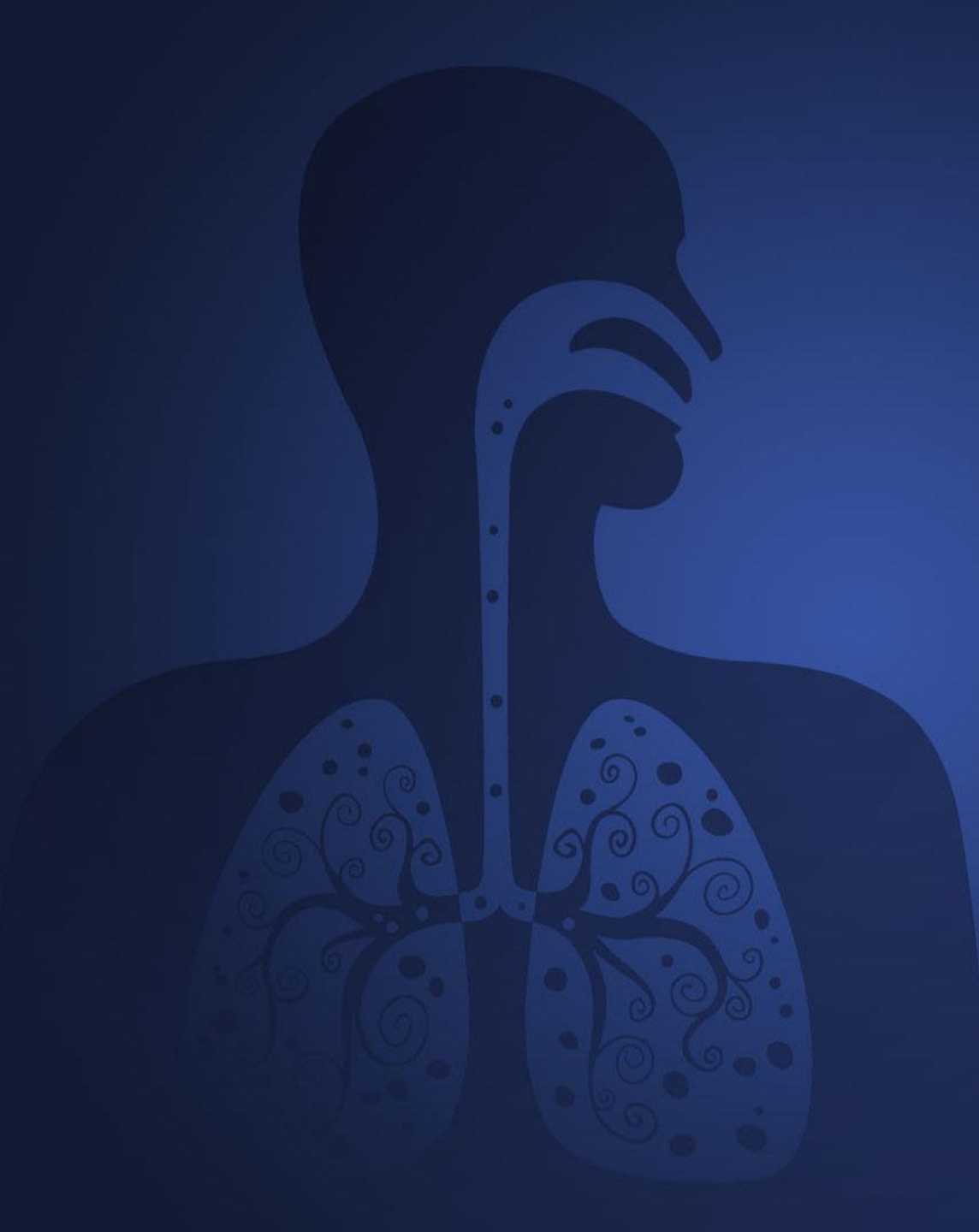
- Main investment is on VR506, VR315 and device technology
- Circ. 5% reduction in R&D expected

Administration

- In line with 2011/2012 excluding amortisation, share based compensation and any exceptional items

Cash flows

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



Summary

Dr Chris Blackwell

Near-term catalysts

	NVA237	QVA149	VR315	VR632	VR506
Short-term	<ul style="list-style-type: none"> Expected EU approval Results from GLOW-2 in H1 2012 	<ul style="list-style-type: none"> Phase III data for COPD in H2 2012 First filing expected in 2012 	<ul style="list-style-type: none"> US development milestones 	<ul style="list-style-type: none"> Final development milestone 	<ul style="list-style-type: none"> Clinical progress

To follow	<ul style="list-style-type: none"> Expected approval in Japan 	<ul style="list-style-type: none"> Expected approval in Europe 	<ul style="list-style-type: none"> Expected European & RoW approvals 	<ul style="list-style-type: none"> Expected approval in Europe 	<ul style="list-style-type: none"> Out-licensing and expected approval
	<ul style="list-style-type: none"> Expected filing in US 	<ul style="list-style-type: none"> Expected approval in Japan 	<ul style="list-style-type: none"> Expected approval in US 	<ul style="list-style-type: none"> Licensing for other territories 	
	<ul style="list-style-type: none"> Expected approval in US 	<ul style="list-style-type: none"> Expected filing in US Expected approval in US 			

Strong competitive profile

- Working in key therapeutic area for existing and new franchises
- Involved with major respiratory players and products
- Key value driving products close to market

Financial security

- Solid revenues of £33m
- Cash position at 31 March 2012 of £75m
- Manage cash spend through product development prioritisation

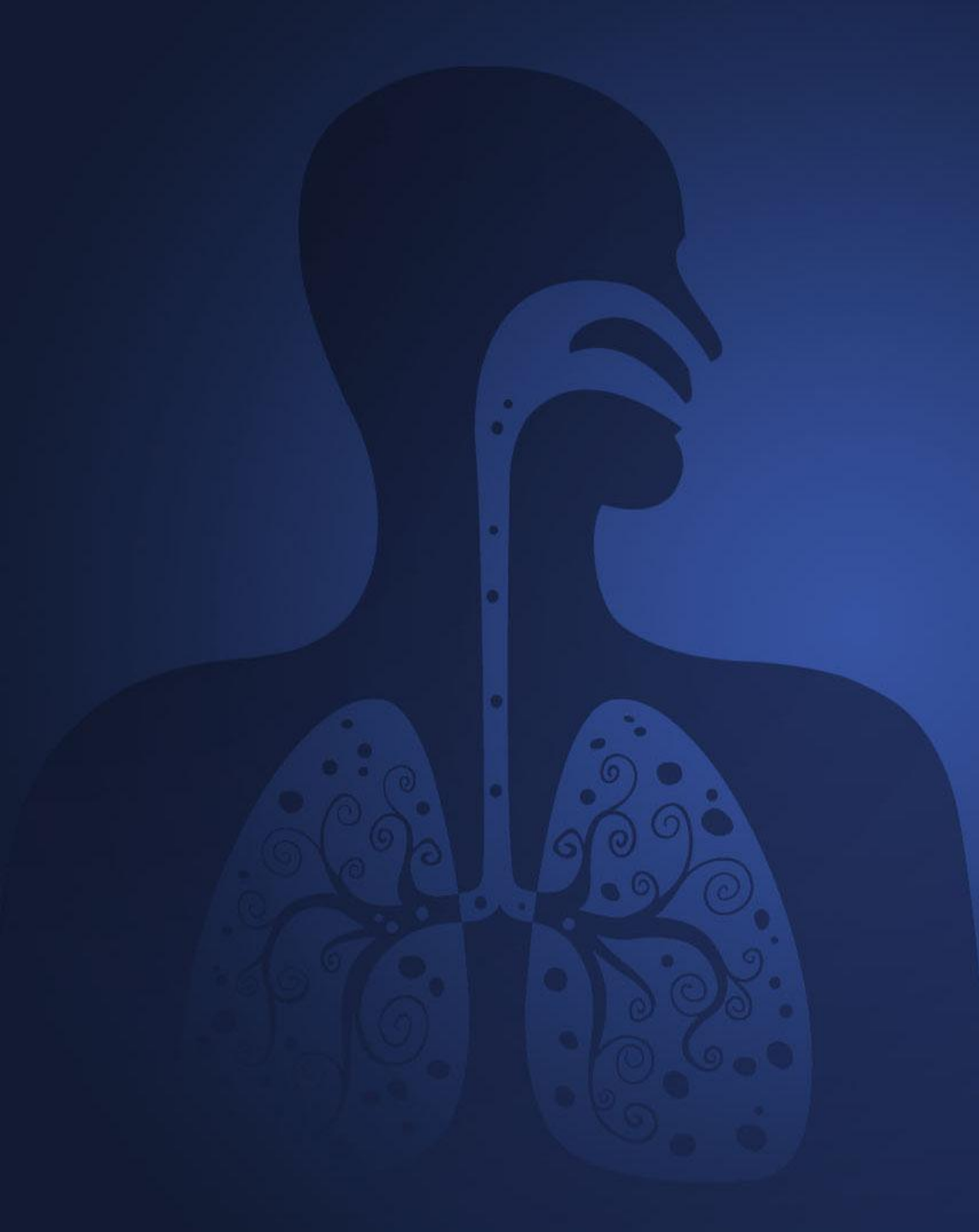
Near-term value potential

- Significant catalysts over the next 12 months
- Near-term regulatory validation
- 4 products in late-stage trials approaching commercialisation
- Step-change in royalty revenues expected
- Partner validated technologies
- Broader market opportunities e.g. emerging markets

On track to become a self-sustainable, cash-generative company



 *vectura*



Appendices:

Priority pipeline details

NVA237 is a once-daily, long-acting, rapid onset drug for COPD



- ✔ NVA237 is an investigational dry powder inhaled formulation of glycopyrronium bromide. It was licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei
- ✔ Mechanism of action
NVA237 is a long-acting muscarinic antagonist (LAMA) with a rapid onset of activity at first dose. It is designed to treat the symptoms of COPD by increasing the diameter of the airways in the lungs (bronchodilation), allowing the patient to breathe more effectively
- ✔ Market opportunity
Twenty million people suffer from this condition in the US. Muscarinic antagonists represent an important part of this global market, treating 30-50% of COPD patients. The American Thoracic Society recommends their use as first-line treatment for COPD
- ✔ Competition
Vectura believes that NVA237 will be the second once-a-day muscarinic antagonist to be approved for COPD. Novartis intends to launch NVA237 as a differentiated LAMA for treating COPD

Key highlights

- ✔ Phase III initiated June 2009; \$7.5m milestone received
- ✔ Phase III data (ERS 2011) confirmed efficacy vs placebo: superior 24-hour bronchodilation, rapid onset of action at first dose and decreased risk of COPD exacerbations, in addition to a positive effect on exercise endurance
- ✔ Filed in Europe in September 2011 under the brand name Seebri® Breezhaler® - \$5m milestone received
- ✔ EU decision expected mid-2012
- ✔ Additional Phase III data expected in H1 2012
- ✔ First launch expected in 2012
- ✔ US NDA filing expected early in 2014

QVA149 is a once-daily combination drug for COPD



- ✔ **QVA149 is a fixed dose combination of NVA237 and Novartis' once-daily, long-acting beta-agonist (LABA) indacaterol (QAB149) and is under development by Novartis**
- ✔ **Mechanism of action**
Indacaterol works by stimulating beta-2 receptors in the smooth muscle of the airways. This causes relaxation of the muscle, thereby increasing the diameter of the airways, which become constricted in asthma and COPD. Indacaterol, given once-daily, has been shown to have a similar rapid onset to NVA237 at first dose and to benefit lung function. The dual activity of a muscarinic antagonist (NVA237) and indacaterol has the potential to be a potent bronchodilator and could address a large unmet need for COPD patients
- ✔ **Market opportunity**
Twenty million people suffer from this condition in the US. Muscarinic antagonists represent an important part of this global market, treating 30-50% of COPD patients. The American Thoracic Society recommends their use as first-line treatment for COPD
- ✔ **Competition**
Vectura believes that QVA149 is the most advanced once-daily LAMA/LABA combination in development and could be the first such combination to come to market for COPD

Key highlights

- ✔ Phase III trial initiated May 2010; \$7.5m milestone received
- ✔ Indacaterol (Onbrez® Breezhaler®) launched in Europe with an FDA approval of the 75 mcg dose received in July 2011
- ✔ Phase II data (ERS 2009) - 110µg/50µg (QAB149/NVA237), 226mL Day 7 trough FEV₁ improvement over placebo, 123mL and 117mL Day 7 trough FEV₁ improvements over indacaterol 300µg and 600µg respectively
- ✔ Positive Phase III data announced in April 2012 achieving all primary endpoints
- ✔ Additional Phase III data to be published at a conference in H2 2012
- ✔ Filing in Europe and other countries, including Japan, expected in 2012
- ✔ First launch expected in 2013
- ✔ US NDA filing is expected at the end of 2014

VR315 is an inhaled combination asthma/COPD therapy



- ✔ **VR315 is an inhaled combination therapy for asthma and COPD that is being developed as a generic product using the GyroHaler® dry powder inhaler (DPI) delivery device. Vectura licensed the European rights for VR315 to Sandoz in March 2006 and the RoW rights to the same Company in August 2011. Also in August 2011 Vectura licensed the US rights to an undisclosed leading International Pharmaceutical Company**
- ✔ **Market opportunity**
There are over 17 million people suffering from asthma in the US and prevalence continues to rise. However, the disease remains under-treated due to a combination of under-diagnosis, inappropriate therapy, and patient non-compliance. Inhaled fixed-dose combination therapy is the use of two or more drugs in combination in an inhaler to gain optimal clinical benefits by improving patient compliance and efficacy. Combination therapy for asthma is the biggest and fastest growing sector of the asthma market
- ✔ **Competition**
In addition to the current branded combination products, VR315 will be competing with new asthma therapies and other generic products. Vectura believes that the unique performance of GyroHaler® gives VR315 a good competitive position against other generics

Key highlights

- ✔ **European rights licensed to Sandoz in March 2006**
 - €22.5m in milestones and development funding
 - Margin on the commercial manufacture and supply of GyroHaler®
 - Royalty on all EU sales
- ✔ **RoW rights licensed to Sandoz in August 2011**
 - Milestones and advance pre-launch royalties of up to €8m
 - Margin on the commercial manufacture and supply of GyroHaler®
 - Royalty on net sales
- ✔ **US rights licensed to an undisclosed leading international pharmaceutical company in August 2011**
 - Upfront payment of \$10m
 - Development milestones
 - Royalty on all US sales

VR632 is an inhaled combination asthma/COPD therapy



- ✔ VR632 is an inhaled combination therapy for asthma and COPD that is being developed as a generic product using the GyroHaler® dry powder inhaler (DPI) delivery device. Vectura licensed the European rights for VR632 to Sandoz in December 2007
- ✔ **Competition**
In addition to the current branded combination products, VR632 will be competing with new asthma therapies and other generic products. Vectura believes that the unique performance of GyroHaler® gives VR632 a good competitive position against other generics

Key highlights

- ✔ European data useful for US/RoW partnering
- ✔ Potential for future licensing ex Europe

VR506 is a monotherapy DPI inhaled corticosteroid for asthma



- ✔ Significant US and EU markets, with the branded product achieving 2010 sales of \$1b
- ✔ Enhanced value opportunity post-LABA moratorium

Key highlights

- ✔ Clinical programmes on-going

Validating deal with GSK

- ✔ Formulation technologies allowing use of some of our drug formulation patents for two late-stage development compounds in asthma/COPD
- ✔ £10m up-front payment received; a further £10m expected and royalties on sales of up to £13m p/a

Key highlights

- ✔ Clinical programmes on-going