

# Berenberg European Conference

4<sup>th</sup> December 2013

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# Highlights

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From our interim financial results 2013/14

## Operational highlights

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- ✔ Approval of Ultibro<sup>®</sup> Breezhaler<sup>®</sup> in Europe
- ✔ Approval of Ultibro<sup>®</sup> Inhalation Capsules in Japan
- ✔ Co-development of innovative product with UCB
- ✔ Chinese JV established

## Financial highlights

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- ✔ Revenues of £17.0m in line with expectations
  - New royalty streams starting
- ✔ Positive EBITDA of £2.3m
- ✔ Loss before tax of £1.2m
- ✔ Robust balance sheet
  - Cash and cash equivalents of £65.5m

# Financial highlights



£m	H1 2013/14	H1 2012/13	FY 2012/13
Revenue	17.0	17.0	30.5
Gross profit	16.9	16.9	29.8
EBITDA	2.3	2.6	(3.4)
Loss before tax	(1.2)	(1.1)	(10.4)
Cash	65.5	72.1	70.1

Positive EBITDA of

**£2.3m**

(H1:2012/13 - £2.6m)

Balance sheet strength  
maintained with cash of

**£65.5m**

(FY:2012/13 - £70.1m)

# Overview & outlook



## Marketed & late-stage respiratory programmes licensed to Novartis

- Seebri® Breezhaler® (glycopyrronium bromide, NVA237) launch underway in EU & Japan
- Two late-stage, branded, investigational assets: NVA 237 (US) & QVA149 (US)
- Comprehensive development programmes for both drugs fully funded by Novartis



## Pipeline portfolio encompasses both branded & generic respiratory drugs

- Ultibro® Breezhaler®(QVA149) approved in Europe and Japan
- Novel biological asset (VR942) from UCB added for severe respiratory disease indication
- Three generic programmes underway; FDA guidelines are a positive step



## JV in China announced on 13 May 2013

- Access to fast growing Asian respiratory markets
- No cash outlay; leveraging our entire asset base



## Strong balance sheet with £65.5m in cash

- Supported by existing royalty streams and additional near-term milestone payments
- New growing royalty streams starting
- Complimented by a disciplined approach to cost control

# Assets licensed to Novartis



## Seebri<sup>®</sup> Breezhaler<sup>®</sup> & Ultibro<sup>®</sup> Breezhaler<sup>®</sup>

- ✔ Seebri<sup>®</sup> Breezhaler<sup>®</sup> approved in more than 50 countries<sup>1</sup>
  - Including the EU, Japan, Switzerland, Canada & Australia
  - Market roll out is underway by Novartis
- ✔ NVA237 Phase III clinical trial programme for US on-going
  - Being undertaken by Novartis
  - US filing expected H1, 2014
- ✔ Ultibro<sup>®</sup> Breezhaler<sup>®</sup> approved in Europe and Japan<sup>2</sup>
  - Launched in the Netherlands and Germany
  - New royalty streams to Vectura anticipated from Q1, 2014
- ✔ Novartis expected to file QVA149 in US by end 2014
  - Comprehensive COPD registration trial programme undertaken by Novartis

<sup>1</sup>Seebri<sup>®</sup> Inhalation Capsules in Japan <sup>2</sup> Ultibro<sup>®</sup> Inhalation Capsules in Japan  
Seebri<sup>®</sup> Breezhaler<sup>®</sup> & Ultibro<sup>®</sup> Breezhaler<sup>®</sup> are registered trademarks of Novartis AG



# VR942 A novel biological therapy

## Targeting severe inflammatory airways disease



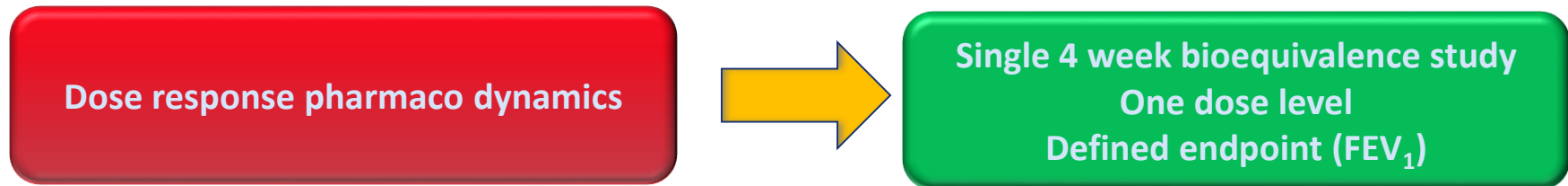
- ✔ Co-development with UCB
- ✔ Endorses Vectura's capability to develop a range of inhaled drugs
  - Formulation and delivery of large and potentially complex molecules
  - Leverages technical, clinical and regulatory expertise
- ✔ Commercially-attractive market segment
  - Severe inflammatory respiratory disease
- ✔ Co-development deal; early-stage
  - Adds a partner with excellent pedigree in biologicals and immunology
  - Innovative asset with attractive, undisclosed terms

# Respiratory generics

## Partnered for success



- ✓ Understanding of complex regulatory requirements
  - Significant interaction with regulators and fit with our on-going process, particularly the EMA and FDA
- ✓ Draft FDA guidelines provide clarity



- ✓ Remainder of guidelines remain the same
- ✓ Similar device shape and instructions
  - Qualitative and quantitative formulation (same ingredients in same ratio as reference; +/- 5%)
  - *In vitro* equivalence at three flow rates (30, 60, 90 litres/min)
  - Pharmacokinetic bioequivalence

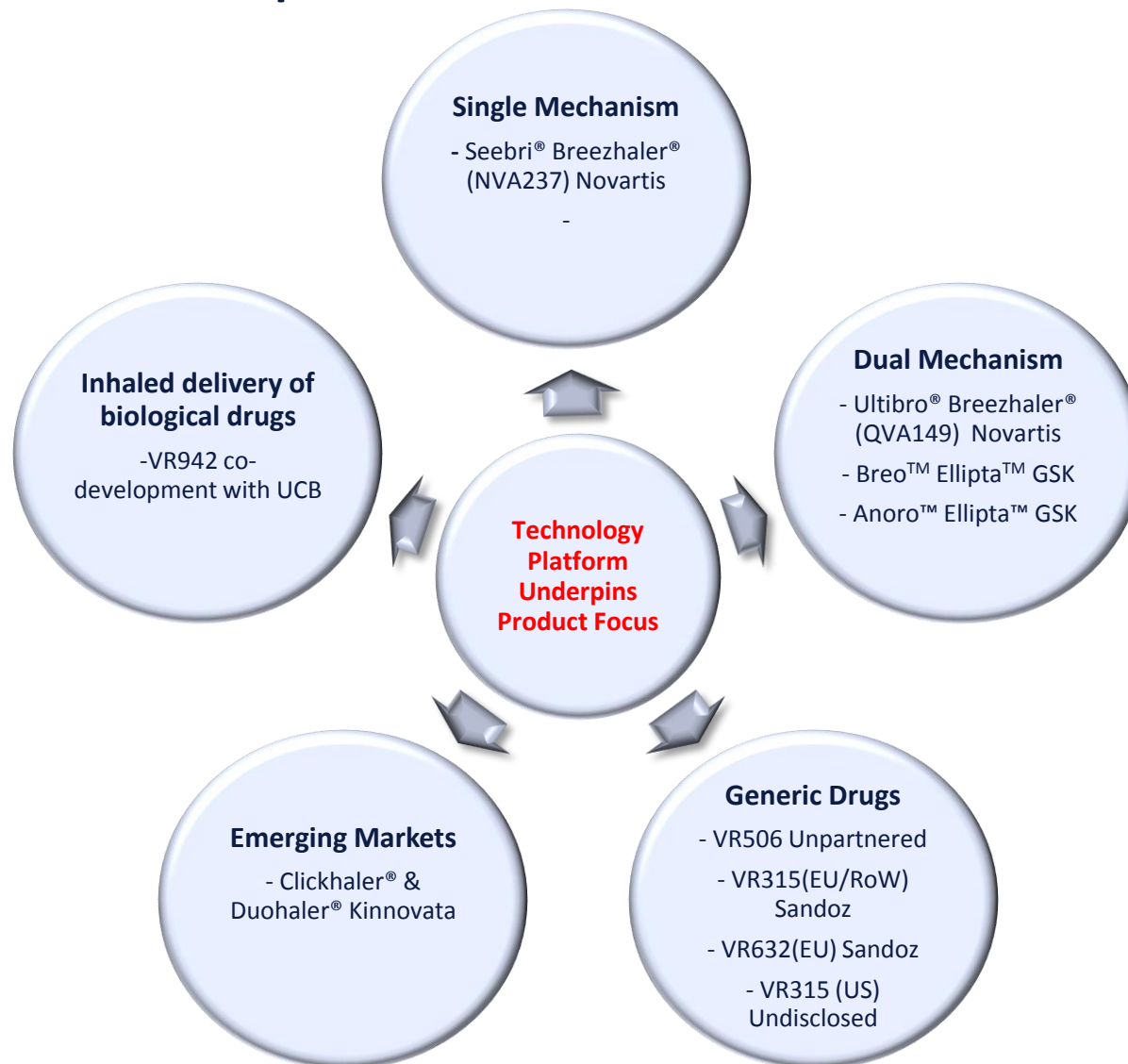
# Respiratory generics



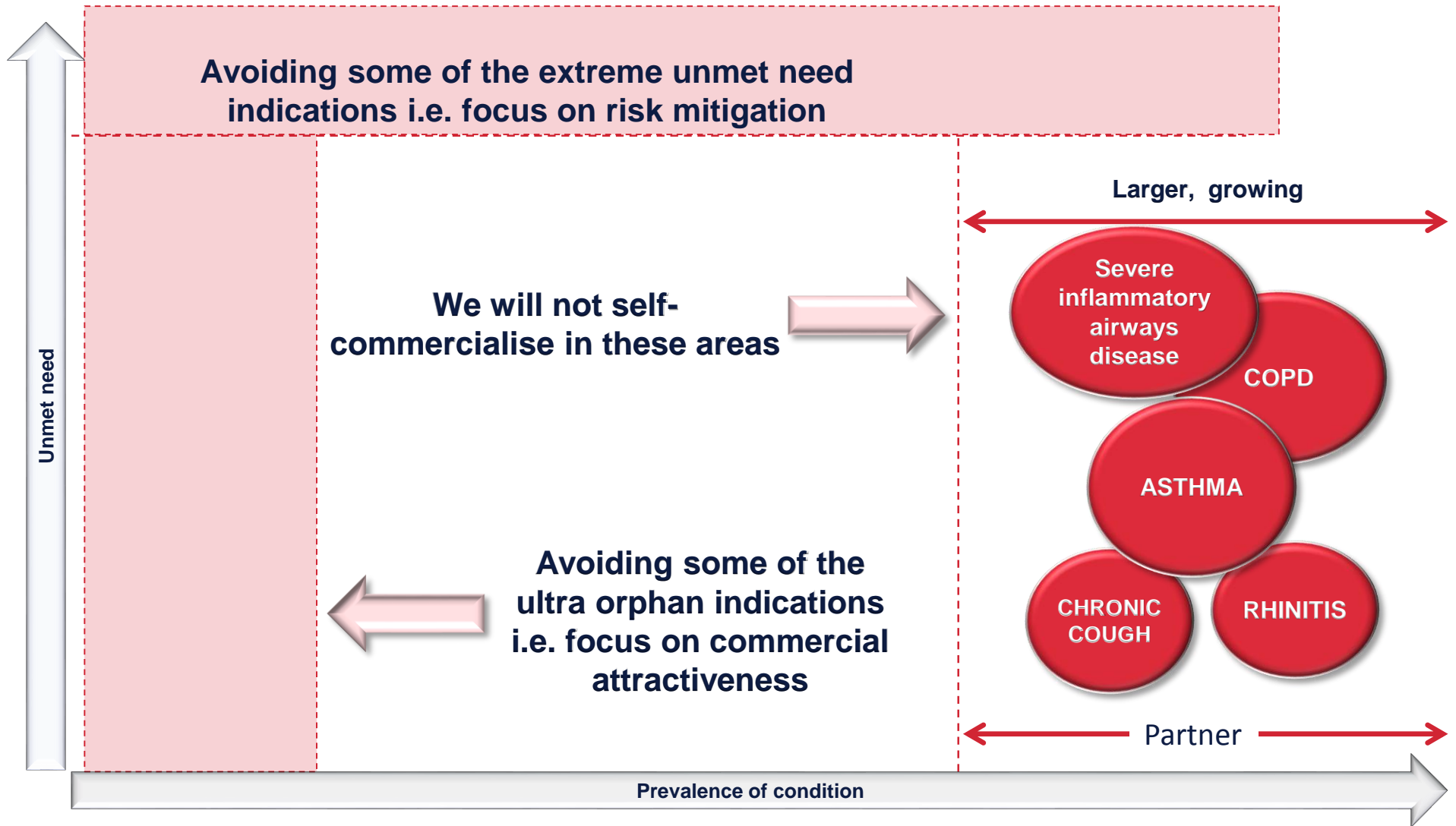
## Leveraging our in-house expertise and know-how

- **Focus on high-value, non-commodity products**
  - VR315 - Licensed in EU/RoW (Sandoz) and in US (undisclosed partner)
  - FDA guidelines positive for companies developing “substitutable products”
  - VR632 - Licensed in EU (Sandoz)
  
- **VR506 - Development on-going; strong out-licensing candidate**
  - Two international, multi-centre clinical trials underway in mild-moderate and moderate-severe asthma
    - Trial 002: 374 patients; recruitment complete; top line results positive
    - Trial 004: 174 patients; expected read-out during H1, 2014
  
- **Delivery device technology - competitive product design**
  - Performance engineered to match brand-leaders
  - Easy-to-use utilising an inexpensive, minimalist design
  - Accurate, reproducible dosing through excellent protection of the powder formulation

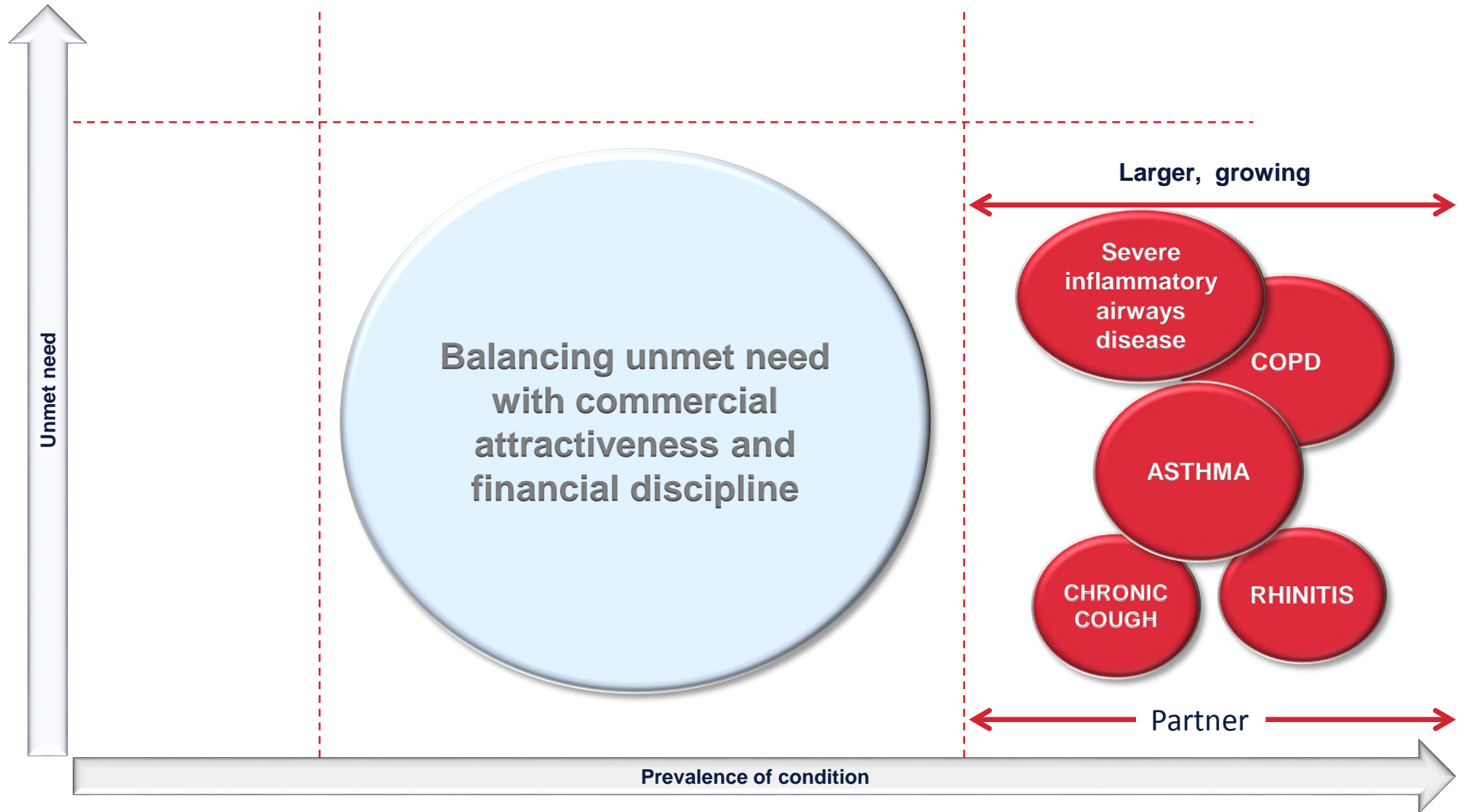
# Vectura's current position in the market



# New areas will be targeted



# Identifying our focus



# Summary



## Business Model

- Validated by continually increasing number of new partners
- License agreements include Novartis, Sandoz, BI, GSK, KingYork & UCB

## Branded Drugs

- Significant clinical and regulatory success
- First launches of Seebri® Breezhaler® are underway by Novartis
- First launches of Ultibro® Breezhaler® are underway by Novartis

## Generic Drugs

- Programmes continue to make progress
- VR506 has one international multi-centre study on-going
- VR506/002 clinical trial top-line data positive

## Emerging Markets

- Leverage all of our assets in a prudent manner

## Strategy

- Willing to consider increased risk for greater share of economics
- Evaluating multiple opportunities from out-licensing through co-development to self-commercialisation
- Prudent, strategic and focus on capital discipline

# Upcoming events



## Progress of Seebri<sup>®</sup> Breezhaler<sup>®</sup> reported quarterly

- \$18m in sales in H1, 2013
- US filing anticipated in H1, 2014

## QVA149 launch in Japan & Europe imminent

- First in class of major new drug class
- Significant milestones triggered by approvals
- Additional growing royalty stream to Vectura from Q1, 2014
- US filing anticipated in H2, 2014

## VR506 clinical trial top line readout (004) expected in H1, 2014

- Important trigger for partnering discussions

## New Board appointment

- Bruno Angelici will join Board on 1 December, 2013
- Will become Non-executive Chairman on 1 February, 2014
- Business update planned for Q1, 2014