



**J.P. Morgan European Healthcare Conference**

**June 2013**



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## 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 (EU/Japan/RoW/US)
- Comprehensive development programmes for both drugs fully funded by Novartis



## Late-stage pipeline encompasses both branded & generic respiratory drugs

- QVA149 under regulatory review in Europe and Japan
- Outcome expected late this year
- Three generic programmes underway



## JV in China announced on 13 May 2013

- Access to fast growing Asian respiratory markets



## Strong balance sheet with £70.1m in cash

- Supported by existing royalty streams and a disciplined approach to cost control

## ✔ **Once-daily maintenance bronchodilator treatment for COPD licensed to Novartis**

- Market suggests that LAMAs as monotherapy are here to stay
  - Analysts expect class to be worth c. \$6bn by 2021

## ✔ **Approved in EU, Japan, Australia, Canada and seven other countries**

- Market roll out is underway by Novartis
- Launched in several countries including Germany, UK, Ireland & Japan\*

## ✔ **NVA237 comprehensive Phase III clinical trial programme for US**

- Being undertaken by Novartis
- US filing expected Q1 2014

## ✔ 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 submitted by Novartis in EU (Oct. 2012)

- Japan regulatory filing submitted by Novartis in November 2012
- Novartis expected to file in US by end 2014

## ✔ Comprehensive COPD registration trial programme undertaken by Novartis (IGNITE)

- > 7,000 patients across 42 countries

## ✔ Potential factors driving expected use of LAMA/LABA combinations:

- Significantly improved bronchodilation
- Combining bronchodilators with different mechanisms of action is already mentioned in the GOLD guidelines as an alternative treatment option
- Increasing concern over the appropriate use of ICS in COPD

• In EU & Japan

• Onbrez<sup>®</sup> Breezhaler<sup>®</sup> and Seebri<sup>®</sup> Breezhaler<sup>®</sup> are registered trademarks of Novartis AG

## ✔ Focus on promising, high value, non-commodity products

- VR315 - Licensed in EU/RoW (Sandoz) and in US (undisclosed partner)
- VR632 - Licensed in EU (Sandoz)

## ✔ VR506 - Development ongoing, strong out-licensing candidate

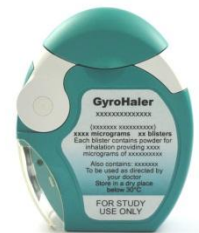
- Two international, multi-centre clinical trials underway in mild-moderate and moderate-severe asthma
  - Trial 002 has 374 patients; recruitment complete
  - Trial 004 is still recruiting; target 174 patients
- Expected to complete in Q4, 13 and Q2, 14, respectively

## ✔ Comprehensive understanding of complex regulatory requirements

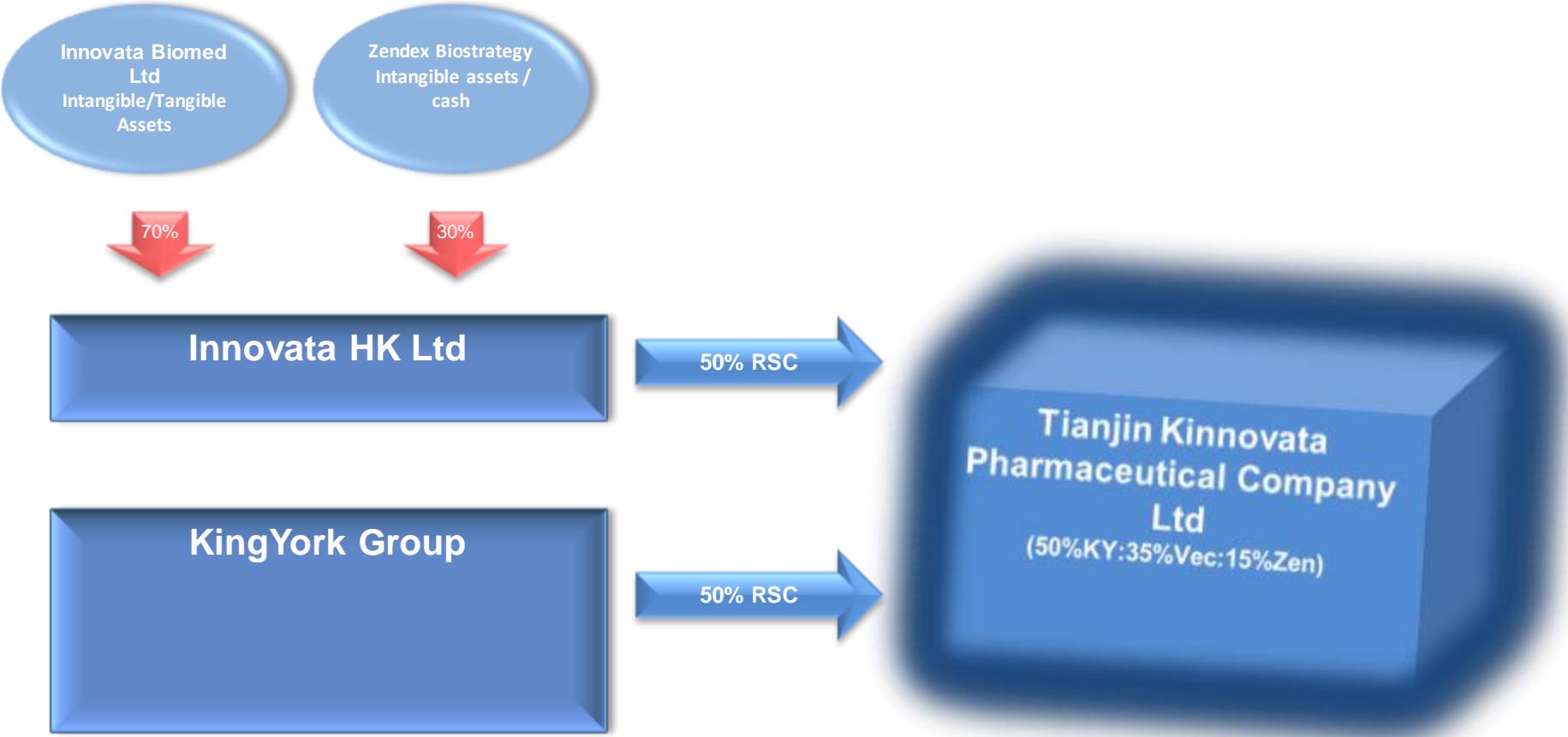
- Significant experience from interaction with regulators, particularly the EMA and FDA

## ✔ GyroHaler® - 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



# Chinese JV – Kinnovata



## ✔ Intangible assets (to the value of RMB 95m)

- Worldwide rights to Clickhaler<sup>®</sup> technology and Asian rights to Duohaler<sup>®</sup> technology
- Access to Vectura's approved European Clickhaler<sup>®</sup> regulatory dossiers
  - Inhaled corticosteroids (“ICS”)
    - Budesonide & beclomethasone
  - Long- and short-acting beta-2 agonists
    - formoterol & salbutamol

## ✔ Fixed assets (to the value of RMB 45m)

- Clickhaler<sup>®</sup> manufacturing facility including automated assembly line
- Duohaler<sup>®</sup> pilot scale manufacturing facility
- Filling equipment

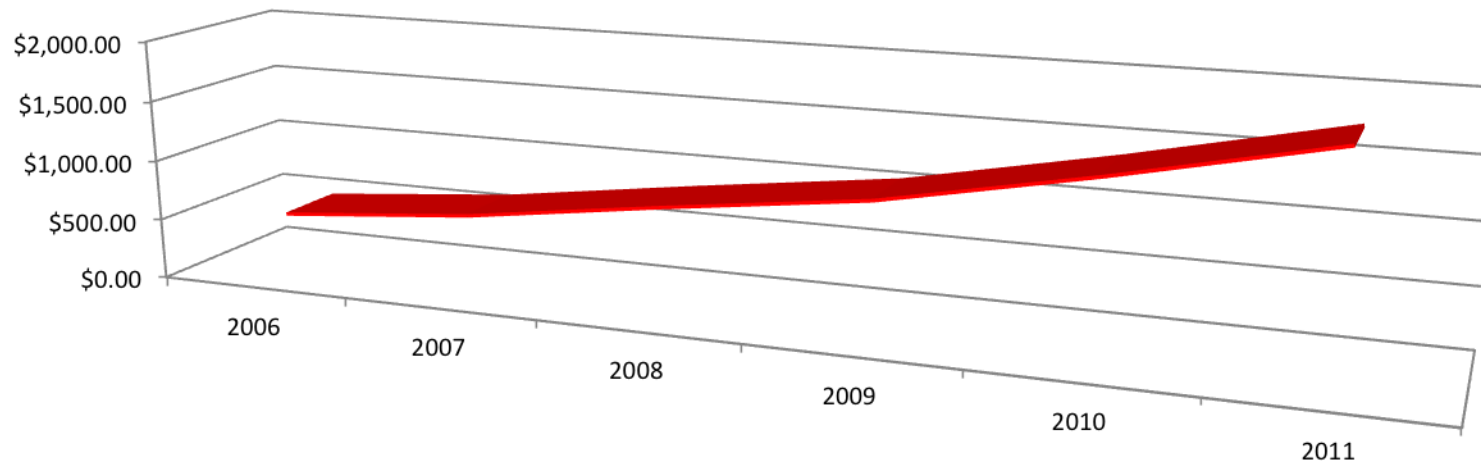
## ✔ Final local government approval expected in 2013



# The Chinese asthma market

- Chinese asthma market has demonstrated strong growth
- 2006-2011 CAGR 23%

Sales (USD m)



Source: LSI China Prescription Drug Sales Report 2012

- ❖ **The initial pipeline will target drugs that currently account for over 50% of this market**
- ❖ **Expectations of up to five drugs on the market in medium term**
  - Sales potential estimates vary for individual products
- ❖ **Next steps**
  - Asmasal<sup>®</sup> file submitted to SFDA earlier this year
  - Enable Kinnovata to gain an import license for salbutamol in Clickhaler<sup>®</sup>
  - Clinical trial go-ahead expected by end 2013
- ❖ **Value to Vectura is realised in both short-term and long-term**
  - Share in associate
  - Mid-single digit royalty on sales

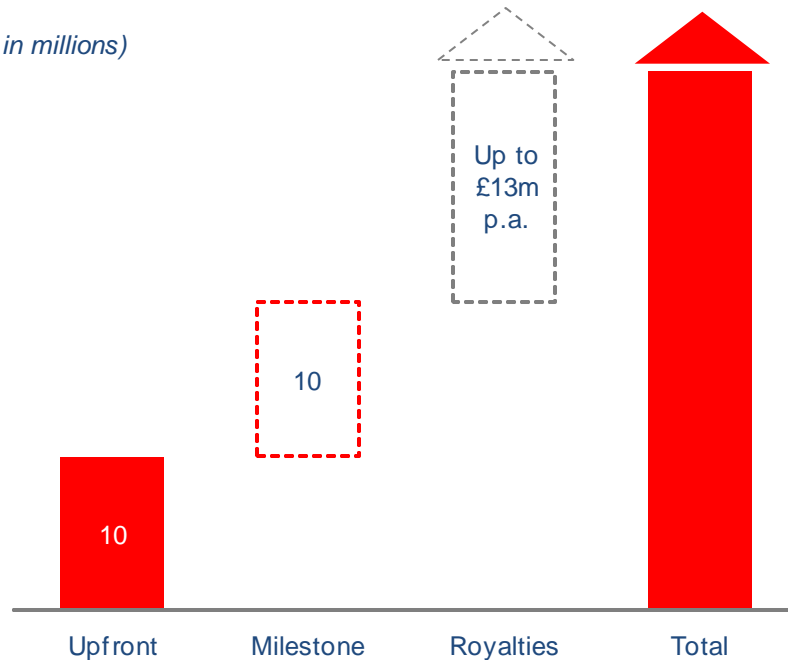
# Vectura's licence agreement with GSK

## Monetising Vectura's IP

### GSK (August 2010)

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

(£ in millions)



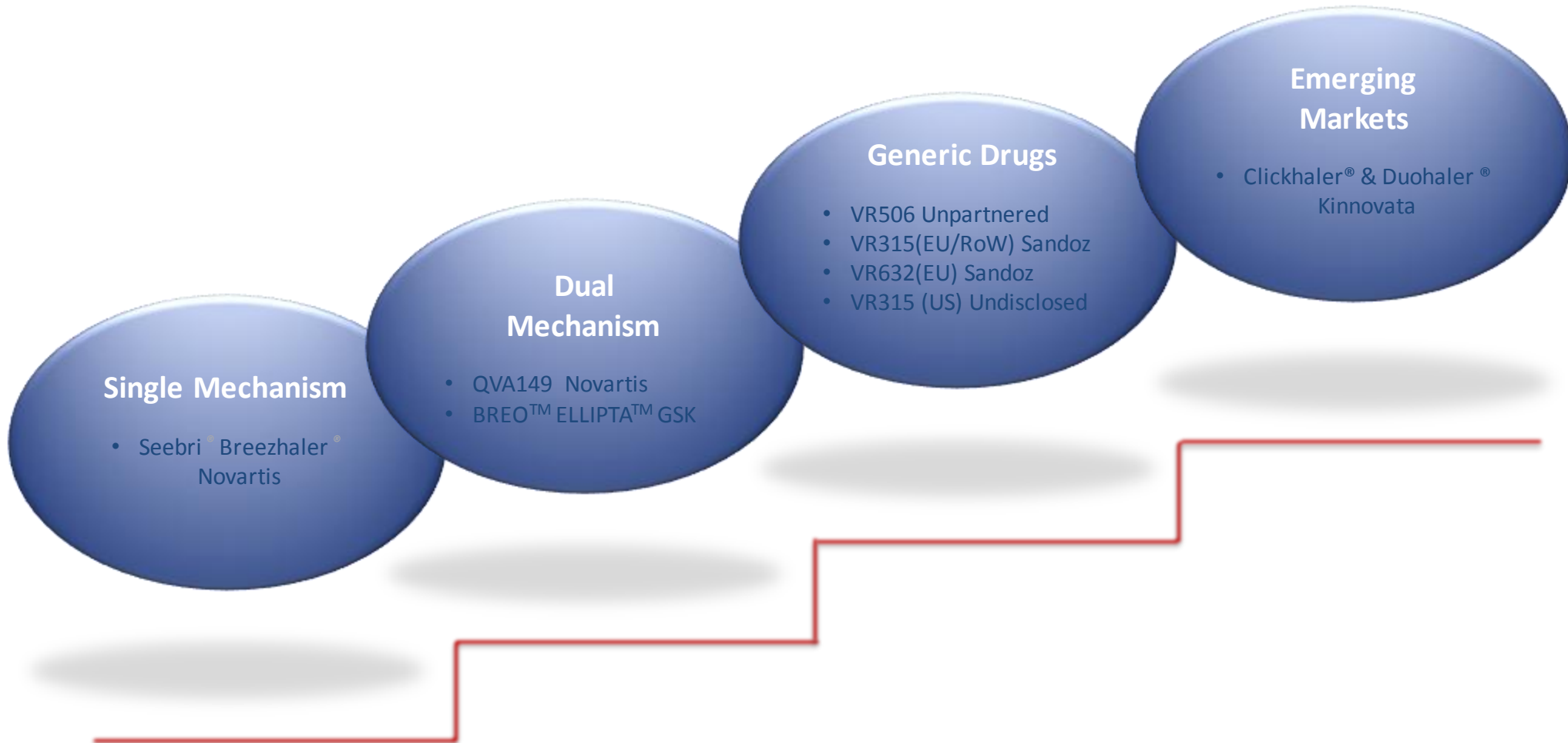
No additional investment required to generate these returns

Vectura invests approx. £2m per annum on its patent portfolio

Various patents covered by the license and option to license agreement have expiry dates extending from 2016 - 2025

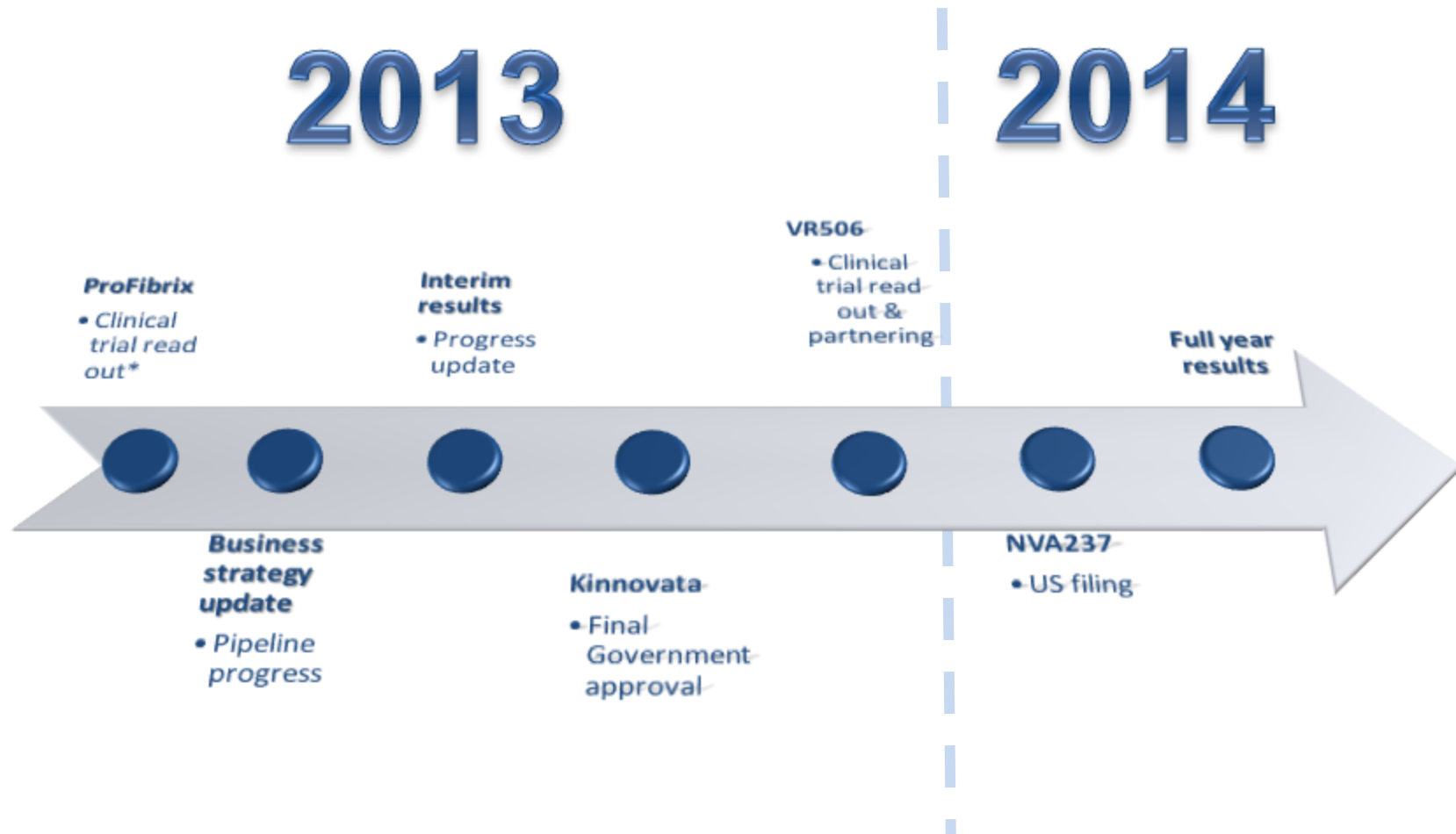
## Attractive returns from IP portfolio and know-how

# Strategic fit across the respiratory market



**Technology Platform Underpins Product Focus**

# Anticipated near-term events



\*Potential completion of acquisition by The Medicines Company

## Business Model

- Business model has been successfully validated
- License agreements include Novartis, Sandoz, GSK & KingYork

## Branded Drugs

- Significant clinical and regulatory success
- First launches of Seebri® Breezhaler® are underway by Novartis
- QVA149 filed for approval in Europe and Japan by Novartis

## Generic Drugs

- Programmes continue to make progress
- VR506 has two international multi centre studies on-going

## Emerging Markets

- Leverage all of our assets in a prudent manner

## Next Steps

- Willing to take on increased risk for greater share of economics
- Potential value-enhancing deal structures vary from co-development through to self-commercialisation
- Prudent, strategic and cost-effective