

## Results for the year ended 31 December 2010

9 March 2011



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# Strategy: Focus, Realism and Results



## Focus

- ❖ On essential 'building-blocks' – science, IP, early stage products and manufacturing

## Realism






- ❖ Form significant third party partnerships and collaborations
- ❖ Out-license later stage assets
- ❖ Dispose of non-core assets

## Results

- ❖ Aiming to bring sustainable increase in market value

# Gene Therapeutics



Product	Indication	Est. Patient No.s*	In-vitro PoP	Disease model PoP			Tox	Clinical
				1st	Mid	Final		
(EG011) VEGF-D shortform	<b>Refractory angina</b>	<b>200,000</b>						
(EG013) VEGF-D shortform	<b>Foetal growth restriction</b>	<b>60,000</b>						
(EG016) VEGF-D shortform	<b>Peripheral vascular disease</b>	<b>300,000</b>						
Targeted integrating vector	<b>Multi-application</b>	-						
Gene regulation technology	<b>Multi-application</b>	-						

\* Company estimates – EU & USA

# EG011 – Refractory Angina

- ❖ VEGF-D $\Delta$ N $\Delta$ C short-form gene (Ad-VEGF-D)
- ❖ Phase I/IIa in refractory angina commenced 2010 - in collaboration with the AI Virtanen Institute
  - Protocol – open study of up to 30 patients (4 + 1 control) x 3 doses in first part
  - Low dose arm completed
  - NOGA catheter procedure to administer EG011 was uneventful and no adverse events of concern
  - Upcoming news flow expected re. end of dose-ranging part of study and choice of therapeutic dose in 2011
- ❖ Commercial Strategy
  - **Refractory angina:** market opportunity: >200,000 patients per year in EU and US
  - Identify partners to fund trials and commercialise on the global market
  - **Post MI:** Very large market – strong interest from stem cell centres to switch to Ark's shortform VEGF-D gene

# EG016 - Peripheral Vascular Disease



- ❖ Patients with chronic lower limb ischemia
- ❖ Market size: 300,000 patients
- ❖ Phase I/IIa with AIV Institute commenced – two further sites being opened
- ❖ Protocol – open study up to 30 patients
- ❖ Dose ranging completed
- ❖ Full study recruited by mid 2012

# EG013 – Foetal Growth Restriction

- ❖ VEGF transfection to uterine artery increases placental blood flow
- ❖ In sheep, significant shift in foetal growth trajectory of VEGF-treated pregnancies demonstrated for two separate measurements: abdominal circumference and renal volume
- ❖ In pre-clinical sheep model of FGR, birth weight increased by 20%
- ❖ No unexpected neonatal complications, abnormalities, changes in blood parameters or any other particular concerns about wellbeing of lambs born after maternal treatment with Ad.VEGF
- ❖ No detrimental effects detected on the structure or function of human placental tissue
- ❖ Meetings with regulators positive
- ❖ Final pre-clinical toxicology studies in planning



# World Class Manufacturing Expertise

- ❖ Three self-contained manufacturing suites, all able to accommodate products requiring BSL-2
- ❖ Process development, cGMP manufacture of bulk drug substance, fill & finish and release testing
- ❖ Access to Ark's proprietary adenoviral and lentiviral vector production platforms
- ❖ Expertise at all phases of product development – research, clinical and commercial
- ❖ Late stage discussions underway

# Small Molecules in Vascular Biology



- ❖ First small molecule antagonists with nanomolar potencies for the NRP-1 receptor
  - Proof-of-principle *in vivo* efficacy demonstrated in tumour model
  - Very significant potential for cancer treatment
  - Acknowledged as important new target for cancer therapy
  - Strong IP
  - Lead optimisation progressing
  - Attractive partnership candidate leading to high level of interest
  
- ❖ Vascular biology expertise means new structures identified with potential for targeting with small molecule therapeutics.

# 2010 Financial Summary



## Consolidated Profit & Loss Summary

(in £ thousands)

	Year ended 31.12.2010	Year ended 31.12.2009
Turnover - Woundcare	2,313	1,576
Turnover - Manufacturing	757	221
Turnover - Licence receipts	-	1,167
<b>Total Turnover</b>	<b>3,070</b>	<b>2,964</b>
Cost of Sales	(1,320)	(1,042)
<b>Gross Profit</b>	<b>1,750</b>	<b>1,922</b>
Research and development	(10,848)	(15,562)
Selling, marketing and distribution	(1,743)	(1,718)
General and Admin expenses	(4,974)	(5,256)
Share based compensation	550	(437)
Other income	404	550
Other expense	(672)	(1,262)
Goodwill impairment	(1,306)	-
Other exceptional items	(447)	-
<b>Operating loss including discount ops.</b>	<b>(17,286)</b>	<b>(21,763)</b>
<u>Reconciliation to Consolidated income statement</u>		
Operating loss on continuing operations	(17,017)	(20,820)
Operating loss on discontinuing operations	(269)	(943)
	(17,286)	(21,763)

Cash as at 31 December 2010 of £10.6m (YE2009 - £21.5m/ 1H2010 - £14.1m)

# Summary

- ❖ **Focus** on what we are good at – science, IP, early stage products and manufacturing
  
- ❖ **Realism**
  - We will not ‘go it alone’ but will seek partnerships and collaborations across our business
  
  - We will seek to out-license later stage assets like Cerepro® and capitalise on our IP
  
  - We will dispose of non-core assets
  
- ❖ **Results**
  - Aiming to bring sustainable increase in market value