



# Renovo Group plc

Interim Results

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# Highlights



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## Pipeline

### Juvista

- First pivotal EU Phase 3 trial in scar revision surgery is fully recruited and scheduled to report H1 2011
- Agreement reached with European Medicines Agency's Paediatric Committee on the Juvista Development Plan for Children
- Licensing Agreement with Shire LLC re-negotiated during the period, giving Renovo rights to develop and license Juvista in all countries except, USA, Canada and Mexico

# Highlights



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## Pipeline

- Adaprev - Clinical trial in tendon repair recruiting patients and on schedule to report H1 2011
- Prevascar - Proof of concept clinical trial in skin incisions and excisions in African Ancestral Group volunteers with new drug product commenced on schedule. Interim data expected : H1 2011
- Juvidex - Following positive clinical trial data, partnering discussions for Juvidex as a cosmetic ingredient are ongoing
- RN1005 - Lead preclinical drug candidate in manufacturing optimisation studies funded by a grant from the Technology Strategy Board's Regenerative Medicine competition

# Highlights



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## Financial

- Cash consumed in operations during the half year £8.3M (2009 : £12.6M)
- Net cash position including investments at 31 March 2010 £58M (31 March 2009 : £73M) – a reduction of £7.3M during the period (period to 31 March 2009 £9.6M)
- As previously guided, annual cash burn reduced to £15 – £20Mpa
- As previously guided, cash on reporting of First Juvista EU Phase 3 Trial in H1 2011 at least £25 - £30M

# ***Juvista(TGFβ3: Avotermin): Large Commercial Potential***



- First in class pharmaceutical for prophylactic improvement of scar appearance in the skin
- Large potential markets of unmet medical need serviced by speciality sales force
- Reimbursed e.g. scar revision, and self pay e.g. cosmetic surgery indications (Botox as an example)
- No near term competition
- Strong and long patent protection (COM, use, manufacturing, formulation, dose)
- Biologic made in *E Coli* – low cost of goods: Manufacturing established at commercial scale
- Strong underpinning science
- Mechanism of action understood
- Comprehensive Phase I/II clinical trial programme in approx 1,500 patients produced consistent efficacy, safety and significant learning about clinical trial design, endpoints, dosing etc to increase the chances of success in Phase III.
- Phase III programme, endpoints, protocol etc reviewed by EMEA and agreed as part of its written Scientific Advice to Renovo: first EU Phase III registration trial ongoing in scar revision surgery.

# ***Juvista Licensing Deal (2007 revised 2010) with Shire Provides Funding and Retains Upside***

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- Shire licensed USA, Canada and Mexico, Renovo retains rights to Rest of World: both can sub-license
- Renovo received (2007) an initial payment of US\$125M
  - US\$75m upfront payment; and
  - US\$50M equity investment in Renovo (at £2 per share)
- Commencement of first Shire clinical trial, after first Juvista EU PhIII trial reports (scheduled H1 2011) triggers US\$5M milestone payment to Renovo
- On acceptance of filing with the FDA, Shire will pay Renovo US\$25M and on FDA approval US\$50 – US\$150M depending on the breadth of the indication on the approved product label
- Renovo will be eligible for sales-related milestone payments of up to US\$525M, giving a total deal size of up to US\$830M
- Renovo will receive escalating royalties on Juvista sales by Shire
- All data and regulatory filings to be shared between Renovo and Shire at no cost to either party
- Each party is responsible for its own development costs, future costs can be shared by agreement

# Consistent Findings from a Wide Ranging Juvista Phase I & II Programme



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<b>Safety:</b>	Favourable profile - 1,500 subjects
<b>Efficacy:</b>	Eight statistically significant PhII efficacy trials. Two negative PhII trials used suboptimal dose and dosing regimen
<b>Dose:</b>	500ng per 100µL per linear cm of wound margin most efficacious dose
<b>Dosing frequency:</b>	Twice dosing more efficacious than once (24 hours apart)
<b>Subjects:</b>	Efficacy demonstrated in volunteers, patients, different ages, sex, skin colour, surgeries, scar lengths, good and poor scars
<b>Multi-centre, multi-national:</b>	Plastic and vascular surgeons
<b>Regulatory:</b>	Development, validation and EMEA agreement on endpoint to measure scar improvement
<b>Indication:</b>	Surgical revision of disfiguring scars chosen for Phase III
<b>Phase III design:</b>	Considerable learning translated into Phase III trial design optimises the chances of success. Written scientific advice from EMEA on programme and protocol followed

# ***Juvista Initial Positioning: Prophylactic Improvement of Disfiguring Scars in Scar Revision Surgery***

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- Highest medical need, lowest regulatory hurdle
- Launch provides access to core cosmetic and reconstructive plastic surgeons and aesthetic dermatologists, high interest in products to reduce scarring
- Easy promotion, medical education – publications, congresses, Patient education – press
- Build and expand the large potential scar revision market, e.g. as Botox built the wrinkles market. **Potential peak sales in the US and Europe of \$1bn** (*pricing c.\$500 per treatment & modest penetration*)
- Scar Revision occurs at multiple body sites in all races, males, females, wide age range
- Surgeon use, safety and efficacy data across all body sites
- Wound healing/scarring biology similar irrespective of body site
- Additional Phase IV trials to expand use and labelling – US and EU regulatory advice suggests 2 further trials for a broad label
- **Potential peak sales with broad label of \$4bn in the US & €4bn in Europe** (*44m & 42m surgical procedures conducted in the US & EU p.a. respectively*)

# *Juvista Phase III EU Scar Revision Trial: On Track*



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- First European pivotal Phase III efficacy trial in scar revision surgery is on track to report data H1 2011
  - Evaluating two doses of Juvista (200ng & 500ng per 100µl per linear cm wound margin) given twice, following wound closure and 24 hours later
  - Recruitment complete with over 350 patients in 56 centres from ten countries
    - UK, France, Hungary, Germany, Italy, Poland, Spain, Denmark, Latvia, USA
    - Regulatory approval granted in all countries
    - Extensive coverage of target surgeons in Europe
  - Incorporated learning from Phase I & II programme
  - Focus on execution excellence

## ***Focus on Risk Reduction in EU Phase III***



### **Operational**

- Optimised dose/dose regimen
- 90% statistical powering
- Scar selection panel (flat surfaces for photography)
- Photography QC'd in real time
- Accurate scar marking (semi-permanent tattoos)
- Site training (surgery/cameras/images)
- Successful advertising (50%)
- Patient retention measures

### **EMA Scientific Advice**

- High medical need indication
- Within-patient design accepted
- Phase III Protocol agreed
- Programme content agreed
- Global Scar Comparison Scale validation accepted
- Primary and secondary endpoints agreed
- Clinical meaningfulness measures agreed
- Paediatric Plan agreed

# ***Paediatric Investigation Plan Agreed with EMA***

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- Required under EU legislation
- Waiver for children under 2 years, and adolescents (14-18 years)
- Three clinical studies required
  - Single dose formulation evaluation
  - Safety study in all surgeries in 2 - <14 years
  - Efficacy study in scar revision 2 - < 14 years
- Safety study commences 2012 and ends 2014
- Efficacy study 2015 - 2019

# ***Juvista: Paediatric Investigation Plan Ongoing study***

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- Clinical trial 1006-0100 to investigate performance of new, single dose formulation
  - Double-blind placebo controlled within subject design
  - 84 normal healthy adult subjects
  - Matched 1cm surgical wounds on upper inner arm
- Safety and efficacy of new formulation compared to existing formulation
- Study fully recruited
- 12m endpoint reports end 2010

# ***Earlobe Keloids - A Good Target for Juvista Pilot Studies***



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- Keloid scars develop and grow beyond the margins of the original wound, often triggered by wounding, piercing or acne
  - More common in dark skin and cause cosmetic and medical problems
  - Double-blind, within-patient, placebo-controlled randomised trial to investigate the safety of Juvista following excision of bilateral earlobe keloids
  - Trial ongoing in the USA under an open FDA IND
  - Rising dose tolerance study 50, 200 or 500ng/100µL/linear cm wound margin (x2 dosing)
  - 50ng (n=10) and 200ng (n=10) groups: passed safety endpoint at month three, 500ng (n=30) group fully recruited
  - Safety and twelve month pilot efficacy data for all doses to report H2 2010
  - Proof of concept trial: keloids represent an additional indication/opportunity beyond normal scars



# ***Prevascar*** ***(IL-10 : Ilodecakin)*** ***Scar Reduction in the Skin***

- *Different mechanism of action to Juvista*
- *Treatment of Juvista non/poor responders*
- *Combination therapy e.g. large burn*
- *Future pharmacogenomic marketing (companion diagnostics)*

# ***Prevascar: Positive first efficacy trial, new clinical trial started – Interim data H1 2011***

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- Scar reduction in initial clinical trial (n=175) with intradermal Prevascar dosed twice
  - Primary endpoint met with statistical significance (P<0.05)
  - Significance met with pre-specified multiple secondary endpoints (p<0.05)
  - Local, acute intradermal applications up to and including doses of 2000ng/100µL have a favourable safety profile
  
- Improved clinical drug product developed
  
- Renovo studies of dark skinned individuals show higher inflammatory cell numbers and activation
  
- Prevascar's modulating effects on inflammatory cells suggests it may work best in subjects of African Ancestral Group origin
  
- Proof of concept clinical study commenced in incisions and excisions of African volunteers
  
- Interim data H1 2011



# ***Adaprev*** ***(Mannose-6-Phosphate – M6P)*** ***Prevention and Reduction of*** ***Tendon Adhesions***

*A rapid low cost path to Market as  
Class III Medical Device*

# ***Adaprev: Significant Near Term Market Opportunity in Tendon Repair***



- Scarring can cause adhesions between the tendon and surrounding tissues resulting in a marked loss of function and pain following injury or surgery
  - ~30% require subsequent tenolysis surgery for adhesions
- Attractive market with over 550,000 hand and wrist procedures conducted per year in US alone and a similar number in the EU
  - Patients continue to suffer from impaired motor function, impact on ADLs and pain following surgery, resulting in economic impact
- High pricing anticipated – avoidance of tenolysis would be a major economic benefit
- Target prescribers are plastic reconstructive and hand surgeons- same as Juvista
- Rapid and low cost development as a Class III medical device
- Ongoing Clinical Trial
  - A randomized, double blind clinical investigation to evaluate the safety, tolerability, and preliminary performance of Adaprev™ in improving recovery of tendon function in subjects undergoing surgical repair of flexor tendons in Zone II of the hand
  - 44 patients 10 UK sites
  - Reporting H1 2011



# **Juvidex**

**(Mannose-6-Phosphate – M6P)**

**Improves Skin Appearance,  
Reduces Redness and Promotes  
Healing of Damaged Skin**

# ***Topical M6P (Juvidex) Accelerates Healing, Improves Skin Appearance, Reduces Redness and is Well Tolerated***



- Safety
  - Topical Juvidex well tolerated
- Efficacy
  - Objective measures demonstrated that over the healing period wounds treated with topical Juvidex had an appearance that more closely resembled normal skin compared to placebo
- Statistically significant results with Juvidex
  - Accelerated healing (Re-epithelialisation)
  - Reduced redness
  - Improved radiance/blending (lighter)
  - Improved overall skin appearance
- Conclude that topical Juvidex data can support key cosmetic claims e.g. for products post chemical/laser peel, dermabrasion, waxing, sunburn, anti-ageing cream, lip salve, after shave, mother and baby, dry skin, foundation.
- Strategy: License to a partner: cosmetic company or cosmetic ingredient company. Deal expected 2010



# **RN-1005**

## **Promising Preclinical Candidate**

Prevention of Scarring and Promotion of  
Tissue Regeneration

## ***RN1005: New Pre-clinical Candidate***



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- New Biological entity in early development
  - Renovo Discovery and Intellectual Property
  - Novel Mechanism (Wnt pathway)
  - Enhanced efficacy in pre-clinical models
  - Pilot toxicology completed
  - Manufacturing scale-up ongoing
  - TSB Grant awarded Dec 2009

## Results in Line with Expectations



	6 Months ended 31 March		
Key figures	2010 (unaudited) £'m	2009 (unaudited) £'m	Movement £'m
Revenue	5.2	4.1	↑ 1.1
Research & Development -Revenue related	(3.6)	(3.0)	↑ 0.6
-Development & discovery programmes	(7.2)	(8.6)	↓ 1.4
Administrative expenses	(2.3)	(3.0)	↓ 0.7
Finance income	0.6	1.8	↓ 1.2
Taxation	1.3	1.8	↓ 0.5
Loss for the period	(6.1)	(7.0)	↑ 0.9
Reduction in cash & cash equivalents	(7.3)	(9.6)	↓ 2.3

## *Results in Line with Expectations*



- Results in line with revised guidance given at time of the reorganisation in September 2009
- Cash reduction in period was £7.3m resulting in a net cash position of £58m at 31 March 2010
- Increase in revenue includes change to the accounting treatment of the upfront payment received from Shire in 2007: this will now be fully released by 30 June 2011 as a result of the renegotiation of the licence agreement with Shire
- Development and Discovery programme expenditure fallen by £1.46m
- Administrative expenses fallen by £670k
- We are maintaining the guidance that we will have at least £25 - £30m cash and investments when the first EU Phase 3 trial for Juvista reports in H1 2011

# Renovo Pipeline



Product	Clinical Indication	Phase of Development	Partner	Anticipated Newsflow
Juvista EU	Prophylactic improvement of skin scar appearance	PhIII in scar revision surgery (1 <sup>st</sup> of 2 efficacy trials for approval)	Shire	Q4 2010 paediatric formulation trial reports H1 2011 1 <sup>st</sup> pivotal EU PhIII trial in scar revision surgery reports
Juvista USA	Prophylactic improvement of skin scar appearance	PhII		Q4 2010 earlobe keloid pilot trial reports
Adaprev	Reduction of adhesions following digital tendon injury	Class III medical device Safety and preliminary performance (1 <sup>st</sup> of 2 trials for approval)		H1 2011 trial reports
Prevascar	Reduction of skin scarring	PhII		PhII clinical trial in African subjects interim data H1 2011
Juvidex	Improve skin appearance and promote healing of damaged skin	Cosmetic ingredient Out-license		2010 out-license/partner
RN1005	Prevent scarring and enhance tissue regeneration	Preclinical		2010 Progress development. TSB grant