



Chairman's Address Shareholder Briefing
July 2012

Disclaimer

From me for what I am about to discuss, there is none

I am going to discuss:

- The decision to conduct H1 – H005
- H1 – H005; its results and what the data may be signaling
- Our Messages to the Market
- The Future
- Board Composition
- Our Cash Position

Our Managing Director will then report

Q&Q

Basis for HI – H005

HI - H 002 & 4 multi centre Phase 2 safety and efficacy studies

HI - H003 Phase 1 safety and mechanism study

HI - H002

- 90% reduction in hospital admissions
- 56% reduction in antibiotic use
- 56% reduction in corticosteroid therapy

Preparation for HI – H005

Team for the Trial

- Professor Clancy
- Dr Doug Wilson
- Dr John Bienenstock – Mc Masters University
- Professor Peter Calverley – Liverpool University
- Professor Christine Jenkins - University of Sydney
- Dr Dennis Niewoehner – University of Minnesota

Protocol

Ethics Committees' Approvals

Engaged:

- Pharmasynth – produce active ingredient
- IDT – produce tablets
- Datapharm to manage the trial

Enrolled 320 participants recruited in 21 centres

HI – H005 Misses End Points

Trial

- Dosing – March to June 2011
- Data Lock – End May 2012
- Board Advised – 14 June 2012
- Market advised – the trial did not deliver on the defined end points. June 28th

Continuous Disclosure

- Missed the end points
- Burden to establish value

Continuous enquiry

Signals from Data

Continuous Enquiry - Why the difference and what does the data tell us?

.. there is something of a disconnect between the scientific approach to the data obtained on the one hand and the “rules of the game” about assessing clinical trial results on the other.

The caveat: data dredging v enquiry and reporting

Enquiry – reports a subset of those under 65 (37%) that;

- 50% reduction in exacerbations
- 50% reduction in hospitalisations
- 65% reduction in the days in hospital

Why ?

Experts Will Weigh Significance of Signals

HI - H002 (Chest) v HI - H005 - The HI-002:

Sputum .. samples were collected to monitor bacteria colonization

HI – H005 protocol provided:

A sputum sample will be collected .. if the patient is able to provide one. This sample will be assessed for ... the presence of Haemophilus influenzae, Pseudomonas aeruginosa, Moraxella catarrhalis and Streptococcus pneumonia.

	HI – H002	HI – H005
Sputa produced on demand	50%	36%
Sputa that grew pathogens	92%	11%
Patients with Haemophilus influenzae	40%	6%

Ways Forward

The ways forward:

- abandonment
 - valuation
 - board composition
 - new ventures
- trade sale or licence
- partnering

Trade sale or licence – possibly morphing in to partnering

- Torrey Partners – timetable
 - package to market – today (~50)
 - NDA – end August
 - Non-binding offers – end November

Board

Board composition:

- internal must deliver the skill set needed to supervise the business
- driven by shareholders

Redefinition is part of the continuum

- present board skill set focused on sale or licensing
- change in business will drive change in board composition (i.e. skill set to reflect new business or allow delivery on partner's expectations)

By end November there will be clarity of direction

Cash

Burn Rate is Being Reduced in line with business:

- Board
- Managing Director
- Consultants
- Newcastle Research Centre
- Administration

