Therapeutic products for respiratory and autoimmune diseases

pharmaxis

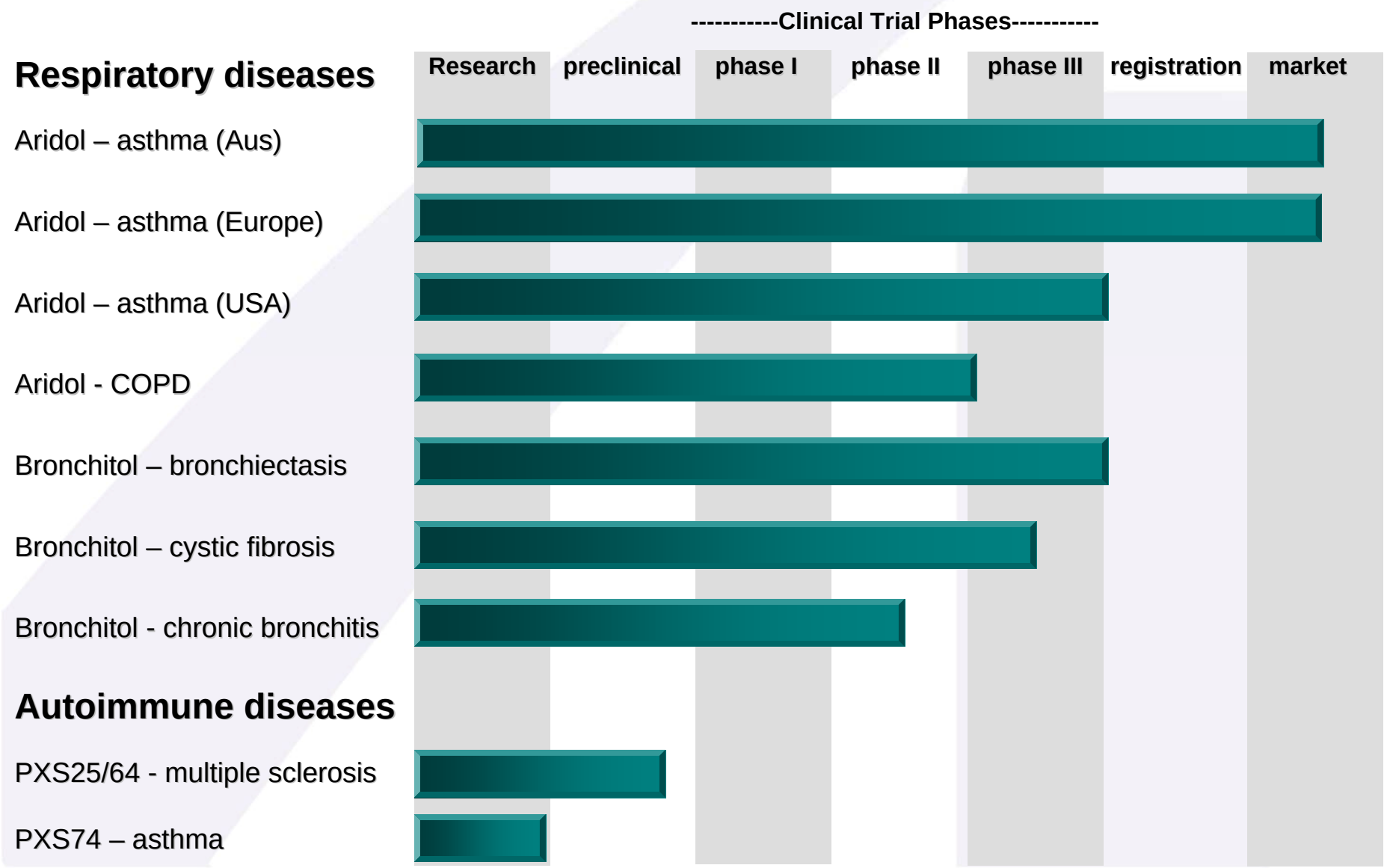
Annual General Meeting

November 2007

Summary……

Objective	The development of products for respiratory and autoimmune diseases
Lead products	Aridol: management of asthma and COPD Bronchitol: therapeutic for cystic fibrosis and COPD
Discovery	PXS64 - multiple sclerosis
Listings	ASX (Nov 2003): PXS; NASDAQ (Aug 2005): PXSL
Location	Sydney, NSW, Australia
Facility	GMP Manufacture of lead products
Employees	70
Cash (30/6/07)	A$78 million
Shares outstanding Options outstanding	191m (12.7m ADS) 11.4m
Key patents	Aridol & Bronchitol granted in USA, Australia, Asia; pending in EU, Canada and Japan
Analyst coverage	Wilson HTM INVESTMENT GROUP; J M P SECURITIES; Bell Potter SECURITIES LIMITED; CREDIT SUISSE; ABN·AMRO Morgans your wealth of experience

Development Pipeline



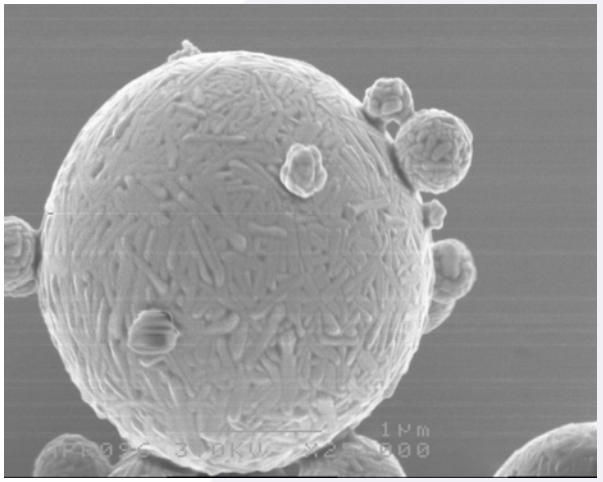
Milestones achieved FY2007…..

1.	Aridol Marketing Application Filed in Switzerland	July 2006
2.	US Aridol Trial Closes	Aug 2006
3.	Pharmaxis Appoints Aridol Distributor for Greece	Oct 2006
4.	UK Approval for Phase 3 Cystic Fibrosis Trial received	Oct 2006
5.	Aridol Distributor for Italy Appointed	Oct 2006
6.	**Swedish Approval for Aridol**	**Oct 2006**
7.	Aridol Endorsed in Global Guidelines	Nov 2006
8.	**US Aridol Phase III results**	**Nov 2006**
9.	Bronchitol Receives Fast Track Status	Nov 2006
10.	Dutch Distributor of Aridol Appointed	Dec 2006
11.	Spanish Distributor of Aridol Appointed	Jan 2007
12.	**Phase III Bronchitol Trial Completes Enrolment**	**Feb 2007**
13.	Phase II CF Study Closes Enrollment	Feb 2007
14.	Phase II Aridol COPD Results Reported	Mar 2007
15.	**Phase III Cystic Fibrosis Trial Begins**	**Apr 2007**
16.	Aridol COPD Study Enrols First Patient	May 2007
17.	**Aridol Gains European Approval**	**Jun 2007**

Milestones achieved since end FY2007.....

1.	**Phase III Bronchiectasis Trial Complete**	July 2007
2.	Korean NDA filed for Aridol	July2007
3.	**Phase III Trial Finds Pharmaxis' Bronchitol Effective**	Aug 2007
4.	**Placement and Share Purchase Plan**	Oct 2007
5.	Korean Distributor appointed for Aridol	Oct 2007
6.	Agreement reached to expand manufacturing capacity	Nov 2007

Bronchitol

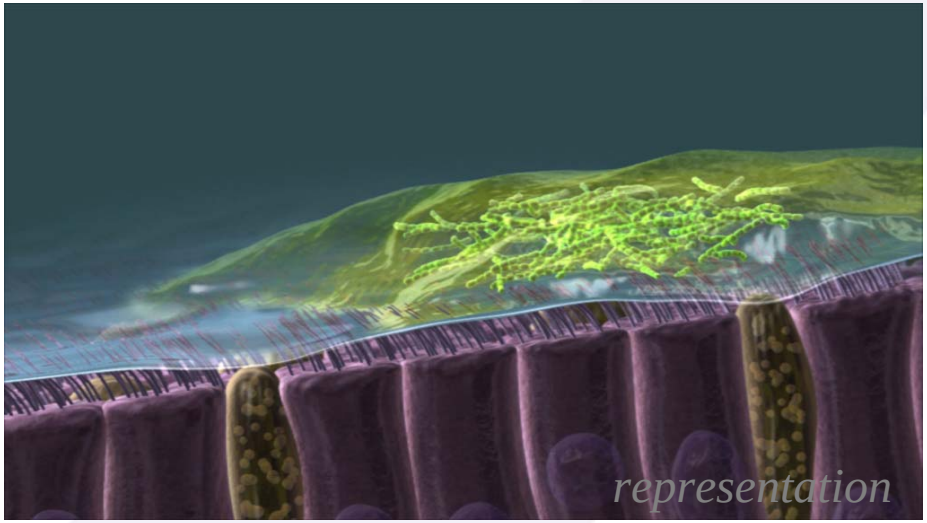


Mucus clearance:

Cystic fibrosis
Chronic Obstructive Pulmonary Disease
Bronchiectasis

Osmotic clearance of abnormal mucus……

Before treatment

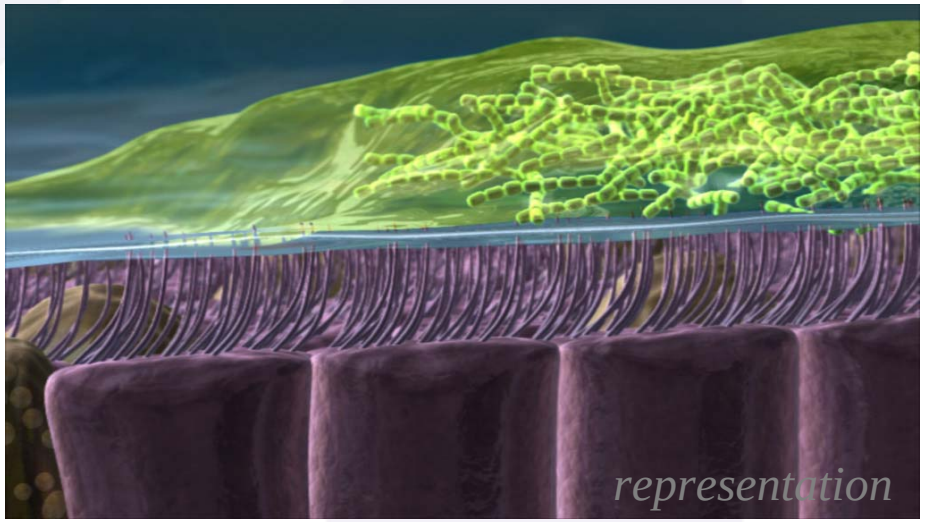


Lung surface dehydrated

Airway surface fluid layer impaired

Lung defense and hygiene compromised

After Bronchitol administration

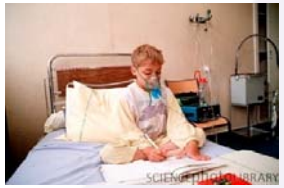


Lung hydrated

Airway surface liquid restored

Normal lung clearance

Bronchitol – cystic fibrosis



- Background
  - Genetic disorder affecting 75,000 worldwide (30,000 in US)
  - Poorly hydrated, tenacious, thick mucus
  - Current life expectancy is 37 years (US)
- Current treatments: rhDNase and tobramycin
  - Delivered by nebulizer (preparation, sterilization)
  - rhDNase (pulmozyme): US$265mm @ ~30% penetration
  - Tobramycin: US$233mm
- Clinical
  - Phase II proof of concept studies completed
  - Dose range finding study in progress (Canada/Argentina)

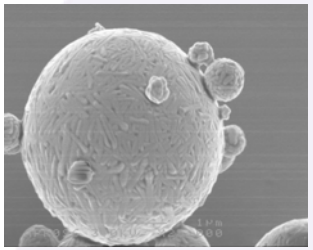
Bronchitol – cystic fibrosis registration (I).....

- **Phase III trial (Aus, NZ, EU):**
  - 90 out of 250 subjects enrolled
  - Primary endpoint: - lung function (FEV1)
  - Placebo-controlled, 6 month dosing, 400mg bd
  - First data expected end 2008
  - Market - 2009
- **Orphan Drug designation in the EU**

Bronchitol – cystic fibrosis registration (II).....

- US Phase III trial design being finalised with FDA
- Expected to commence 1Q 2008
- Similar size, design to EU trial
- Scheduled completion 2H 2009
- Orphan drug designation – EU and U.S.
- Fast track designation – U.S.

Bronchitol - bronchiectasis



- Abnormal, irreversible dilation of the lower airways
- Daily mucus production, constant coughing, breathlessness, recurrent acute bronchitis with infective exacerbations : low quality of life
- In 30-50% of cases, the cause is unknown
- Normal lung clearance impaired
- Current treatments: bronchodilators, antibiotics
- *No* drugs proven effective to clear mucus

1: Clin Pulm Med 2005;12:205

Number of patients seeking treatment

	EU	Australia	USA	Asia	Total
% of pt pool seen by respiratory specialists	Average 14%	9%	N/A	Average 5%	
Trend	Stable or increasing	Stable	Increasing	Stable or decreasing	
Mod/Severe	55%	70%	55%	75%	
Patients seeking treatment	210,000	18,000	110,000	250,000 ++	600,000+

Prevalence: Much higher. Bronchiectasis is often missed but has been measured as >10% of COPD patients in a US patient cohort ~ 800k

Note: US Data comes from Datamonitor research, other data from Frost & Sullivan research

Bronchitol – bronchiectasis Phase III trial completed….

- Phase III trial (Europe, Australia, NZ)
  - 363 patient, placebo controlled, double blind, randomised 12 week treatment. 12 month Open Label Extension
  - 320mg twice a day

- Primary endpoints
  - quality of life – validated Patient Reported Outcome
  - mucus clearance – 24hr sputum volume

- Primary Analysis
  - Quality of Life — SGRQ, p<0.001 versus baseline
    SGRQ, p<0.05 versus placebo
  - Mucus Clearance — ↑28%, p<0.001 versus placebo
  - Adverse Events — not significant versus placebo

Bronchitol – second bronchiectasis PIII trial….

- Phase III trial (USA)
  - 375 patient, placebo controlled, double blind, randomised, 26 week treatment
  - 400mg twice a day

- Primary endpoints
  - quality of life – validated Patient Reported Outcome
  - mucus clearance – 24hr sputum volume
- Status
  - Special Protocol Assessment discussion with FDA
  - Orphan Drug designation
  - Target first patient enrolment Q1 2008
  - Target last patient enrolment Q4 2008
  - Data 2H 2009

Impact of Bronchitol on people living with bronchiectasis

Aridol™

A rapid and simple test for airways inflammation that facilitates diagnosis and management of asthma.

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Clinical applications for Aridol

An easy to use, 'point of care' test with a high degree of sensitivity (85%) and specificity (95%) for airway inflammation

1. **Asthma diagnosis and assessment of disease severity[1]**

2. **Monitor patient's disease / managing effectiveness of treatment[2]**

3. **Identification of COPD patients who will respond to steroids[3]**

NOTES: *1 = Evidence available from phase III study*

2 = Proof of concept only; definitive studies ongoing

3 = Evidence available from phase II study

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International Regulatory Status

- **Australia**
  - Launched — June 2006
- **Europe**
  - Approved for marketing (Sweden) — October 2006
    - Launched — January 2007
  - Approved European Union (MRP) — May 2007
    - 1st Launch — September 2007
  - Submitted – Switzerland
  - Regional marketing partners appointed
- **South East Asia**
  - Submitted - Korea
- **USA**
  - Phase III completed. NDA to be filed 1Q08

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Aridol distribution agreements to date…

Country	Partner	Review	National
• Sweden	Nigaard	approved	✓
• Finland	Nigaard	approved	
• Germany	TBA	approved	
• Ireland	Pharmaxis	approved	✓
• Norway	Nigaard	approved	
• Portugal	TBA	approved	
• UK	Pharmaxis	approved	
• France		approved	
• Greece	Allertec	approved	
• Italy	Italchimici	approved	
• Holland	Romedic	approved	✓
• Spain	Aldo-Union	approved	
• Denmark	Nigaard	approved	✓
• Switzerland	Trimedal	Under review	
• South Korea	BL&H	Under review	

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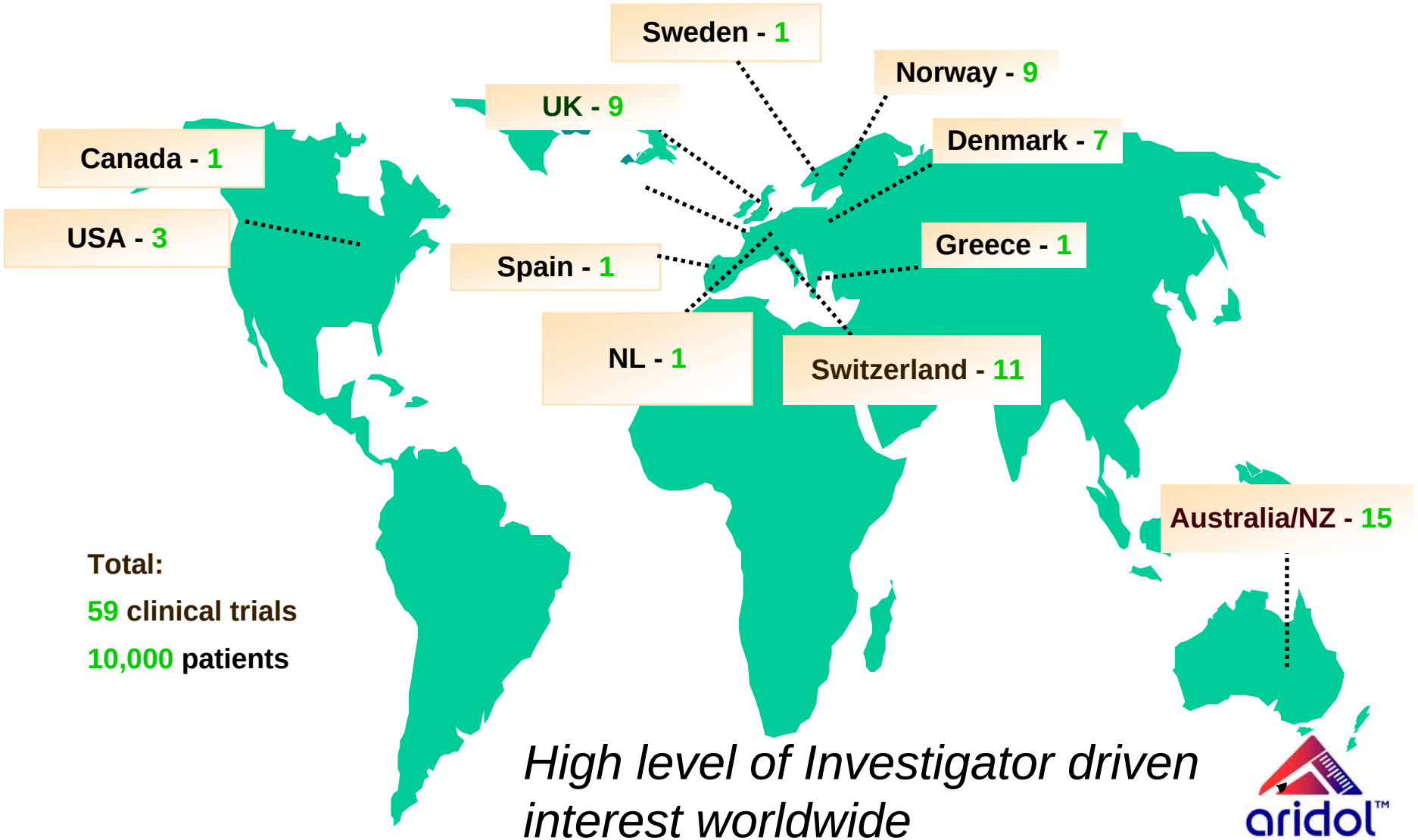
Worldwide development of Aridol……



Total:

59 clinical trials

10,000 patients

High level of Investigator driven interest worldwide

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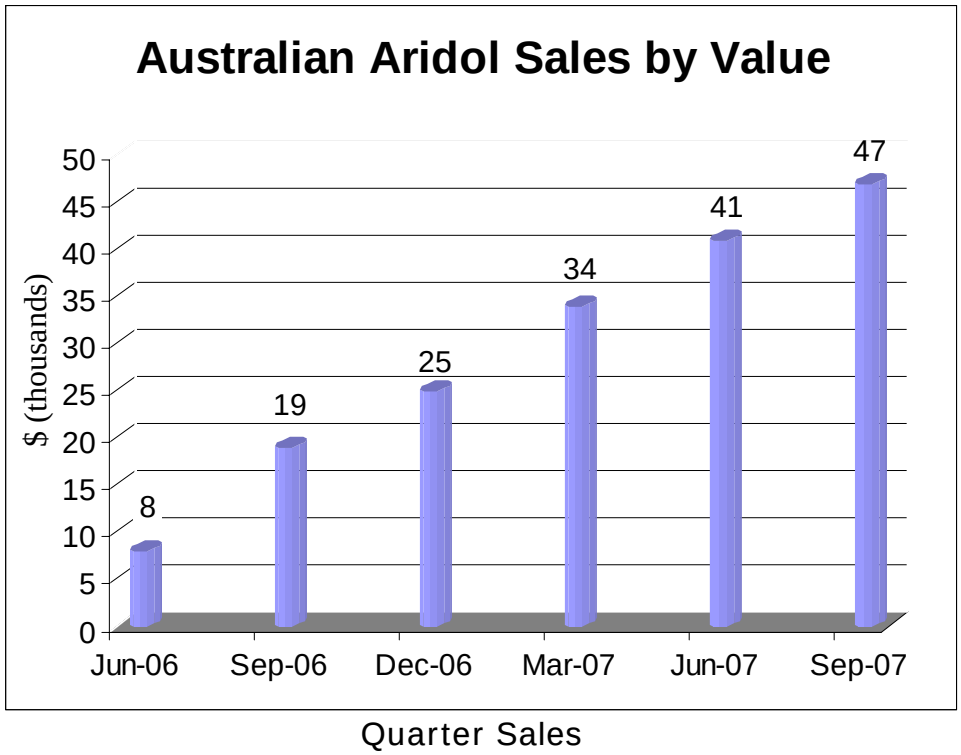
Aridol in Australia.....



- Steady growth in Australia
- Price sensitivities
- Aridol challenges current practice
- Sales by education
- Australia represents ~1% global opportunity
- Slow EU approvals have had an impact

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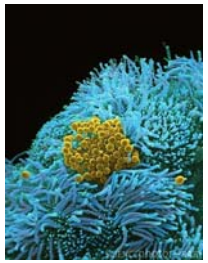
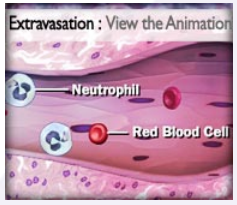
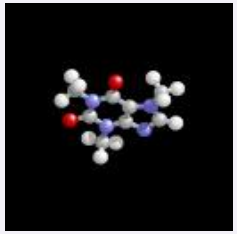
Research and Development activities…..







- PXS25 for immune disease
  - Reduces lung inflammation
    - Acute lung injury (ARDS), chronic lung injury (COPD)
  - Preclinical work completed
    - 1st human exposure Q1 2008
- Research group in North Ryde
  - Target protein identified
  - Potent, selective inhibitors discovered
  - Research in progress

Near term catalysts ahead…..

Milestone	4Q-07	1Q-08	2Q-08	3Q-08
Bronchitol - bronchiectasis				
Finalise US protocol with FDA				
Commence Phase III (US)				
File 1st marketing appln (Aus)				
Bronchitol – cystic fibrosis				
PII dosing trial data (Can/Arg)				
Close EU P III trial recruitment				
Commence US Phase III trial				
Aridol				
File NDA (US)				
Facilities				
New facility construction begins				
PXS25/64				
Complete preclinical studies				

Financial Statements – Australian GAAP

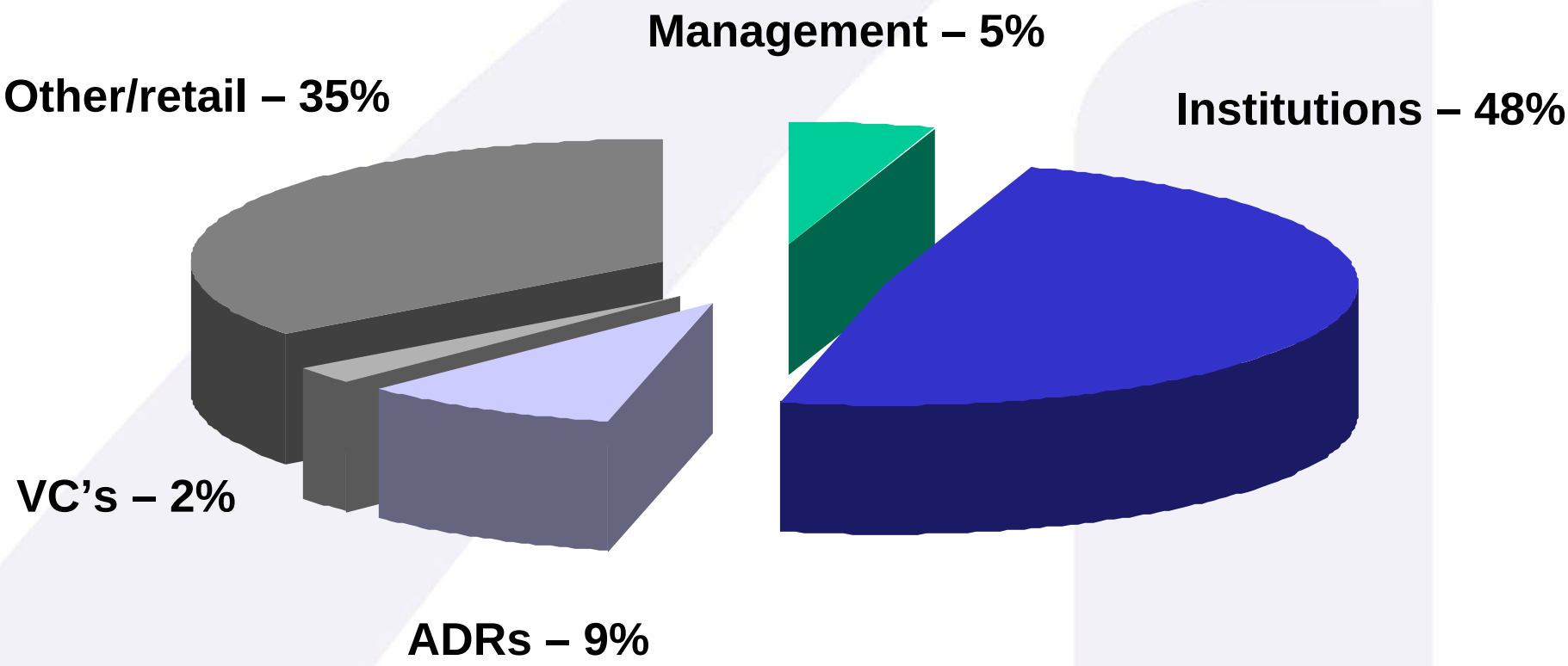
Income Statements	Year ended 30 June 2005 A$'000	2006 A$'000	2007 A$'000
Revenue from sale of goods	-	8	205
Cost of sales	-	(2)	(49)
Gross profit	-	6	156
Other income			
Interest	1,702	4,282	5,278
Grant income	1,219	1,299	2,152
Other	-	-	-
Expenses			
Research & development	(9,269)	(16,978)	(23,840)
Commercial	(963)	(1,946)	(3,240)
Administration	(3,134)	(4,391)	(4,666)
Total expenses	(13,366)	(23,315)	(31,746)
Net loss before tax	(10,445)	(17,728)	(24,160)
Income tax expense	-	(5)	(19)
Net loss after tax	(10,445)	(17,733)	(24,179)
Basic and diluted earnings (loss) per share - $	(0.084)	(0.111)	(0.136)
Depreciation & amortisation	646	947	939
Fair value of employe options issued	260	1,488	1,488

Financial Statements – Australian GAAP

	As at		
	30-Jun-05	30-Jun-06	30-Jun-07
Balance Sheets	A$'000	A$'000	A$'000
Cash and cash equivalents	33,390	97,840	76,182
Plant & equipment	2,477	3,205	3,521
Intangible assets	1,106	1,195	1,239
Total assets	37,937	104,267	82,648
Total liabilities	(2,470)	(5,379)	(6,089)
Total shareholders' equity	35,467	98,888	76,559
Share Data	'000	'000	'000
Ordinary shares on issue	134,770	176,904	177,949
Options on issue	10,914	9,692	9,836

Share Capital – post 2007 equity issue

(including options)



12 Oct 2007: 191m shares; 11.4m options