Therapeutic products for respiratory and autoimmune diseases

pharmaxis

October 2006

Forward Looking Statements

This presentation may contain forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The forward-looking statements contained in this presentation include statements about future financial and operating results, results of our clinical trials, status of our regulatory submissions, possible or assumed future growth opportunities and risks and uncertainties that could affect Pharmaxis' product and products under development. These statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein. In any forward-looking statement in which Pharmaxis expresses an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished.

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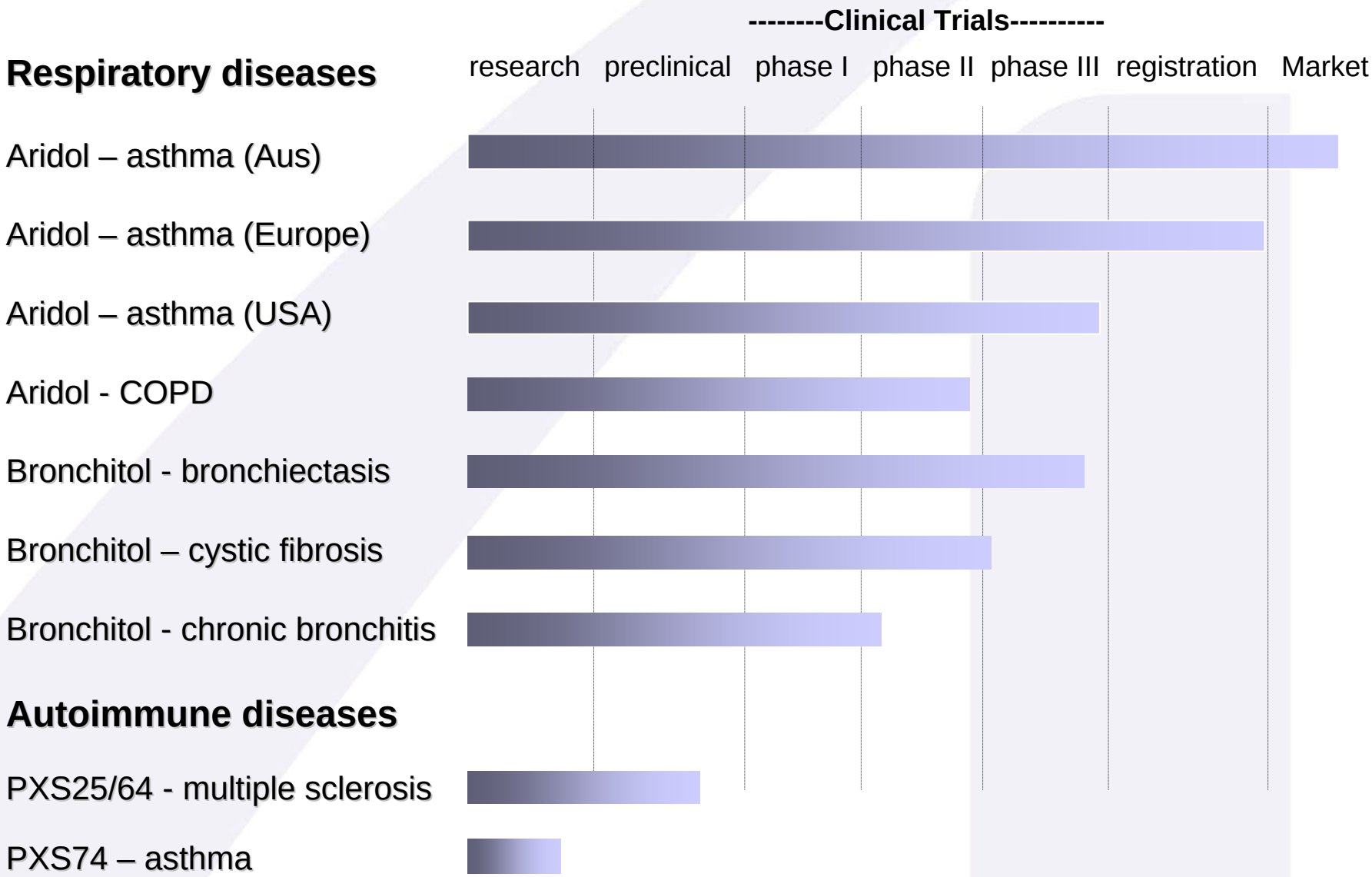
This investor presentation is not an offer of the sale of securities.

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 (30/06/06)	65
Cash (30/06/06)	A$98 million
Shares outstanding Options outstanding	177m (11.8m ADS) 10.2m
Key patents	Aridol & Bronchitol granted in USA, Australia, Asia; pending in EU, Canada and Japan
Analyst coverage	Wilson HTM INVESTMENT GROUP; CIBC World Markets; J | M | P SECURITIES; Bell Potter SECURITIES LIMITED

Development Pipeline



Near term catalysts to end 2006……

Bronchitol – bronchiectasis

- Europe Phase III trial to complete enrolment

Bronchitol – cystic fibrosis

- Phase II dosing study to complete enrolment
- Commencement of Phase III trial (EU)

Bronchitol – chronic bronchitis

- Phase II acute study to complete enrolment

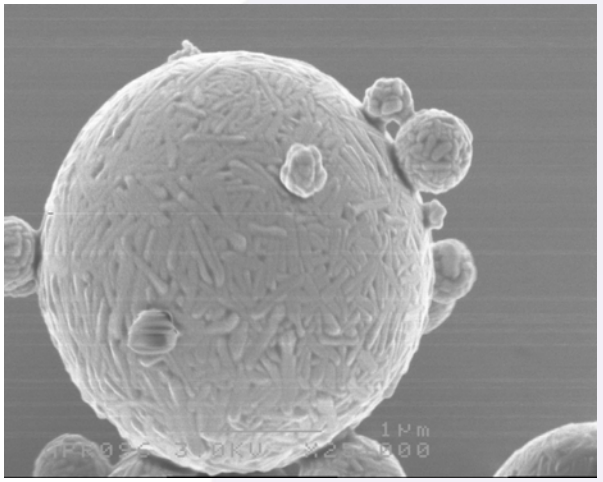
Aridol

- US Phase III clinical data
- Marketing approval in Sweden
- Initiation of European Union approval process
- Prediction of COPD treatment response clinical data

PXS64

- Completion of preclinical studies

Bronchitol

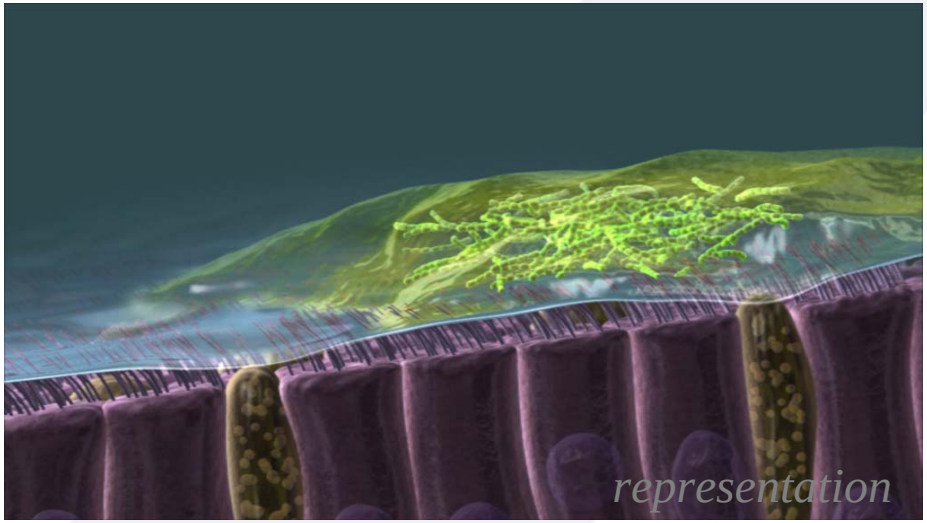


Mucus clearance:

Cystic fibrosis
Chronic Obstructive Pulmonary Disease
Bronchiectasis

Osmotic clearance of abnormal mucus……

Before treatment

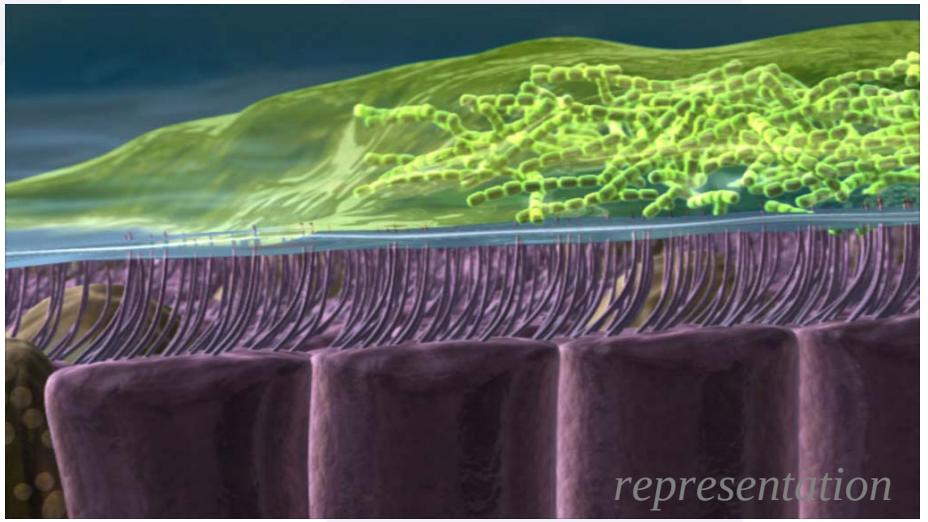


Lung surface dehydrated

Airway surface fluid layer impaired

Lung defense and hygiene compromised

After Bronchitol administration

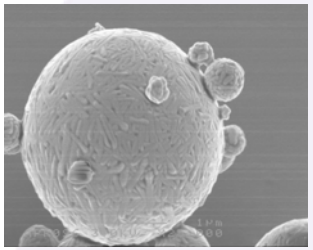


Lung rehydrated

Airway surface liquid restored

Normal lung clearance

Bronchitol - bronchiectasis



Background

- 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 remains unknown
- Normal lung clearance impaired
- 500,000 affected worldwide (110,000 in the U.S.)[1]

Current treatments: bronchodilators, antibiotics

- No drugs proven effective to clear mucus

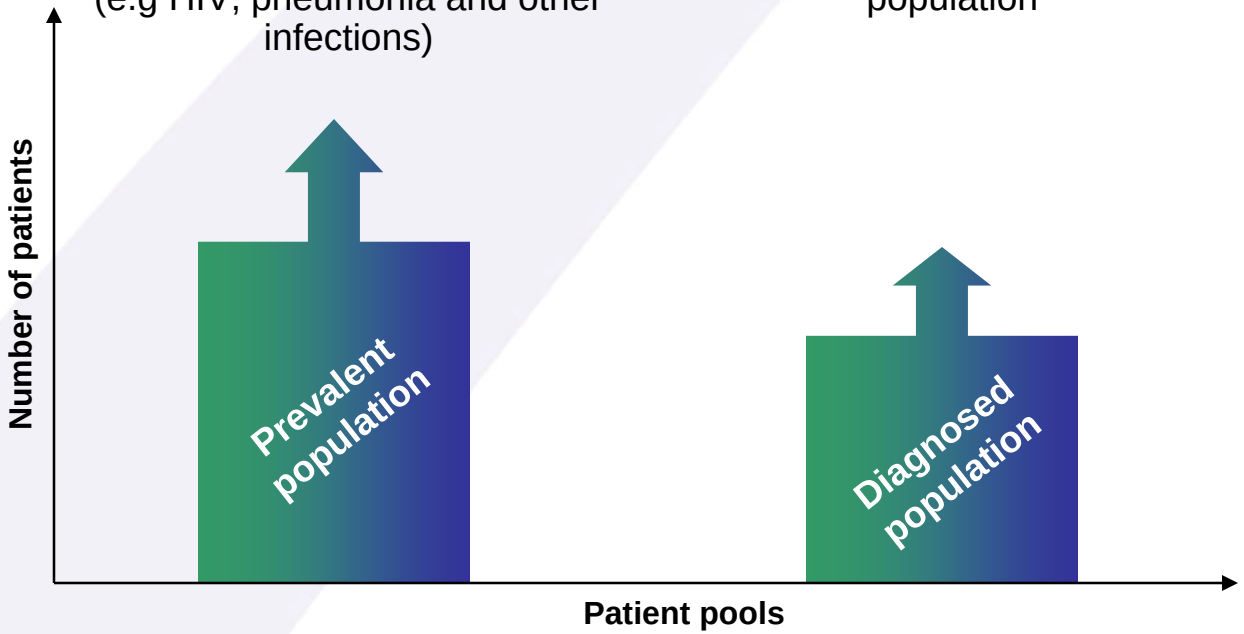
1: Clin Pulm Med 2005;12:205

Bronchiectasis - epidemiology and disease burden

The diagnosed and treated patient population will continue to grow in the future, due to the growing use of CT scans for diagnosis and the increasing prevalence of some underlying causes of bronchiectasis

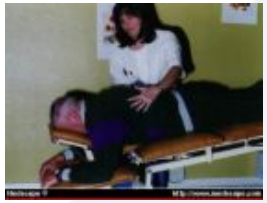
Prevalence is increasing due to the rising incidence of some underlying causes of the disease (e.g HIV, pneumonia and other infections)

The growing use of CT scans is increasing the diagnosed and therefore treatable patient population



- There are currently approximately 110,000 diagnosed patients in the US
- Over 30% of patients are currently misdiagnosed representing a significant opportunity to further increase the size of the treated population

Bronchitol - bronchiectasis



Phase II clinical trial

- 60 patient, double-blind, crossover, placebo-controlled
- 400mg twice a day for 14 days
- Primary end point – quality of life

- Improvement in quality of life ($p<0.05$)
- Improvement in sleep ($p<0.02$)
- Improvement in chest congestion ($p<0.05$)
- Improvement in small airway function ($p<0.05$)

Bronchitol - bronchiectasis

Phase III trial (for Europe)

- scheduled close of recruitment - end 2006
- data - mid 2007

Primary endpoints

- quality of life
- mucus clearance

Design

- 354 patient, placebo controlled, double blind, randomised 12 week treatment

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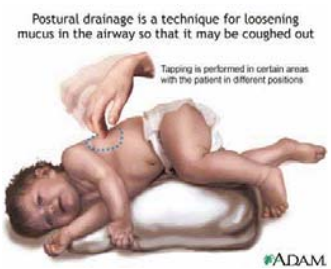
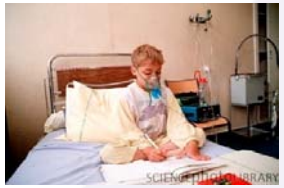
Phase III trial (for U.S.)

- to commence 2007

Bronchitol – cystic fibrosis





Background

- Genetic disorder affecting 75,000 worldwide (30,000 in U.S.)
- Poorly hydrated, tenacious, thick mucus
- Current life expectancy is 31 years

Current treatments: rhDNase and tobramycin

- Delivered by nebulizer (preparation, sterilization)
- rhDNase (Pulmozyme): US$265mm @ ~30% penetration
- Tobramycin: US$233mm

Phase II cystic fibrosis trial…..

- Crossover, 8 site study in 39 CF patients
- Randomised two week treatment periods
- Double-blind, placebo controlled
- Primary Endpoint:
  - Change in FEV_1
- Secondary Endpoints:
  - Effect on other lung function measures
  - Effect on symptoms/signs
  - Effect on Quality of Life
  - Safety (including microbiology)

CF Phase II trial results – lung function…..

	Bronchitol	Control	p value
Change in FEV_1	7 ± 2%	0 ± 2%	0.008
Change in FEF_{25-75}	15.5 ± 5%	0.6 ± 5%	< 0.01

- Includes patients being treated with rhDNAse
- FEF_{25-75} is a measure of small airway function

Bronchitol – cystic fibrosis registration.....

Phase III trial (EU & Aus):

- Commence dosing Q4 2006
- Primary endpoint: same as Phase II (FEV_1)
- Placebo-controlled, 6 month dosing
- Scheduled completion mid 2008

Phase III trial (US) to commence 1H 2007

- Similar size, design to EU/Aus trial
- Scheduled completion beginning 2008

Orphan drug designation – EU and USA

Bronchitol – clearance of lung secretions

Proof of concept demonstrated with ICU patients

- Currently supplied on request to patients with life threatening condition

Clinical conditions include:

- asthma, COPD, cystic fibrosis, secondary respiratory disease, neurogenic disorder

Complete acute care pilot study (COPD) Q4 2006

Complete pivotal Phase III study Q4 2007

- 30 million COPD exacerbations per year in the U.S.[1]
- 1 million U.S. emergency room visits per year

1: ATS San Diego 2006

Aridol™

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

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Potential clinical applications for Aridol

An easy to use, ‘point of care’ test with a high degree of sensitivity and specificity 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[2]**

NOTES: *1 = Evidence available from phase 3 study*

2 = Proof of concept only; definitive studies ongoing / planned

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International Regulatory Status

Australia

- Launched

European marketing authorization

- Dossier submitted to Sweden - May 2005
  - Anticipated notification - Q4 2006
- Rest of Europe through Mutual Recognition Procedure
  - To be filed after Swedish review
  - Anticipated notification - early 2007
- Swiss Dossier submitted - July 2006
- 1st marketing partners appointed

USA

- Phase III data expected Oct-Dec 2006

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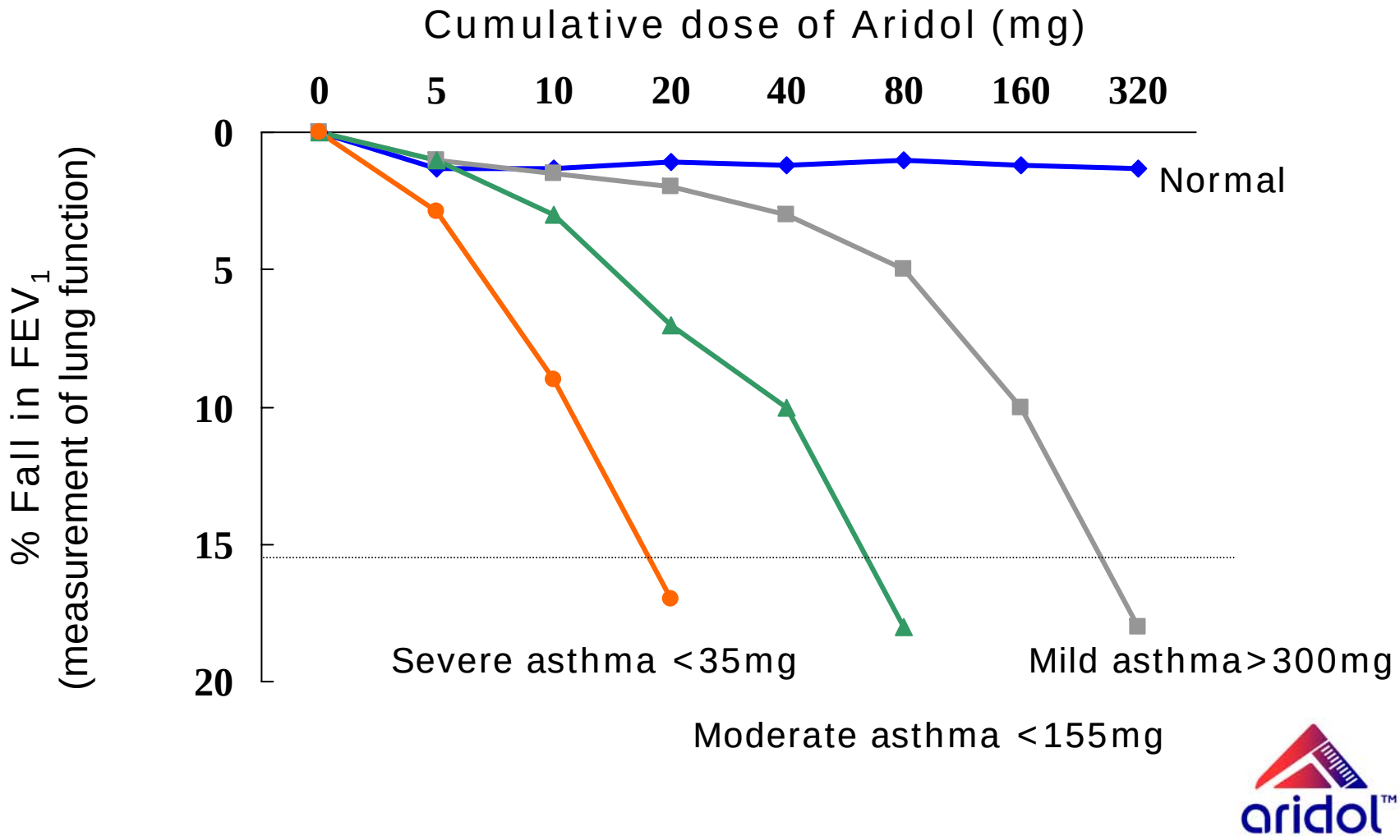
Aridol - airway hyper-responsiveness in asthma



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Asthma diagnosis – EU Phase III trial results

Patient characteristics

- 557 asthmatic (428 adult, 129 children)
- 97 non asthmatic (82 adult, 15 children)
- Age 6 – 83
- Majority had mild disease
  - Half the asthmatic cohort had infrequent symptoms
  - Only 11.9% reported symptoms interfering with normal activity.
- Majority had good lung function.
  - 50% of the asthmatics had a FEV1 > 95% of predicted.
  - The mean FEV1 was 3.0 L in the asthmatics and 3.2 L in the non-asthmatics.
- 74% of asthmatics were on ICS
  - 228 on combination therapy / 164 on monotherapy with ICS

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Asthma diagnosis – Phase III trial results

Results – Highly specific test for asthma

Aridol vs.:	Sensitivity	Specificity
Hypertonic Saline	81%	87%
Clinical diagnosis (ICS naive)	89%	95%
Clinical diagnosis (all patients)	60%	95%

- Mean dose for PD15 = 186mg
- Mean FEV_1 fall in negative patients was 4.9%
- High sensitivity in steroid naive patients
- Reduced sensitivity to clinical diagnosis in patients on ICS

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Asthma diagnosis – Phase III trial results

Results: Sensitivity to inhaled steroid usage yields valuable disease insights in treated asthmatics

	Aridol Positive		Aridol Negative	
	Not on ICS N = 87	**Using ICS N = 204**	**Not on ICS N = 37**	**Using ICS N = 159**
Clinical diagnosis of asthma N=487	Asthmatic with active airway inflammation that will respond to ICS	Maintain or increase ICS dosage	Consider alternative diagnosis	Well controlled asthmatic. Consider reducing dosage of ICS

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U.S. Asthma Phase III trial (DPM-A305)

Primary end point

- Comparison of Aridol and exercise and methacholine and physician diagnosis
- Safety

Subjects

- 415, aged 6 – 40, male and female with symptoms suggestive of asthma but no definitive diagnosis. FEV_1 >70%

No of sites

- 30

Status

- Recruitment closed Aug 06. Data due Q4 2006

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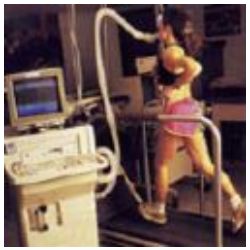
Key international studies underway



Steroid Management

Mannitol versus BTS guidelines in ICS treated asthmatics

- UK multicentre GP study
- 300 patients in parallel design with 12 month follow up
- Endpoint = exacerbations

Steroid responsive COPD patients

Does a +ve mannitol test predict patients who respond to ICS?

- Australian multicentre open label study
- 80 patients
- Endpoint = improvement in FEV1

Various

- Use in a number of new anti-asthma clinical trials

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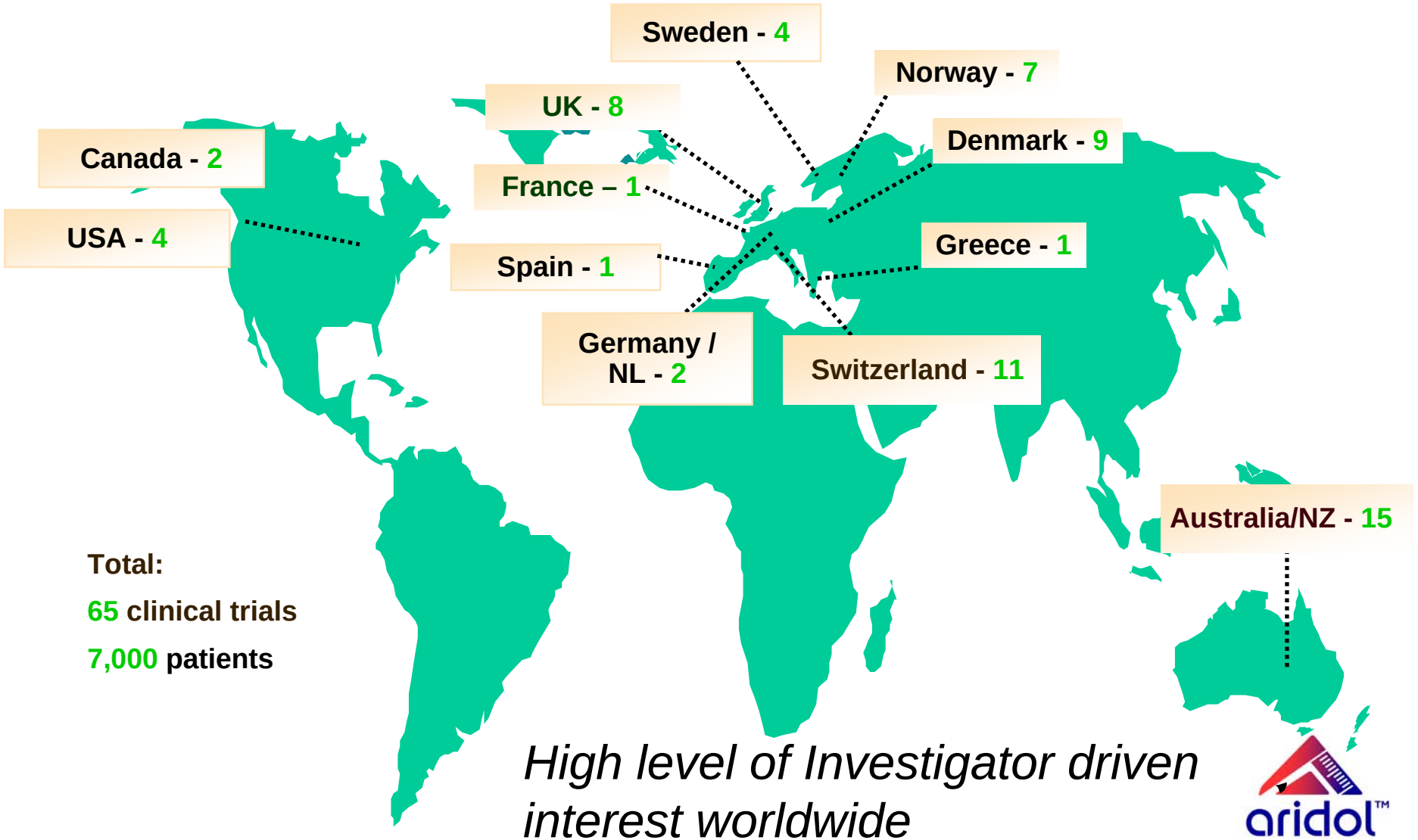
Worldwide development of Aridol……



Total:

65 clinical trials

7,000 patients

High level of Investigator driven interest worldwide

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Near term catalysts ahead…..

Milestone	4Q-06	1Q-07	2Q-07	3Q-07
Aridol				
Ph III US clinical data				
Approval – Sweden				
Launch - Sweden				
COPD clinical data				
Bronchitol – cystic fibrosis				
PII dosing study data				
Commence PIII trial (EU)				
Combination trial enrolled				
Bronchitol – bronchiectasis				
PIII trial enrolment complete				
PIII data available				
File EU marketing application				
Bronchitol – COPD				
Commence PII hospital trial				
Data available				
PXS64				
Complete preclinical studies				

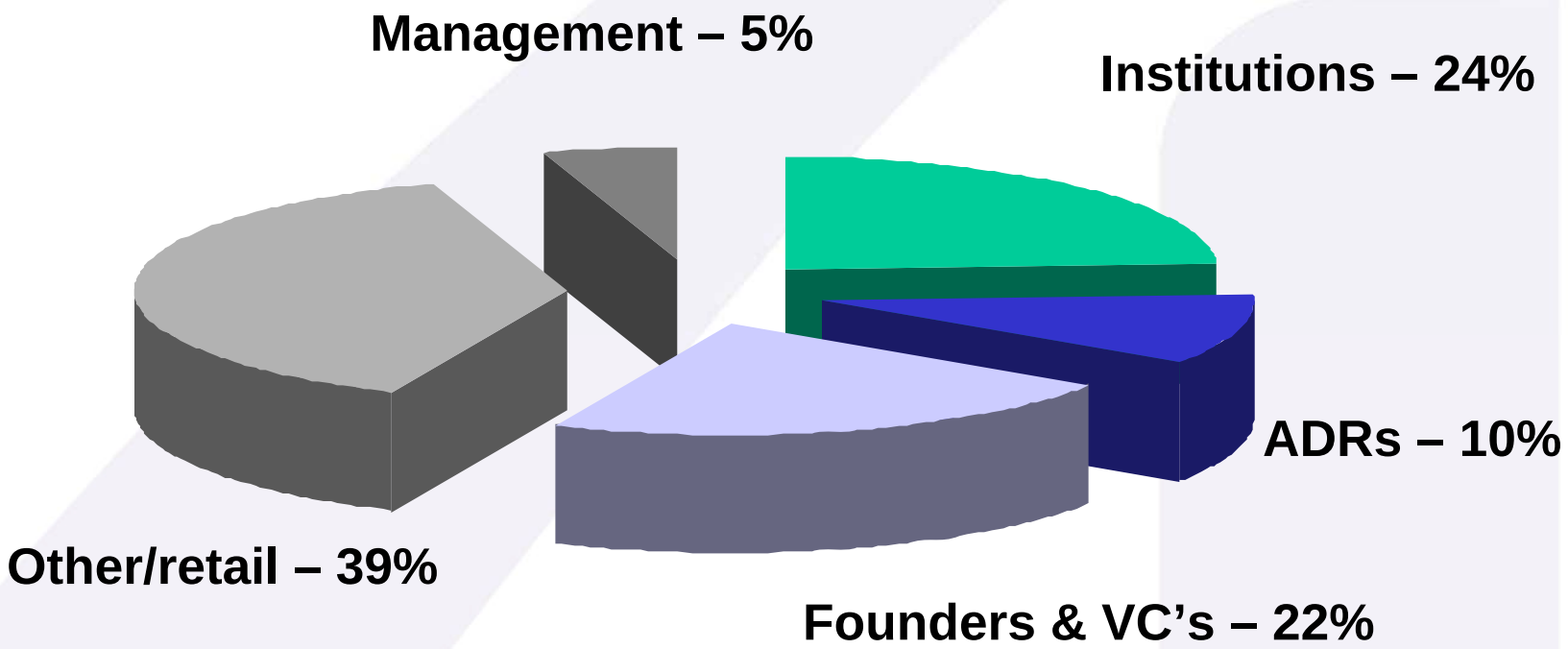
Financial Statements

	Year ended 30 June				
	2002	2003	2004	2005	2006
	A$	A$	A$	A$	A$
	(in thousands)				
Income Statements					
Revenue from sale of goods	-	-	-	-	8
Cost of sales	-	-	-	-	(2)
Gross profit	-	-	-	-	6
Interest	43	284	1,075	1,702	4,282
Grant income	646	779	1,152	1,219	1,299
Other income	-	43	48	-	-
Expenses					
Research & development	(1,151)	(2,051)	(6,301)	(9,269)	(16,978)
Administration	(140)	(1,103)	(2,461)	(3,134)	(4,386)
Commercial	-	-	-	(963)	(1,951)
Loss before income tax	(602)	(2,048)	(6,486)	(10,445)	(17,728)
Income tax expense	-	-	-	-	(5)
Loss for the year	(602)	(2,048)	(6,486)	(10,445)	(17,733)

Financial Statements

	As at 30 June				
	2002	2003	2004	2005	2006
	A$	A$	A$	A$	A$
	(in thousands, except per share data)				
Balance Sheets					
Cash and cash equivalents	750	7,384	25,217	33,390	97,840
Plant & equipment	116	1,515	1,474	2,477	3,205
Total Assets	2,144	10,495	28,261	37,937	104,267
Total liabilities	190	802	1,630	2,470	5,379
Total shareholders' equity	1,953	9,693	26,631	35,467	98,888
Share Data					
Ordinary shares on issue	11,200	11,200	108,016	134,770	176,904
Converting preference shares	16,000	46,816	-	-	-
Options on issue	3,680	9,024	10,751	10,914	9,692

Share Capital
(including options)



31 July 2006: 177m shares; 10.2m options