

pharmaxis

**Therapeutic products
for respiratory and
autoimmune diseases**

April 2007

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.

Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors and Other Uncertainties" section of our Form 20-F filed with the US Securities and Exchange Commission

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Summary.....

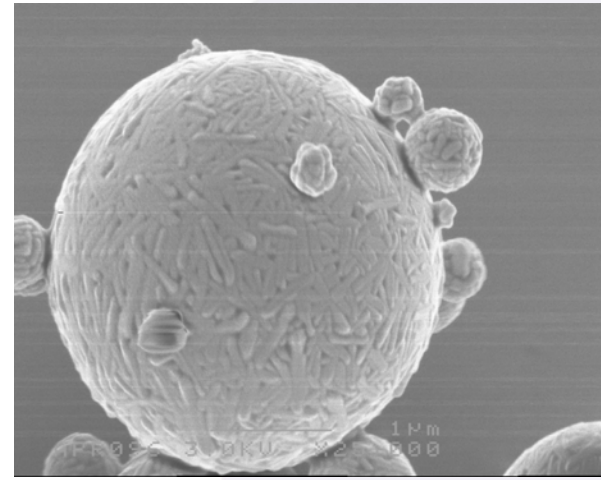
Objective	The development of products for respiratory and autoimmune diseases
Lead products	Aridol: management of asthma and COPD Bronchitol: therapeutic for cystic fibrosis and COPD
Discovery	PXS64 - multiple sclerosis
Listings	ASX (Nov 2003): PXS; NASDAQ (Aug 2005): PXSL
Location	Sydney, NSW, Australia
Facility	GMP Manufacture of lead products
Employees (31/3/07)	64
Cash (31/3/07)	A\$80 million
Shares outstanding	177m (11.8m ADS)
Options outstanding	10.3m
Key patents	Aridol & Bronchitol granted in USA, Australia, Asia; pending in EU, Canada and Japan
Analyst coverage	    

Near term catalysts 2007.....



- **Bronchitol – bronchiectasis**
 - Europe Phase III trial data
- **Bronchitol – cystic fibrosis**
 - Phase IIb dosing trial data (Canada/Argentina)
 - Phase III Protocol assessment finalised with FDA
- **Bronchitol – chronic bronchitis**
 - Phase II exacerbation trial data
- **Aridol**
 - Completion of European Union MRP process
 - Filing of US NDA
- **PXS64**
 - Completion of preclinical studies

Bronchitol

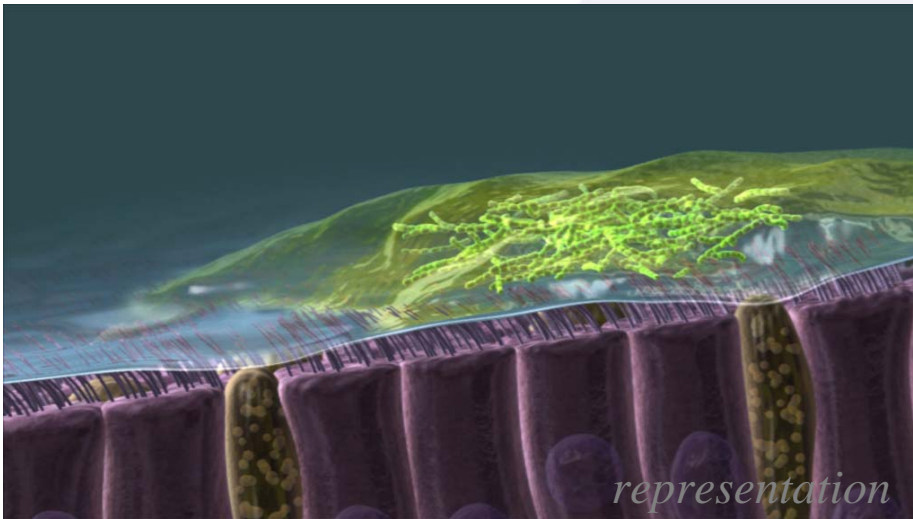


Mucus clearance:

***Cystic fibrosis
Chronic Obstructive Pulmonary Disease
Bronchiectasis***

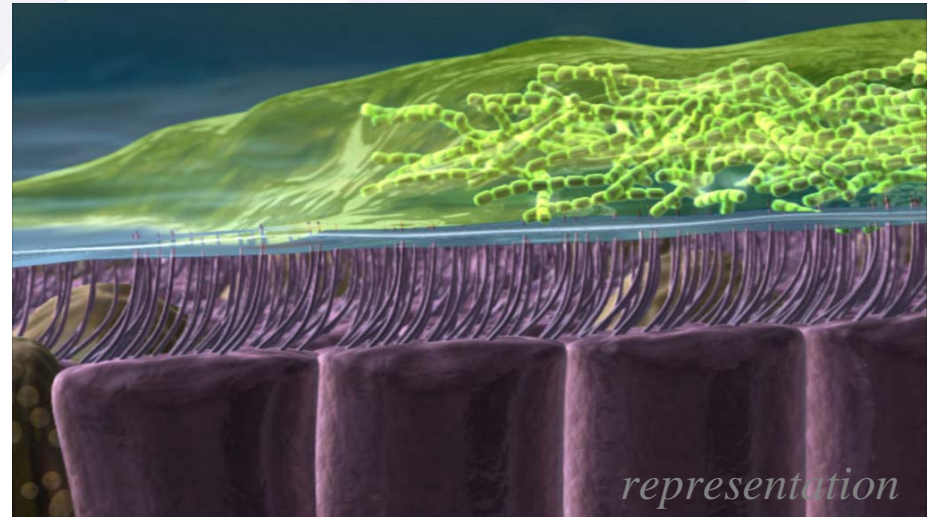
Osmotic clearance of abnormal mucus.....

Before treatment



Lung surface dehydrated
Airway surface fluid layer impaired
Lung defense and hygiene compromised

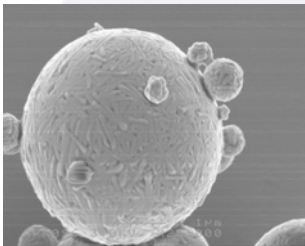
After Bronchitol administration



Lung hydrated
Airway surface liquid restored
Normal lung clearance

Bronchitol - bronchiectasis

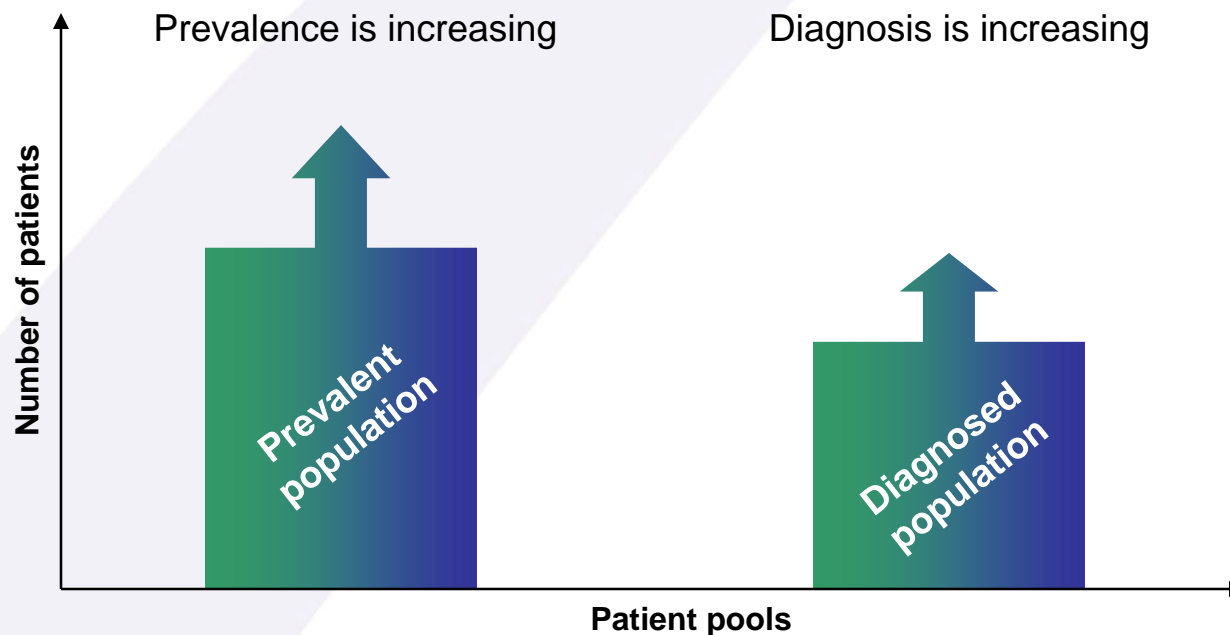
•Background



- 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

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



- There are approximately 110,000 patients being treated in the US
- Over 30% of patients are currently misdiagnosed
- Over 500,000 patients worldwide

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)

- fully recruited and enrolled
- data - mid 2007

- Primary endpoints

- quality of life
- mucus clearance

Additional endpoints

- MRI, CT, exercise, lung function



- Design

- 363 patient, placebo controlled, double blind, randomised 12 week treatment. 12 month Open Label Extension
-



- Phase III trial (for U.S.)

- to commence 2007
- Orphan drug designation

Bronchitol – cystic fibrosis

•Background

Postural drainage is a technique for loosening mucus in the airway so that it may be coughed out



- 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 FEV₁
- 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

FEF₂₅₋₇₅ is a measure of small airway function

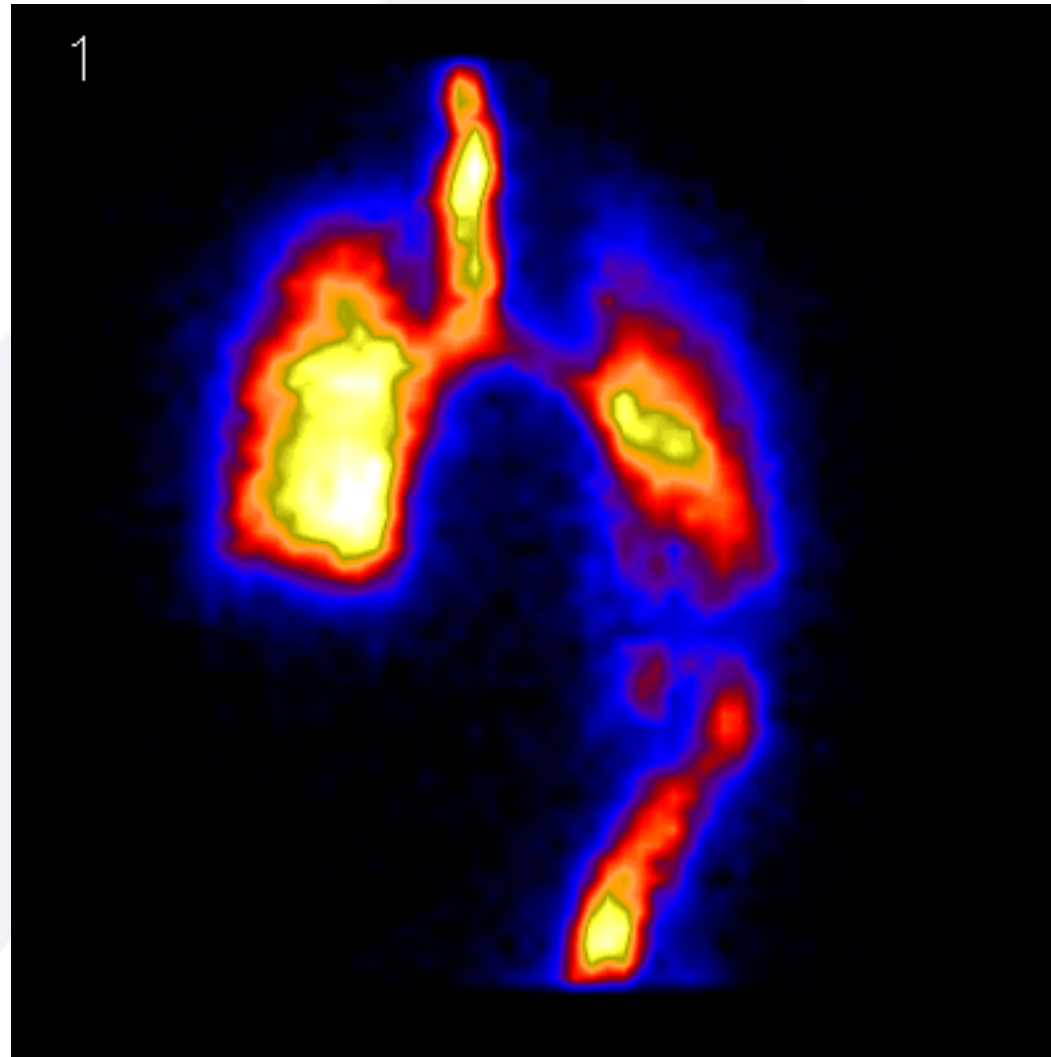
Bronchitol – cystic fibrosis registration.....

- Phase III trial (EU):
 - Now enrolling - 250 subject target
 - Primary endpoint: - lung function (FEV1)
 - Placebo-controlled, 6 month dosing, 400mg bd
 - Scheduled completion 2H 2008
- Phase III trial (US) to commence 2H 2007
 - Similar size, design to EU trial
 - Scheduled completion 1H 2009
- Orphan drug designation – EU and U.S.
- Fast track designation – U.S.



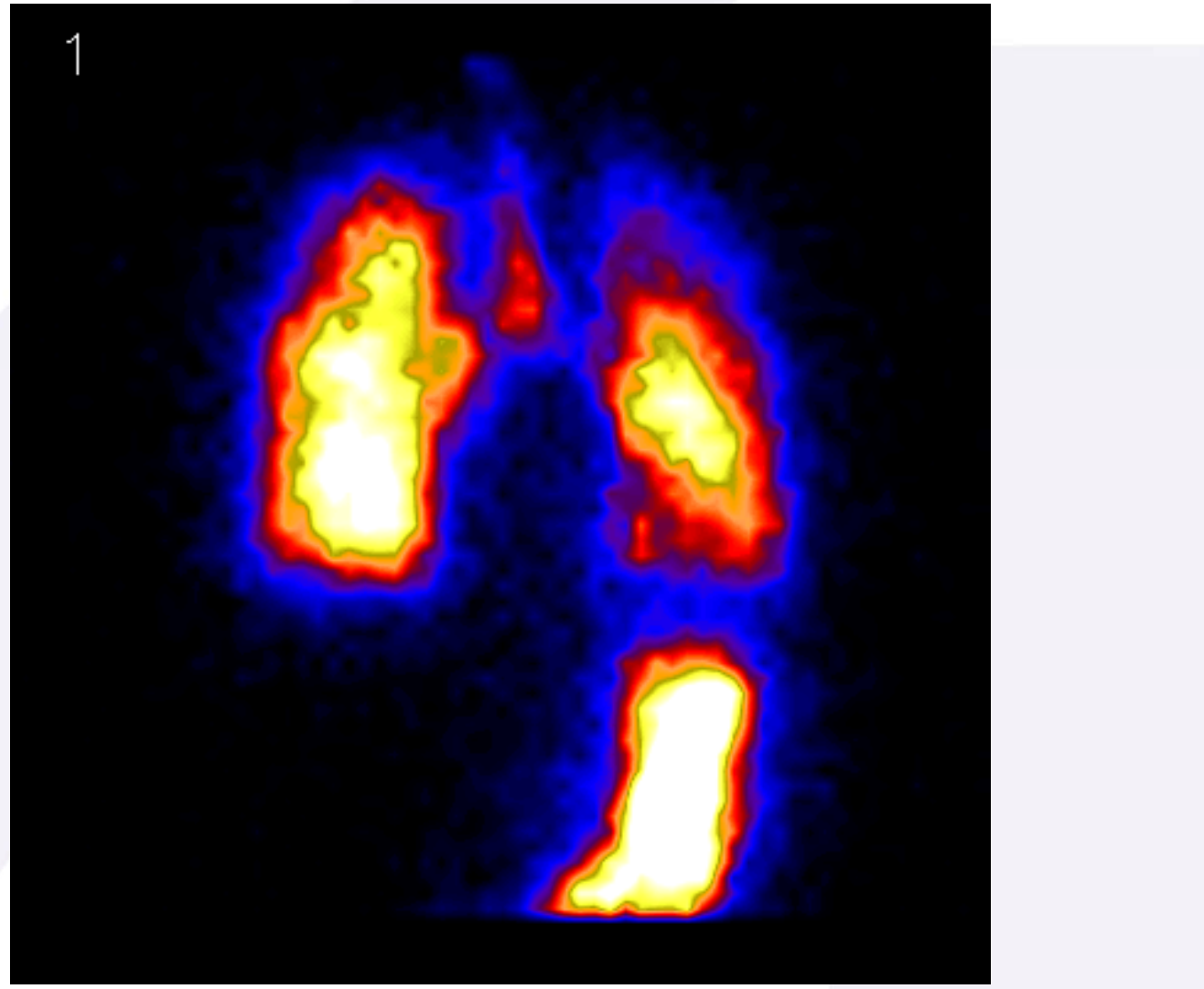
Bronchitol in the clinic.....

Chronic bronchitis – without Bronchitol



Bronchitol in the clinic.....

Chronic bronchitis – with 400 mg Bronchitol



Bronchitol – clearance of lung secretions



- Proof of concept demonstrated with ICU patients
 - Currently supplied on individual compassionate use basis
- Clinical conditions include:
 - asthma, COPD, cystic fibrosis, secondary respiratory disease, neurogenic disorder
 - 30 million COPD exacerbations per year in the U.S.¹
 - 1 million U.S. emergency room visits per year
- Complete acute care pilot trial (COPD) 1H 2007
- Complete pivotal Phase III trial 2H 2008

Aridol™



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



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 severity¹**
- 2. Monitor patient's disease / managing effectiveness of treatment²**
- 3. Identification of COPD patients who will respond to steroids³**

NOTES: 1 = Evidence available from phase III study

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

3 = Evidence available from phase II study



International Regulatory Status

- **Australia**

- Launched June 2006



- **Europe**

- Approved for marketing October 2006

- Launched - Sweden January 2007

- Rest of EU through Mutual Recognition Procedure

- Anticipated notification 1H 2007

- Swiss Dossier submitted July 2006

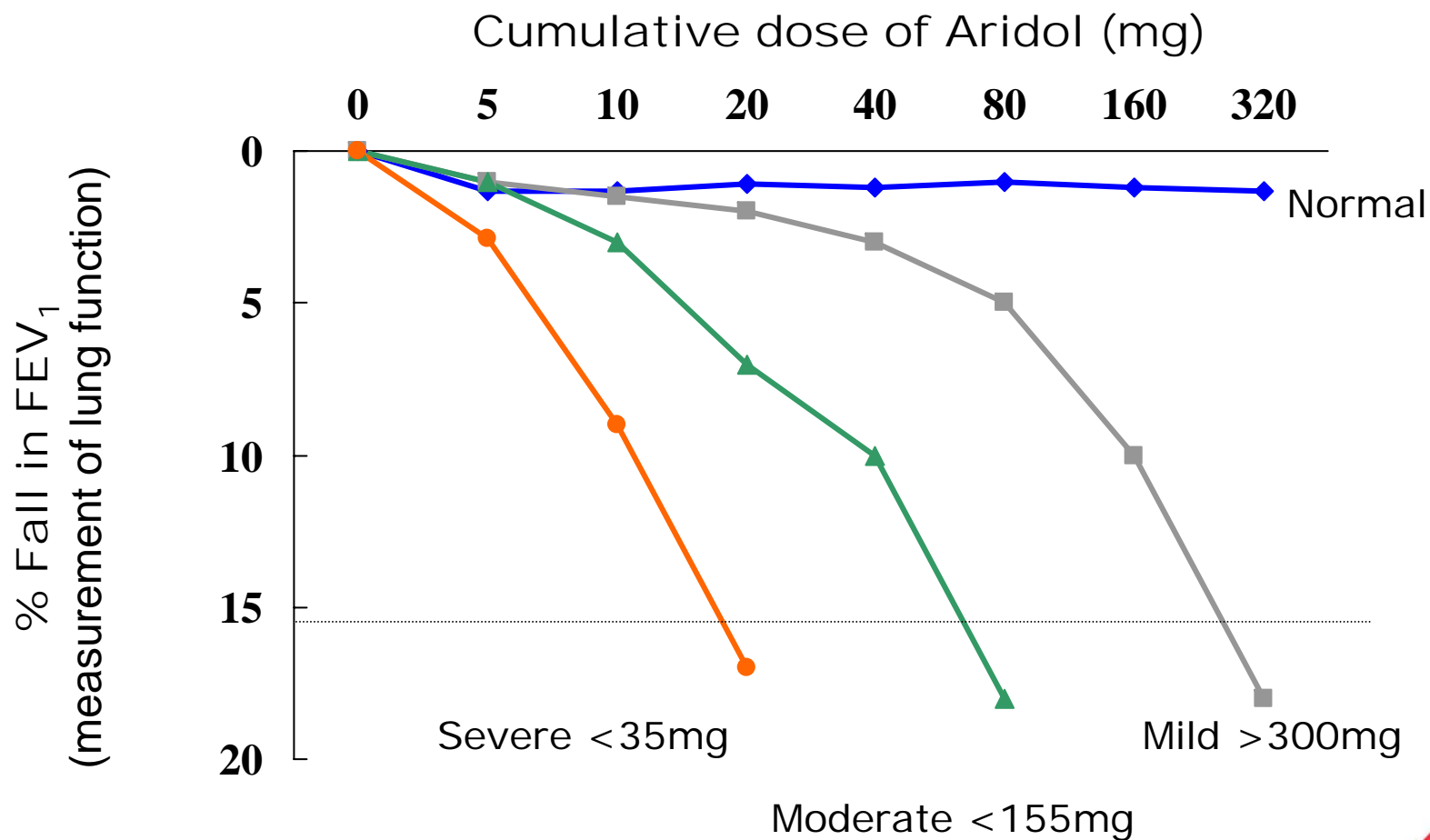
- Regional marketing partners appointed

- **USA**

- Phase III completed



Aridol - airway hyper-responsiveness in asthma



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



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 FEV₁ fall in negative patients was 4.9%
- High sensitivity in steroid naive patients
- Reduced sensitivity to clinical diagnosis in patients on ICS

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



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



- **Primary end point**

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

- **Subjects**

- 500, aged 6 – 40, male and female with symptoms suggestive of asthma but no definitive diagnosis. FEV₁ >70%

- **No of sites**

- 30

- **Outcome**

- Aridol equivalent to the US approved test (methacholine)



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 ICS responders?

- Australian multicentre open label study
- 80 patients
- Airway positivity reduced by steroids ($p < 0.004$)

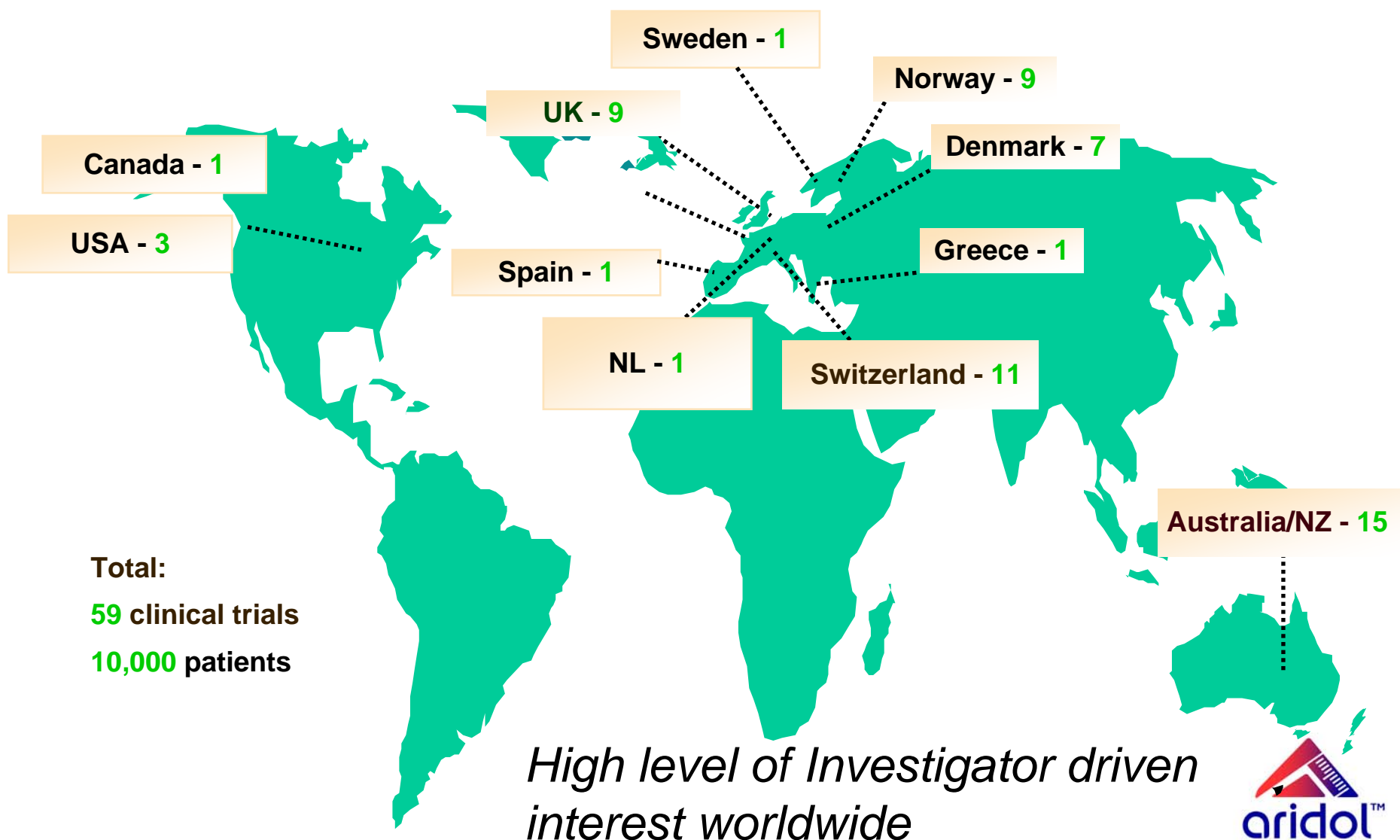
- Further study in progress



- **Various**

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

Worldwide development of Aridol.....



Addressable market summary (US, Europe, Japan)



- Bronchitol – chronic bronchitis
 - Total patients 64 million
 - Seeking treatment 23 million



- Bronchitol – bronchiectasis
 - Total patients 550,000
 - Seeking treatment 500,000



- Bronchitol – cystic fibrosis
 - Total patients 75,000
 - Seeking treatment 75,000

- Aridol – asthma
 - Total patients 45 million
 - Severe persistent 6 million



Near term catalysts ahead.....

Milestone	2Q-07	3Q-07	4Q-07	1Q-08
Aridol File US NDA Conclusion of EU MRP process Commence 2 nd COPD study				
Bronchitol – cystic fibrosis PII dosing trial data (Can/Arg) Commence PIII U.S. trial				
Bronchitol – bronchiectasis PIII data (360 subjects) File 1 st marketing applications				
Bronchitol – COPD Commence PII hospital trial Data available				
PXS64 Complete preclinical studies				

Financial Statements – US GAAP

Income Statements	<u>Year ended</u>			<u>Nine months to</u>	
	<u>Jun-30</u>			<u>Mar-31</u>	
	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2006</u>	<u>2007</u>
	A\$'000	A\$'000	A\$'000	A\$'000	A\$'000
Revenue from sale of goods	-	-	8	-	159
Cost of sales	-	-	2	-	(39)
Gross profit	-	-	6	-	120
Expenses					
Research & development	4,806	7,885	14,982	8,641	16,882
Administration	2,182	3,105	4,005	2,930	2,770
Commercial	-	807	1,764	963	2,257
Amortization - intangibles	89	90	136	68	70
Stock options	532	260	1,123	811	1,092
	7,609	12,147	22,010	13,413	23,071
Loss from operations	(7,609)	(12,147)	(22,005)	(13,413)	(22,951)
Interest & other income	1,123	1,702	4,282	2,854	4,059
Foreign exchange gains	(161)	-	(5)	-	(49)
Loss before income tax	(6,647)	(10,445)	(17,728)	(10,559)	(18,941)
Income tax expense	-	-	(5)	-	(12)
Loss for the year	(6,486)	(10,445)	(17,733)	(10,559)	(18,953)

Financial Statements – US GAAP

	<u>As at</u>			
	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>Mar-31</u> <u>2007</u>
	<u>A\$'000</u>	<u>A\$'000</u>	<u>A\$'000</u>	<u>A\$'000</u>
Balance Sheets				
Cash and cash equivalents	25,101	33,268	97,840	79,915
Plant & equipment	1,324	2,376	3,289	3,723
Total Assets	28,111	37,836	104,213	86,341
Total liabilities	1,480	2,369	5,325	5,125
Total shareholders' equity	26,631	35,467	98,888	81,216
Share Data	<u>'000</u>	<u>'000</u>	<u>'000</u>	<u>'000</u>
Ordinary shares on issue	108,016	134,770	176,904	177,365
Options on issue	10,751	10,914	9,692	10,188

Financial Statements – AIFRS

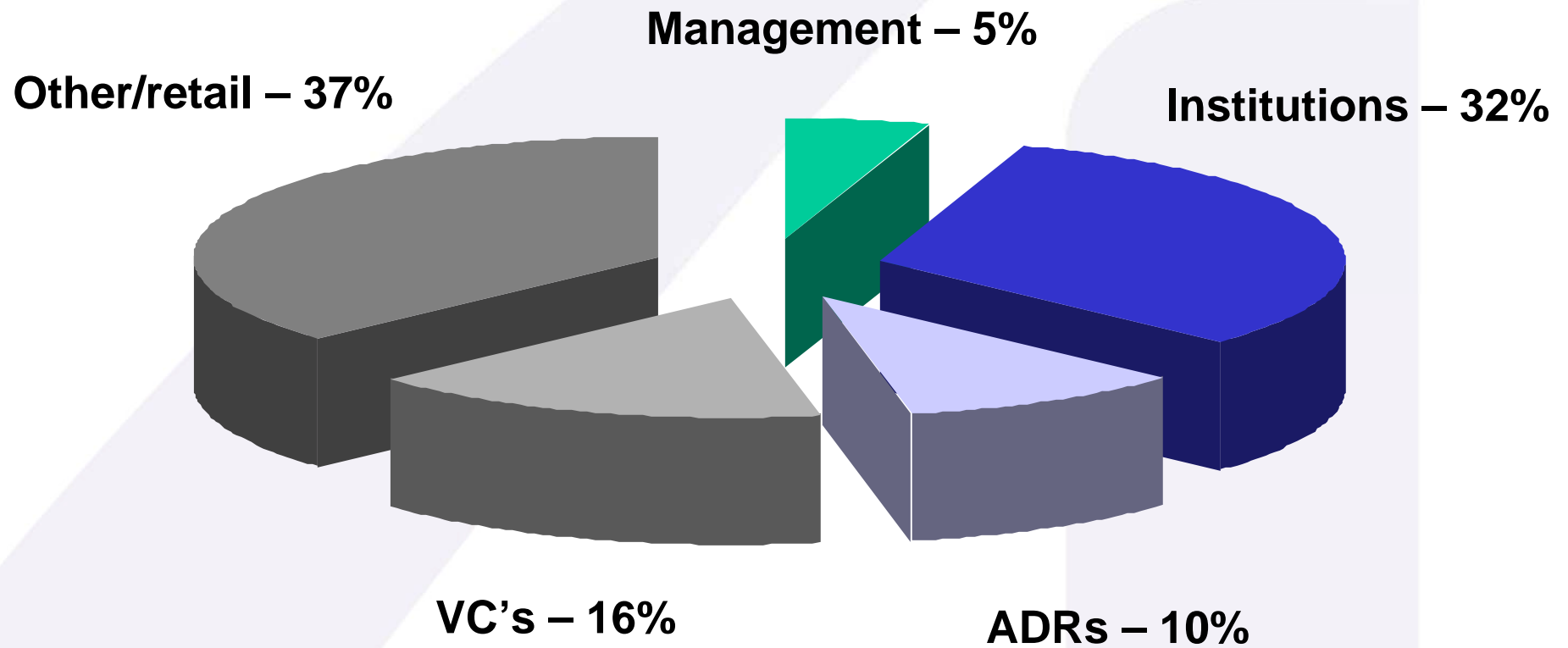
	<u>Year ended 30 June</u>			<u>Year-to-date</u>	
	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>31-Mar-07</u>	<u>31-Mar-06</u>
	<u>A\$'000</u>	<u>A\$'000</u>	<u>A\$'000</u>	<u>A\$'000</u>	<u>A\$'000</u>
Income Statements					
Revenue from sale of goods	-	-	8	159	-
Cost of sales	-	-	(2)	(39)	-
Gross profit	-	-	6	120	-
Other income					
Interest	1,075	1,702	4,282	4,059	2,854
Grant income	1,152	1,219	1,299	1,583	898
Other	48	-	-	-	-
Expenses					
Research & development	(6,301)	(9,269)	(16,978)	18,984	10,051
Commercial	(2,461)	(3,134)	(4,386)	2,461	1,100
Administration	-	(963)	(1,951)	3,210	3,163
Foreign exchange (gains)losses	-	-	-	49	-
Total expenses	(8,762)	(13,366)	(23,315)	24,704	14,314
Net loss before tax	(6,486)	(10,445)	(17,728)	(18,942)	(10,562)
Income tax expense	-	-	(5)	12	-
Net loss after tax	(6,486)	(10,445)	(17,733)	(18,954)	(10,562)
Basic and diluted earnings (loss) per share - \$	(0.071)	(0.084)	(0.111)	(0.107)	(0.068)
Depreciation & amortisation	490	646	947	693	706
Fair value of employe options issued	532	260	1,123	1,091	812

Financial Statements – AIFRS

	<u>As at</u>			
	<u>30-Jun-04</u>	<u>30-Jun-05</u>	<u>30-Jun-06</u>	<u>31-Mar-07</u>
	<u>A\$'000</u>	<u>A\$'000</u>	<u>A\$'000</u>	<u>A\$'000</u>
Balance Sheets				
Cash and cash equivalents	25,217	33,390	97,840	79,915
Plant & equipment	1,474	2,477	3,205	3,559
Intangible assets	28,261	37,937	1,195	1,167
Total assets	1,630	2,470	104,267	86,359
Total liabilities	26,631	35,467	(5,378)	(5,143)
Total shareholders' equity	26,631	35,467	98,888	81,216
Share Data				
	<u>'000</u>	<u>'000</u>	<u>'000</u>	<u>'000</u>
Ordinary shares on issue	108,016	134,770	176,904	177,365
Options on issue	10,751	10,914	9,692	10,188

Share Capital

(including options)



31 March 2007: 177m shares; 10.2m options