

pharmaxis

**Therapeutic products
for respiratory and
autoimmune diseases**

March 2008

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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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	Anti-inflammatory agent - asthma/COPD
Listings	ASX (Nov 2003): PXS; NASDAQ (Aug 2005): PXSL
Location	Sydney, NSW, Australia
Facility	GMP Manufacture of lead products
Employees	80
Cash (31/12/07)	\$120.8 million
Shares outstanding	194m (12.9m ADS)
Options outstanding	11.6m
Key patents	Aridol & Bronchitol granted in USA, Australia, Asia, Canada, Japan; pending in EU, Japan.
Analyst coverage	     

Development Pipeline

-----Clinical Trial Phases-----

Respiratory diseases

Aridol – asthma (Aus)

Aridol – asthma (Europe)

Aridol – asthma (USA)

Aridol - COPD

Bronchitol – bronchiectasis

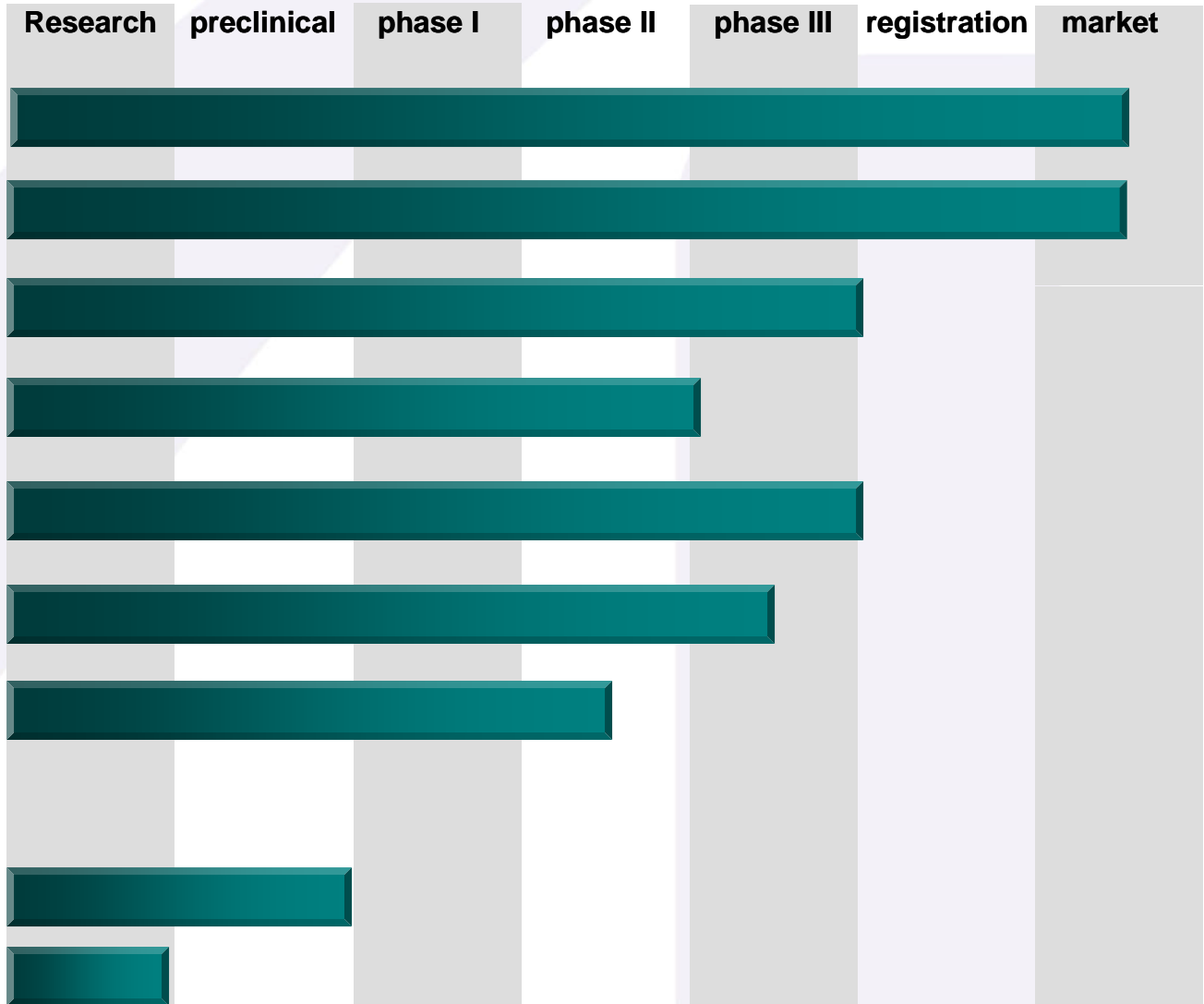
Bronchitol – cystic fibrosis

Bronchitol - chronic bronchitis

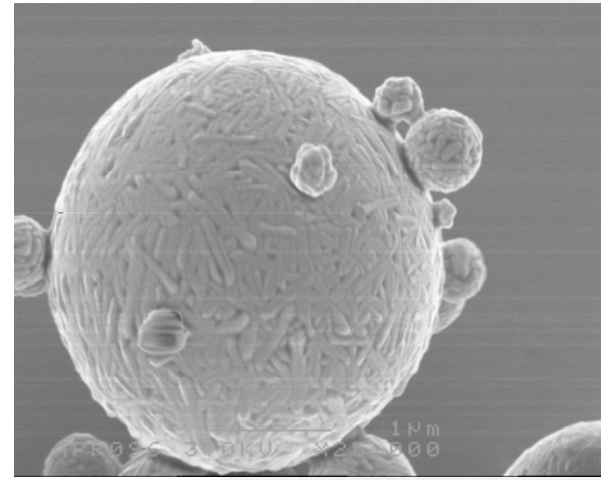
Autoimmune diseases

PXS25/64 – COPD/asthma

VAP-1 project – inflammation



Bronchitol

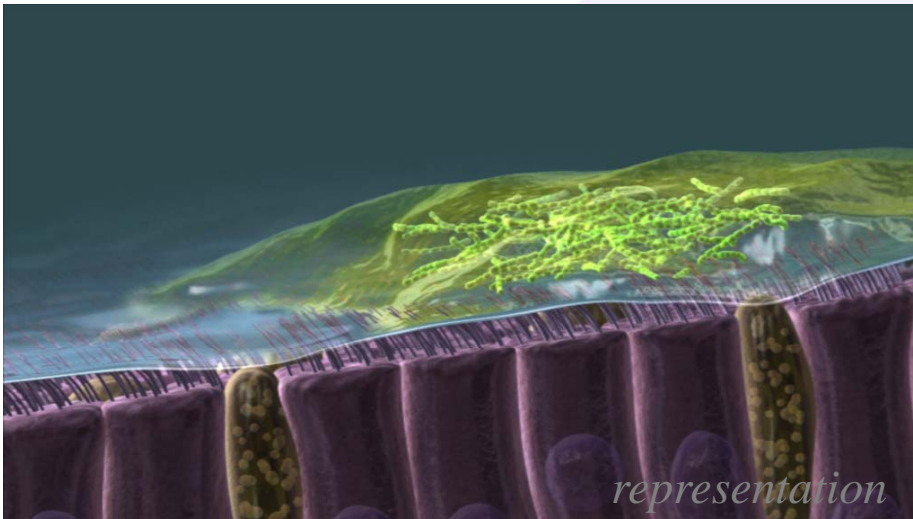


Mucus clearance:

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

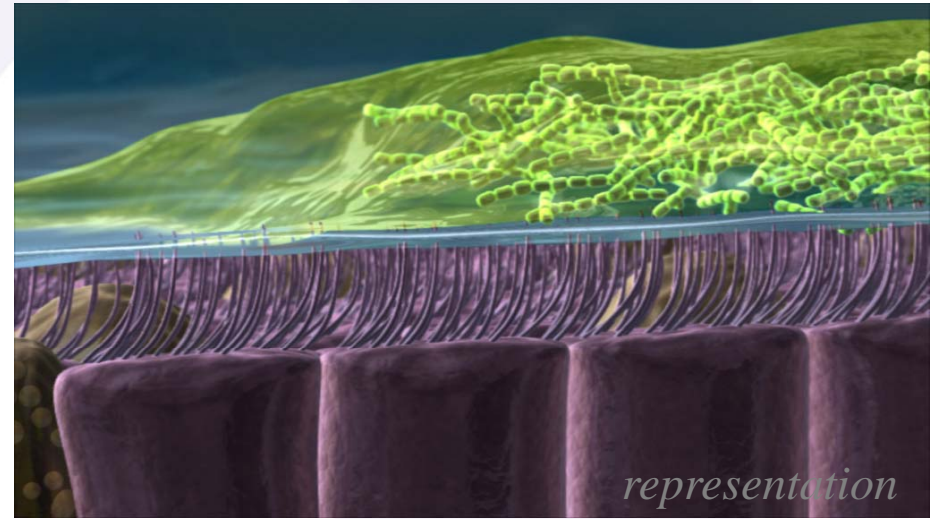
Osmotic clearance of abnormal mucus.....

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% market penetration
- Tobramycin: US\$233mm



Bronchitol Phase II cystic fibrosis programme.....

- Study 1

- Crossover, multicentre study in 39 CF patients
- Randomised 2 week treatment
- Reported
 - FEV₁ improvement of 7% (p=0.008)



- Study 2

- Crossover, 2 site study in 20 patients
- Randomised 3 month treatment including comparison with pulmozyme
- To report Q1 2008



- Study 3

- Crossover, multicentre study in 36 patients
- Randomised 2 week treatment including comparison of 4 doses of Bronchitol
- To report Q2 2008



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

•Phase III trial (Aus, NZ, EU):



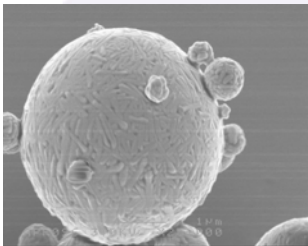
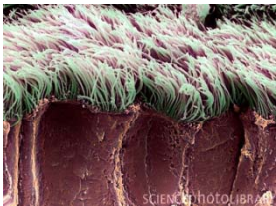
- Protocol assistance received from EMEA
- >150 out of 250 subjects enrolled
- Primary endpoint: - lung function (FEV1)
- Placebo-controlled, 6 month dosing, 400mg bd
- Top line efficacy data expected end 2008
- 1st market approval - 2009
- **Orphan Drug designation in the EU**

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



- **Phase III trial (US) finalised with FDA under SPA scheme**
 - 250 subject comparator controlled in adults and children
 - 6 month duration
 - 1^o endpoint - lung function by spirometry
 - 2^o endpoints – antibiotic use, exacerbations, lung function
- To commence enrolment 2Q 2008
- First data 2H 2009
- Orphan drug designation – 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

Number of bronchiectasis 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 registration (I)...

- Phase III trial (Europe, Australia, NZ)



- 363 patient, placebo controlled, double blind, randomised 12 week treatment (twice per day) + 12 month open label extension

- 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
 $\uparrow 30\%$, $p < 0.001$ versus placebo
- Antibiotic use
 $p < 0.05$ versus placebo
- Adverse Events
not significant versus placebo



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- First marketing applications to be filed – Q3 08

Bronchitol – bronchiectasis registration (II)....

- **Phase III trial (USA)**



- 375 patient, placebo controlled, double blind, randomised, 26 week treatment
- 400mg twice a day

- **Primary endpoint**

- Antibiotic use

- **Secondary endpoints**

- Quality of Life
- Mucus Clearance

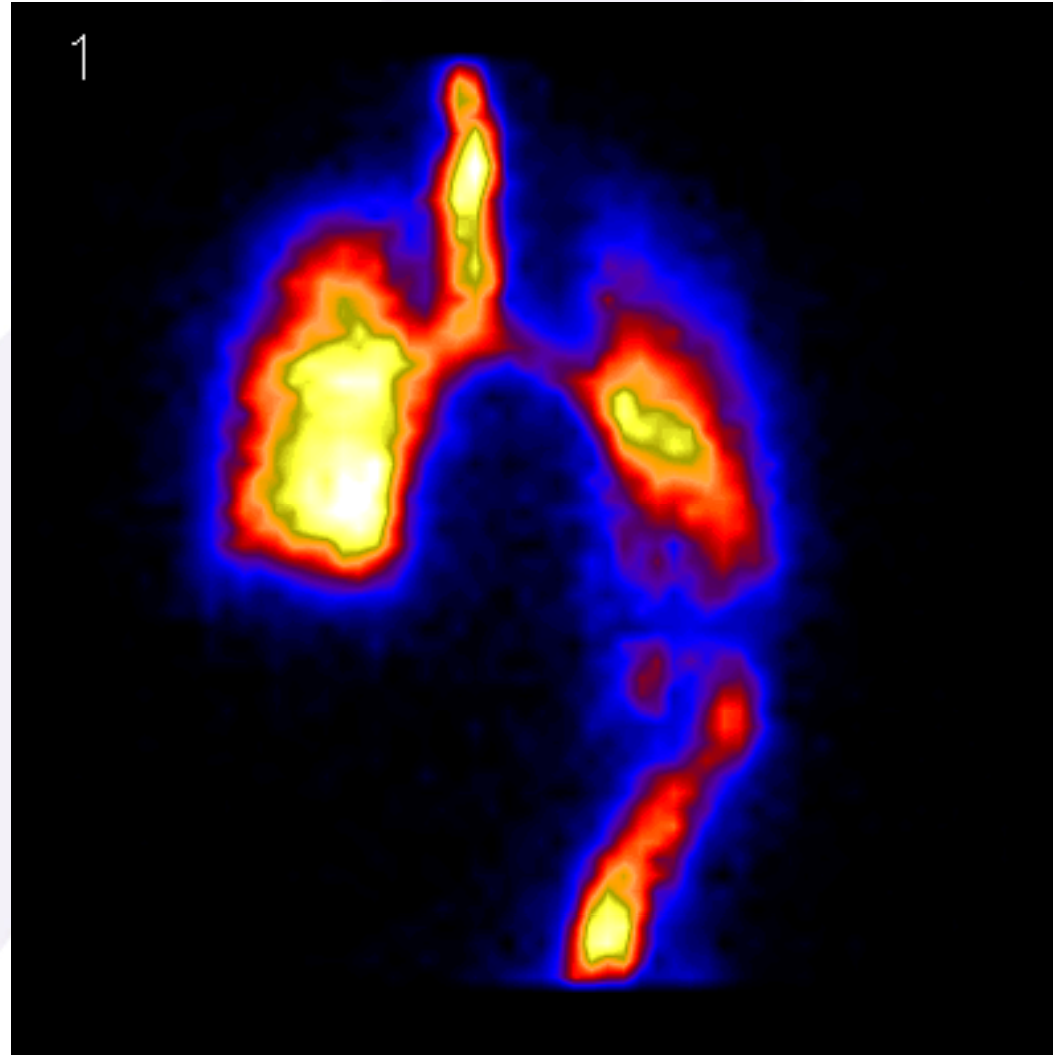
- **Status**



- Special Protocol Assessment discussion with FDA
- Orphan Drug designation USA
- Target first patient enrolment Q2 2008
- Target last patient enrolment Q4 2008
- Data 2H 2009

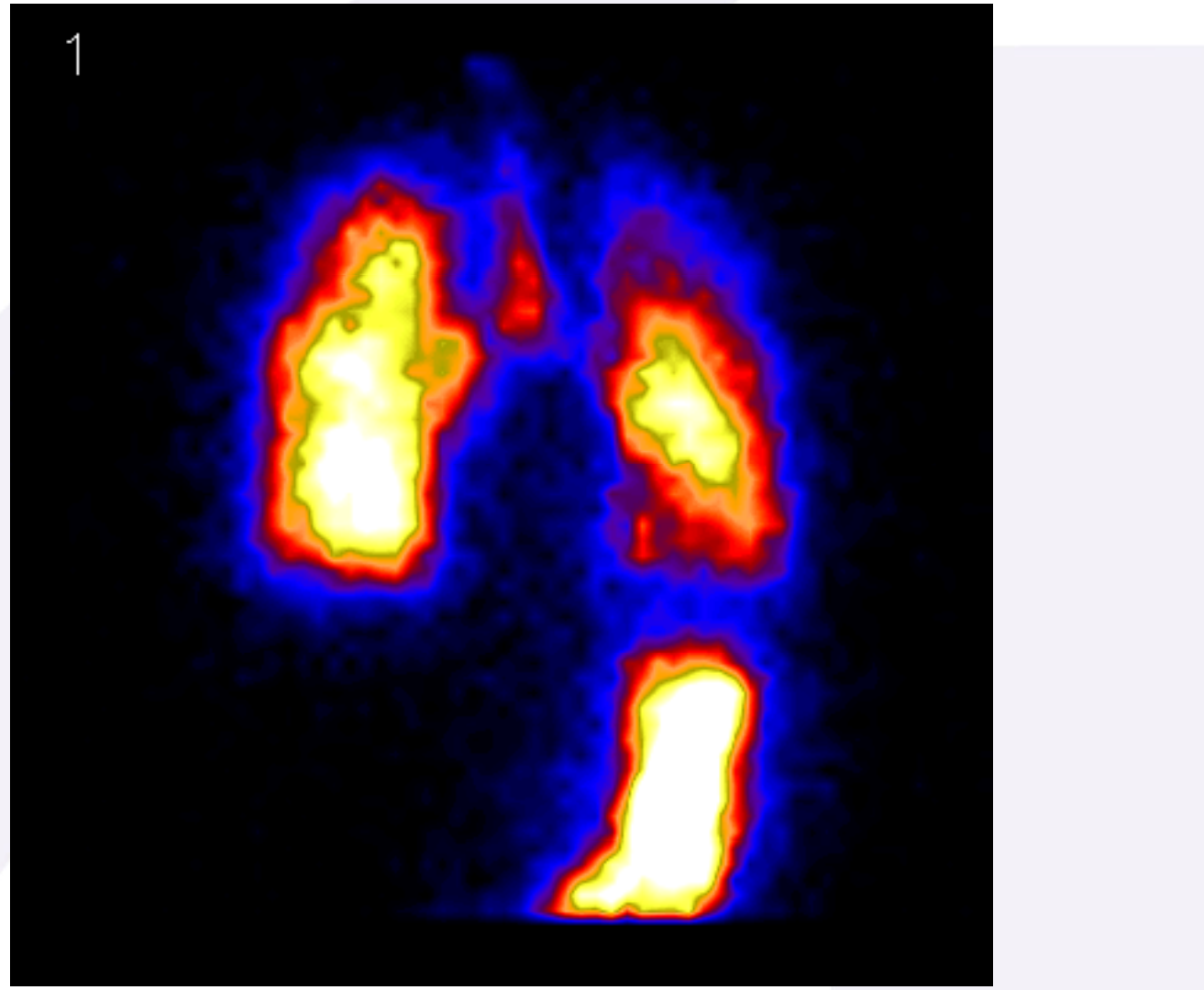
Bronchitol in the clinic.....

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 2008

Aridol™



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



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 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
3 = Evidence available from phase II study*



International Regulatory Status - Aridol



- **Australia**

- Launched June 2006

- **Europe**

- Approved for marketing (Sweden) October 2006
 - Launched January 2007
- Approved European Union (MRP) May 2007
 - Launch September 2007
 - Working through regional authorisations
- Submitted and review complete – Switzerland
- Regional marketing partners appointed



- **South East Asia**

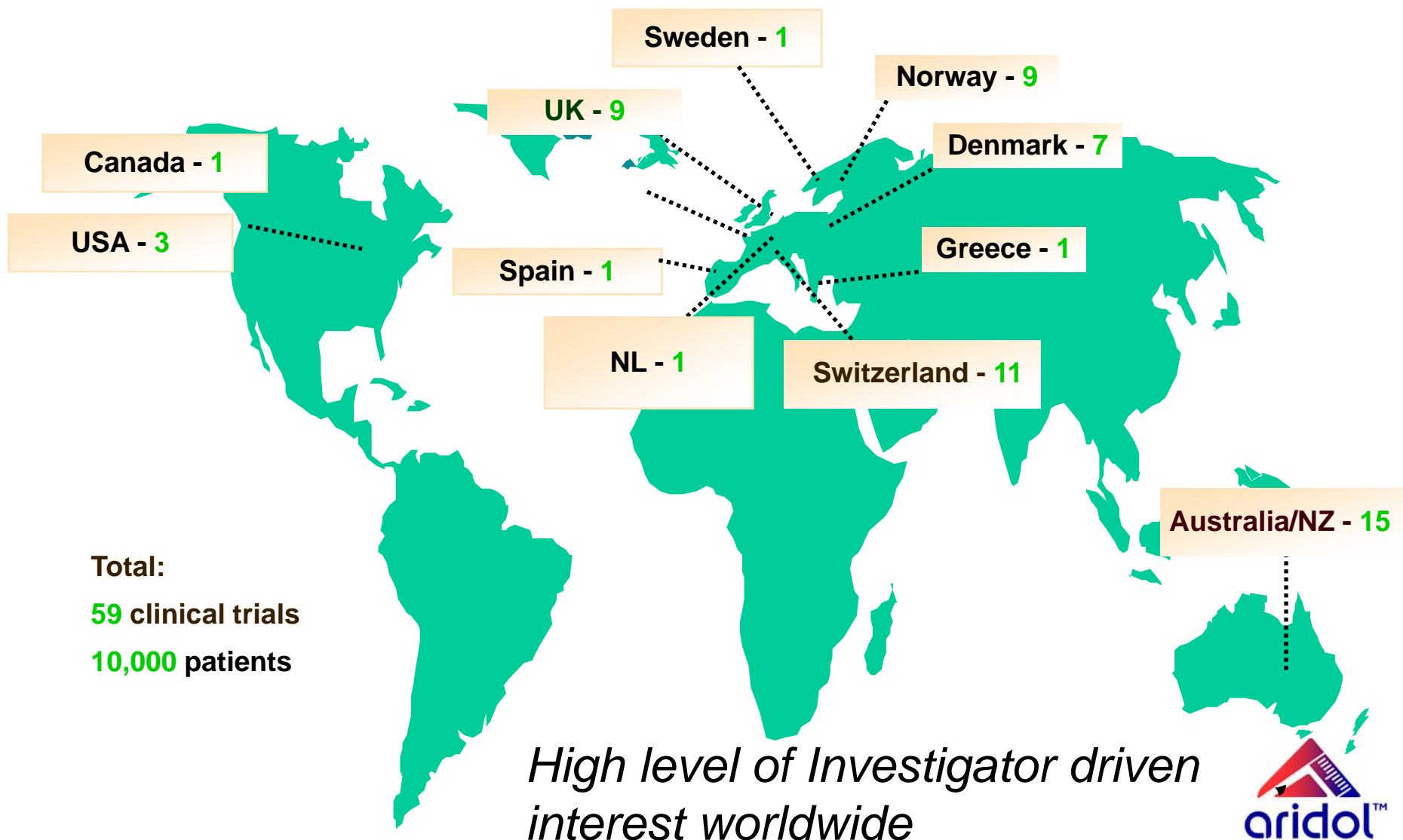
- Approved for marketing – Korea January 2008

- **USA**








- Phase III completed
- Pre-NDA meetings concluded with FDA March 2008
- New Drug Application to be filed with FDA 2Q 2008



Worldwide development of Aridol.....



Near term catalysts ahead.....

Milestone	1Q-08	2Q-08	3Q-08	4Q-08
Bronchitol – cystic fibrosis Complete EU PIII enrollment Commence Phase III (US) Additional PII trial data (x2)				
Bronchitol – bronchiectasis Pre - MAA meeting with EMEA Commence US Phase III trial File MAA (Australia)				
Aridol File NDA (US)				
Facilities New facility complete				
PXS25/64 Commence Phase I program				

Financial Statements

Income Statement

	Three months ended		Year-to-date	
	31-Dec-07	31-Dec-06	31-Dec-07	31-Dec-06
	A\$	A\$	A\$	A\$
Revenue from sale of goods	146	68	193	117
Cost of sales	(34)	(20)	(51)	(29)
Gross profit	112	48	142	88
Other income				
Interest	1,909	1,366	3,061	2,776
Grant income	(172)	688	128	1,187
Other	62	-	107	-
Expenses				
Research & development	4,607	7,251	9,640	13,772
Commercial	1,053	919	1,951	1,616
Administration	1,411	973	2,464	1,933
Total expenses	7,071	9,143	14,055	17,321
Net loss before tax	(5,160)	(7,041)	(10,617)	(13,270)
Income tax expense	8	6	16	8
Net loss after tax	(5,168)	(7,047)	(10,633)	(13,278)
Basic and diluted earnings (loss) per share - \$	(0.027)	(0.040)	(0.058)	(0.075)
Depreciation & amortisation	260	238	519	455
Fair value of options issued under employee plan	1,042	308	1,681	629

Financial Statements

Balance Sheet Data

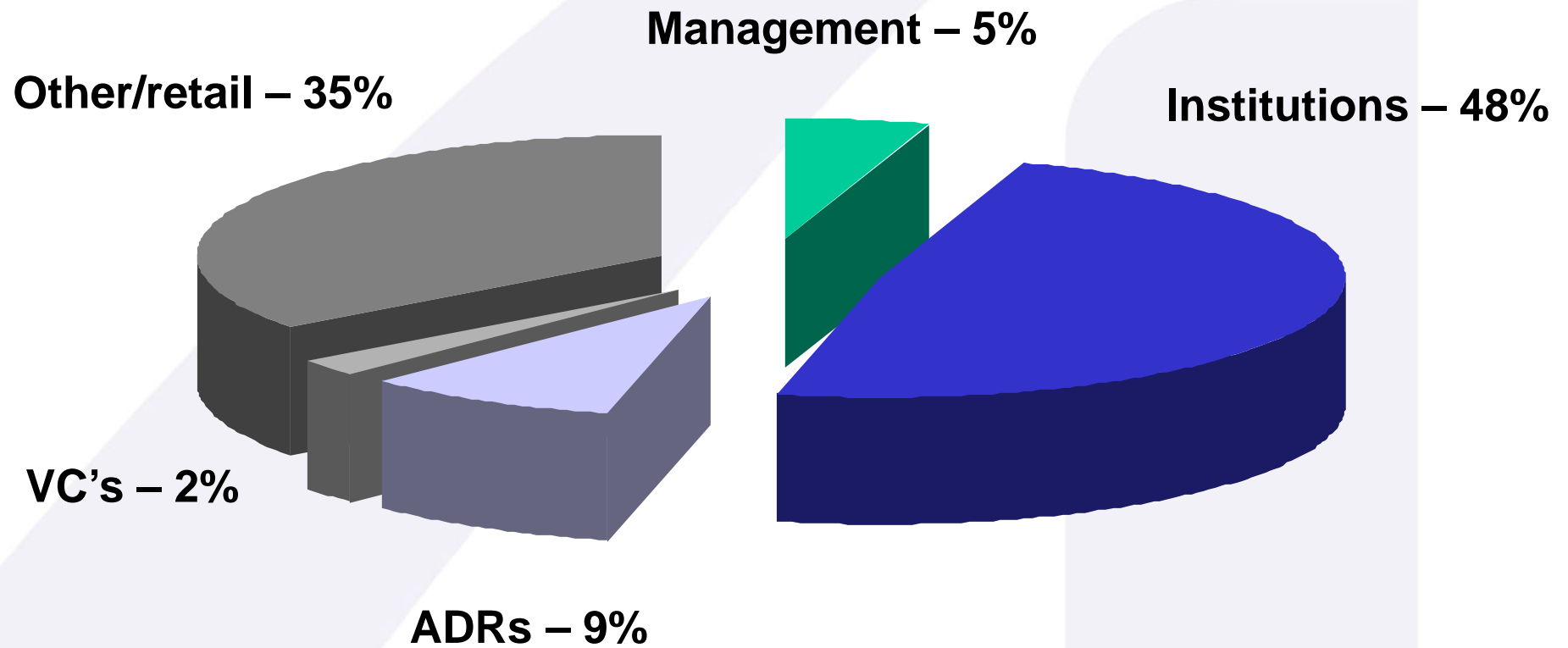
	As at	
	31-Dec-07	30-Jun-07
	A\$	A\$
Cash and cash equivalents	120,844	76,182
Plant & equipment	5,435	3,521
Intangible assets	1,194	1,239
Total assets	130,403	82,712
Total liabilities	(3,264)	(6,089)
Total shareholders' equity	127,139	76,623

Cash Flow Data

	Three months ended		Year-to-date	
	31-Dec-07	31-Dec-06	31-Dec-07	31-Dec-06
	A\$	A\$	A\$	A\$
Cash flows from operating activities	(4,588)	(6,516)	(12,311)	(11,072)
Cash flows from investing activities	(1,469)	(427)	(2,551)	(876)
Cash flows from financing activities	59,497	23	59,540	180
Net increase (decrease) in cash held	53,440	(6,920)	44,678	(11,768)

Indicative Share Capital

(including options)



31 Dec 2007: 194m shares; 11.6m options