Therapeutic products for respiratory diseases

pharmaxis

May 2009

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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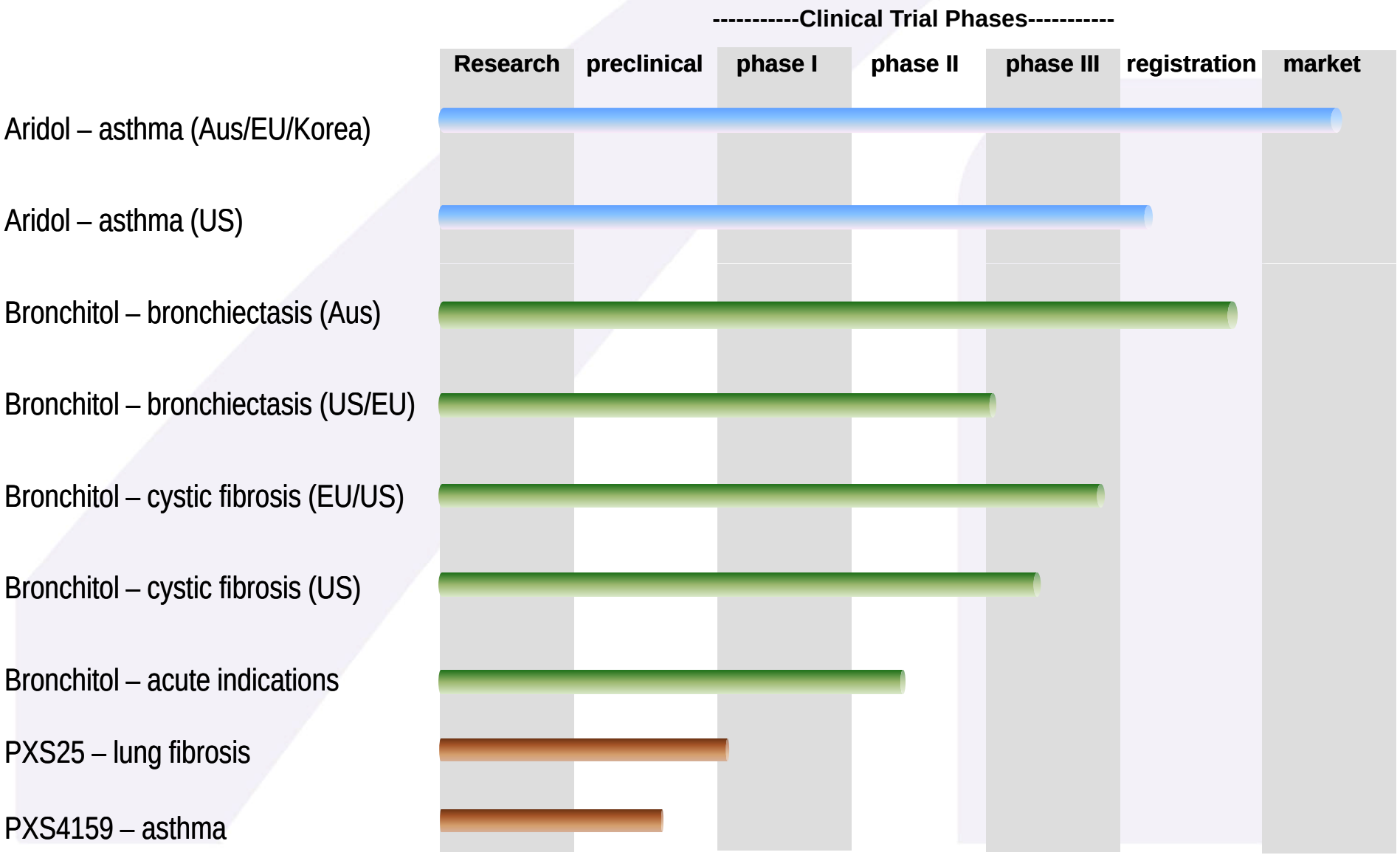
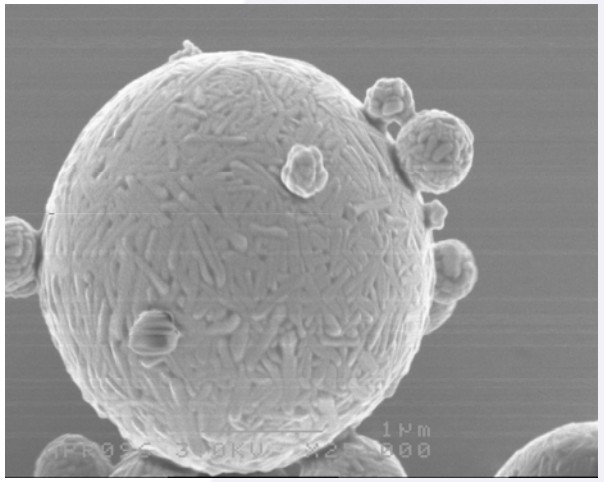
Summary

Objective	The development of products for respiratory and inflammatory diseases
Lead products	Aridol: management of asthma and COPD Bronchitol: therapeutic for cystic fibrosis and COPD
Discovery	PXS25 (M6P receptor blocker). PXS4159 (VAP1 inhibitor)
Listings	ASX (Nov 2003): PXS; Nasdaq (Aug 2005): PXSL
Location	Sydney, NSW, Australia
Facility	GMP Manufacture of lead products
Employees	108
Cash (31/03/09)	A$86 million (approx US$60m)
Shares outstanding Options outstanding	195m (13m ADS) 13.6m
Key patents	Aridol & Bronchitol granted in USA, Australia, Asia, Canada, Japan; pending in EU, Japan.
Analyst coverage	JMP Securities, Wilson HTM Investment Group, Credit Suisse, ABN·AMRO Morgans your wealth of experience, BBY, Shaw Stockbroking

Development Pipeline



Bronchitol

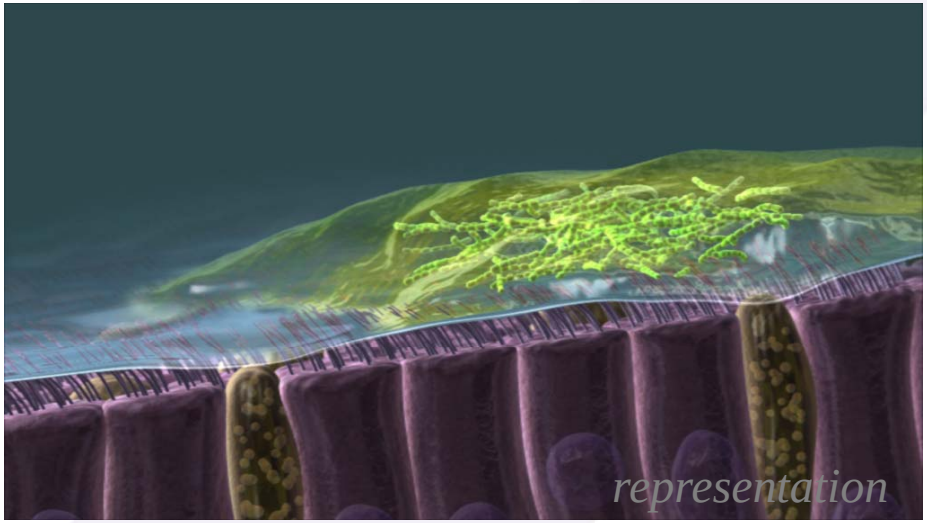


Mucus clearance:

Cystic fibrosis
Chronic Obstructive Pulmonary Disease
Bronchiectasis

Osmotic clearance of abnormal mucus

Before treatment

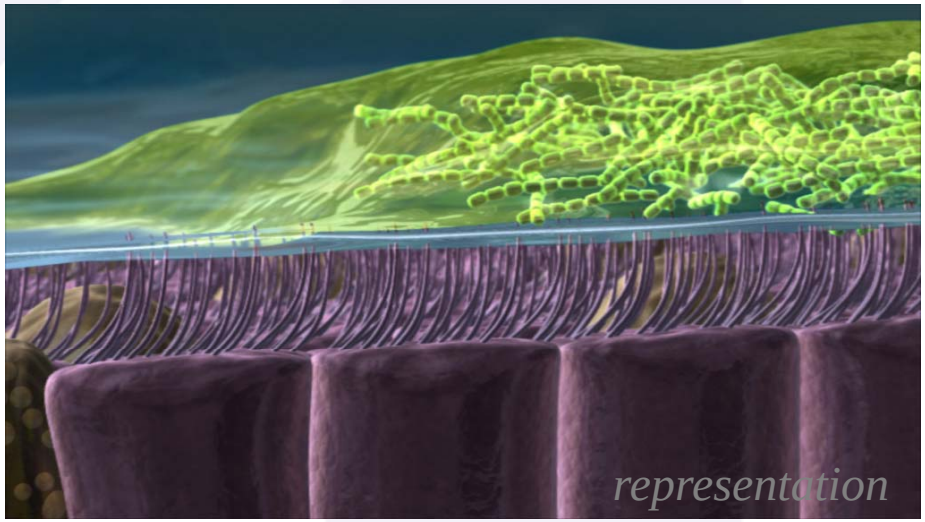


Lung surface dehydrated

Airway surface fluid layer impaired

Lung defense and hygiene compromised

After Bronchitol administration



Lung hydrated

Airway surface liquid restored

Normal lung clearance

Bronchitol for 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): global sales US$440mm (2007)
  - Tobramycin: global sales US$233mm (2007)

Bronchitol Phase II cystic fibrosis program

- Study 1
  - Crossover, placebo controlled, multicentre study in 39 CF subjects
  - Randomised **2 week** treatment twice per day
  - 420mg twice per day by inhalation
    - FEV_1 improvement of 7% (p=0.008)
    - Published: *Chest 2008;**133**;1388-1396*
    - 50% of subjects on background pulmozyme

- Study 2
  - Randomised crossover **2 week** treatment including comparison of four doses of Bronchitol (38 subjects)
  - 400 mg: FEV_1 increased by +8.6% (p=0.0006 vs 40 mg)
  - 240 mg: FEV_1 increased by +4.6%
  - 120 mg: FEV_1 increased by +3.7%
  - 40 mg: FEV_1 decreased by -1.6%

- Study 3
  - Pharmacokinetic study in CF patients

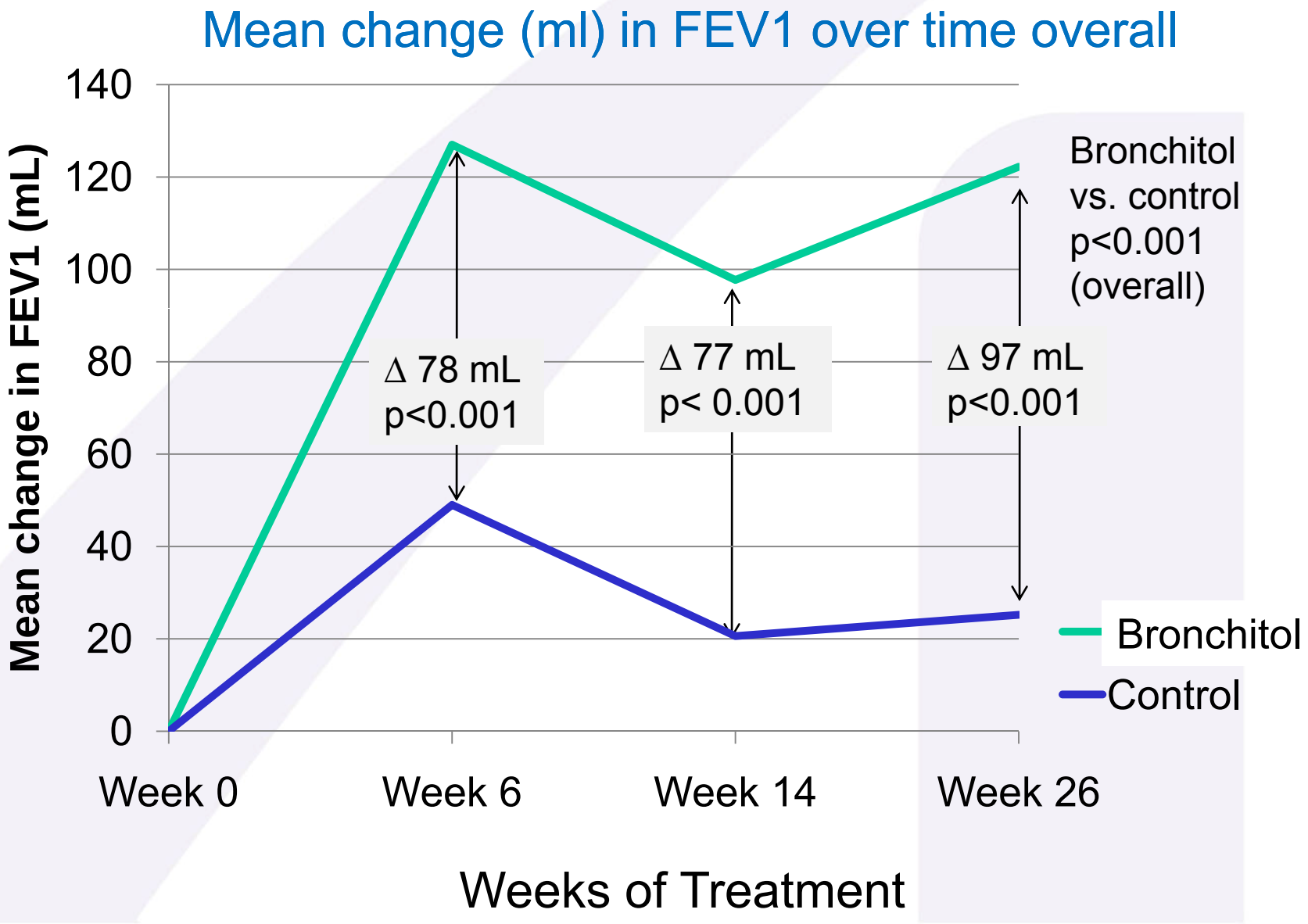
Bronchitol – cystic fibrosis registration

- **1st Pivotal Phase III trial**
  - Multicentre, double blind, placebo controlled
  - 325 subjects greater than 6 years old
  - 6 month treatment, 400mg twice per day followed by 6 month open
  - Primary endpoint:
    - lung function (FEV1)
  - Key secondary endpoint:
    - Lung function (FEV1) in patients on rhDNase
  - Other endpoints
    - exacerbations
    - antibiotic use
    - QOL and safety

Key demographics at baseline

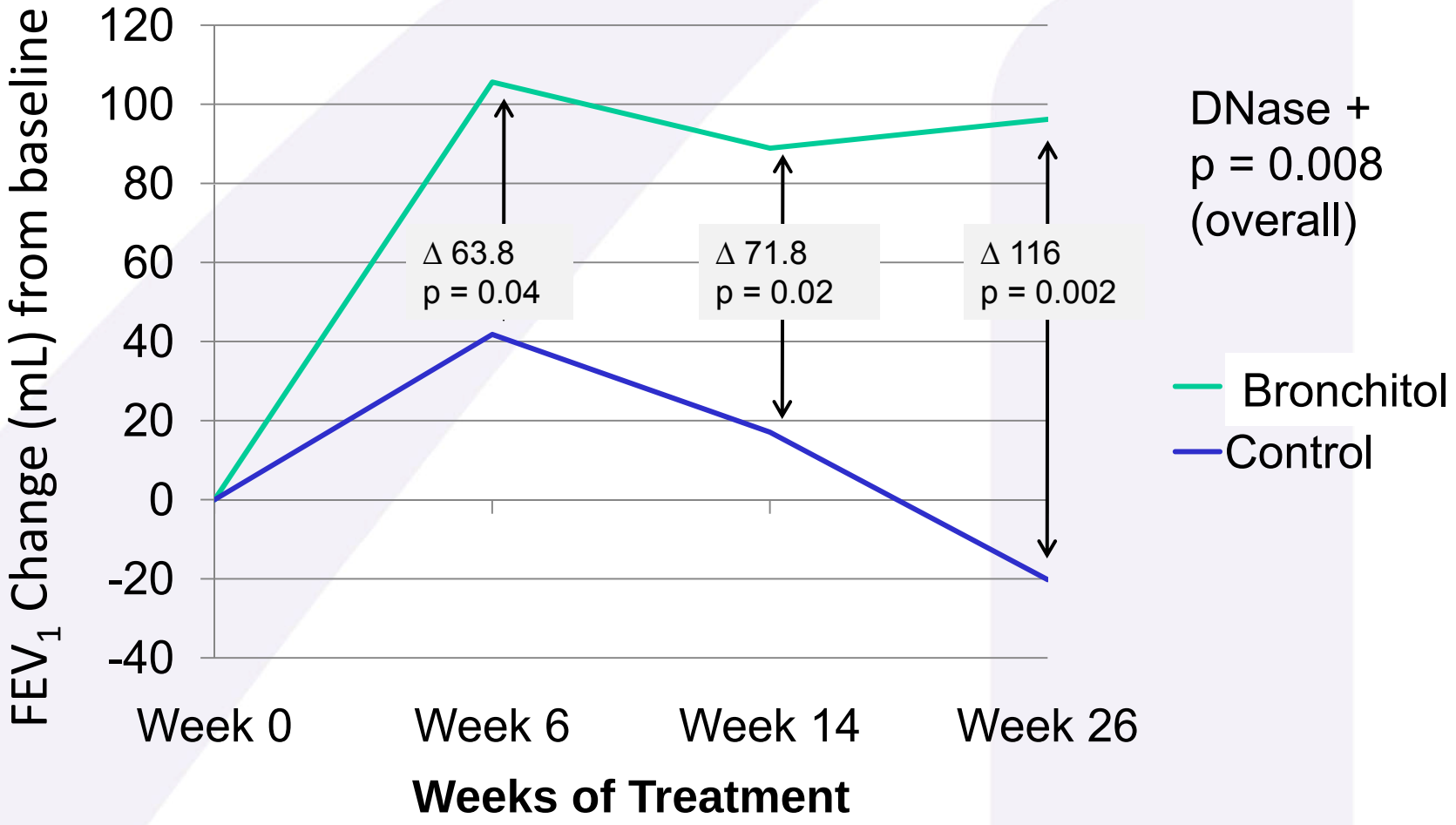
	Bronchitol n = 177	Placebo n = 118
Mean age in years 6 – 11 years (%) 12 – 17 years (%) >18 years (%)	23.1 7.5 18 64	22.8 14 21 64
Gender: Female (%)	40.1	51.7
BMI; mean (SD) kg/m^2	4.0	3.6
FEV1; mean (range) L % predicted	2.07 (0.71, 4.92) 62.4 (26, 93)	1.95 (0.78, 3.75) 61.4 (30,94)
Regular medication n(%) RhDNase Antibiotics B_2 agonists	96 (54.2) 94.8% 83.9%	67 (56.8) 90.2% 87.1%

CF 301 – primary endpoint



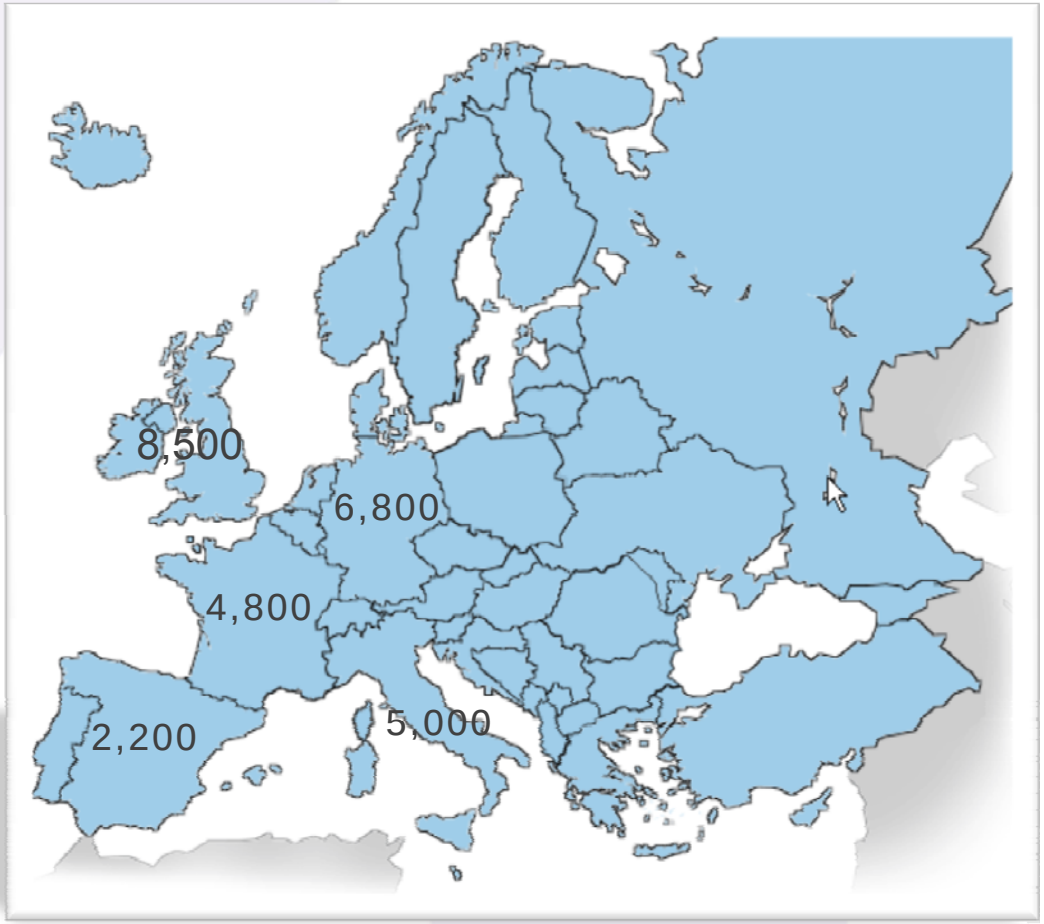
CF301 – key secondary endpoint

Absolute (ml) change from baseline in FEV1 over time for rhDNase+ subjects



Bronchitol – commercialisation in EU

- **European marketing application via centralised procedure**
  - Filing and dossier review plan to be agreed with EMEA
- **Earliest approval 2H 2010**
- **Orphan drug – up to 12 years exclusivity**
- **Promotion by PXS augmented by single EU partner**
- **Centralised approach to pricing**

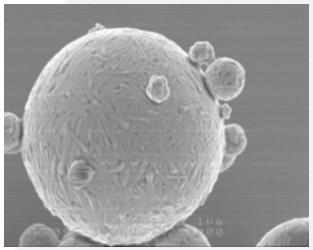


27,000 sufferers in top 5 EU countries

Bronchitol – cystic fibrosis registration

- **2nd Pivotal Phase III trial**
  - Protocol review through Special Protocol Assessment (FDA)
  - Double blind, placebo controlled
  - 300 subject 6 years and older
  - 400mg, twice per day for 6 months
  - 1o endpoint - lung function by spirometry (FEV1)
  - 2o endpoints – antibiotic use, exacerbations, lung function
- **Enrolment commenced** **Sep 2008**
- **Scheduled enrolment completion** **Mid 2009**
- **Orphan drug designation – U.S.**
- **Fast track designation – U.S.**

Bronchitol for 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 bronchiectasis patients seeking treatment

	EU	Australia	USA	Asia	Total
% of patients with bronchiectasis (resp. specialists)	14%	9%	N/A	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

- 1st Pivotal Phase III trial
  - 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	↑30%, p<0.001 versus placebo
• antibiotic use reduction	p<0.05 versus placebo
• adverse events (52 wks)	cough 9%, sore throat 5%
	no SAE attributed to treatment

- First marketing application filed (Aus) in Sep 2008

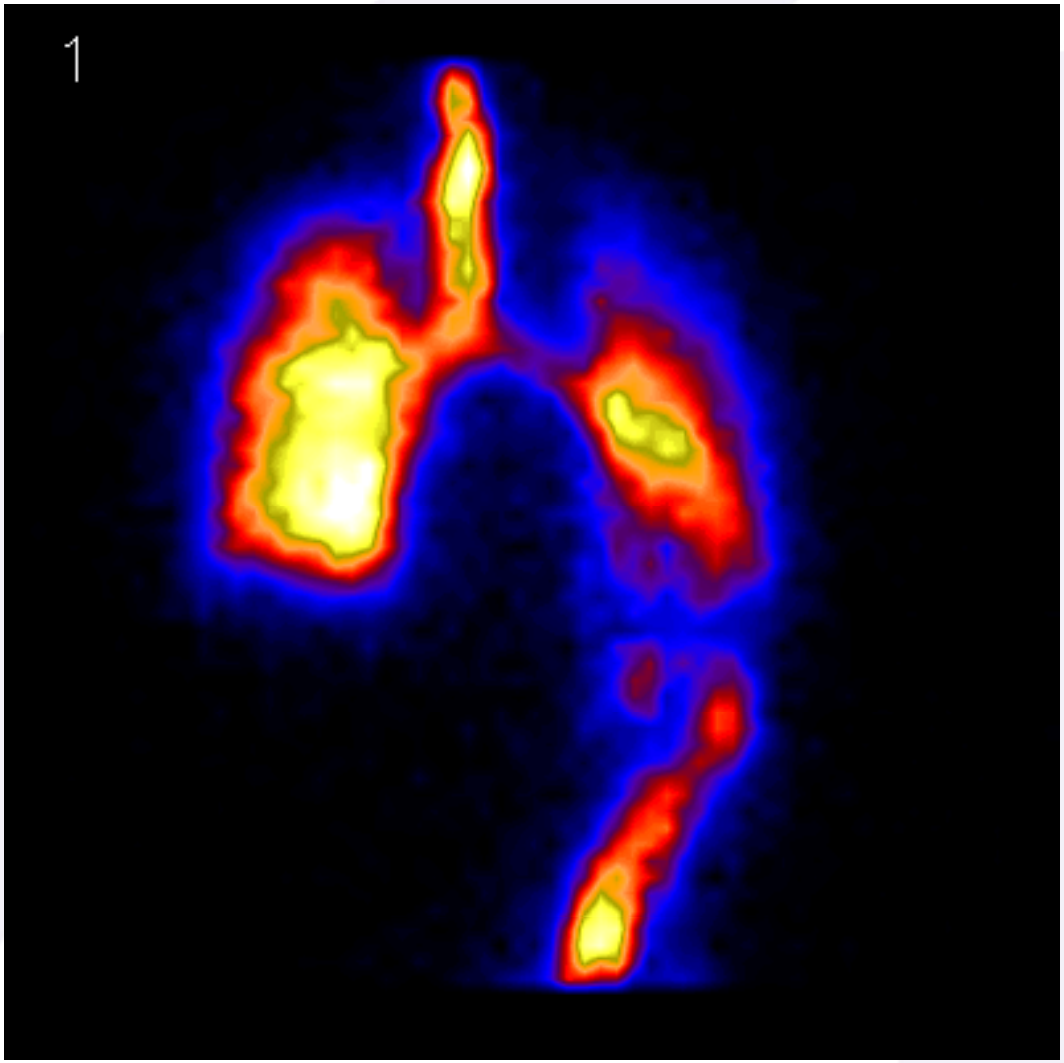
Bronchitol – bronchiectasis registration

- **2nd Pivotal Phase III trial**
  - 350 patient, placebo controlled, double blind, randomised, 52 week treatment
  - 400mg twice a day
- **Primary endpoint**
  - Reduction in number of exacerbations
  - Quality of life

- **Secondary endpoints**
  - Exercise, mucus clearance, antibiotic use
- **Status**
  - Special Protocol Assessment concluded with FDA
  - Orphan Drug designation — USA
  - Target commencement — 1H 2009
  - Data — 2010

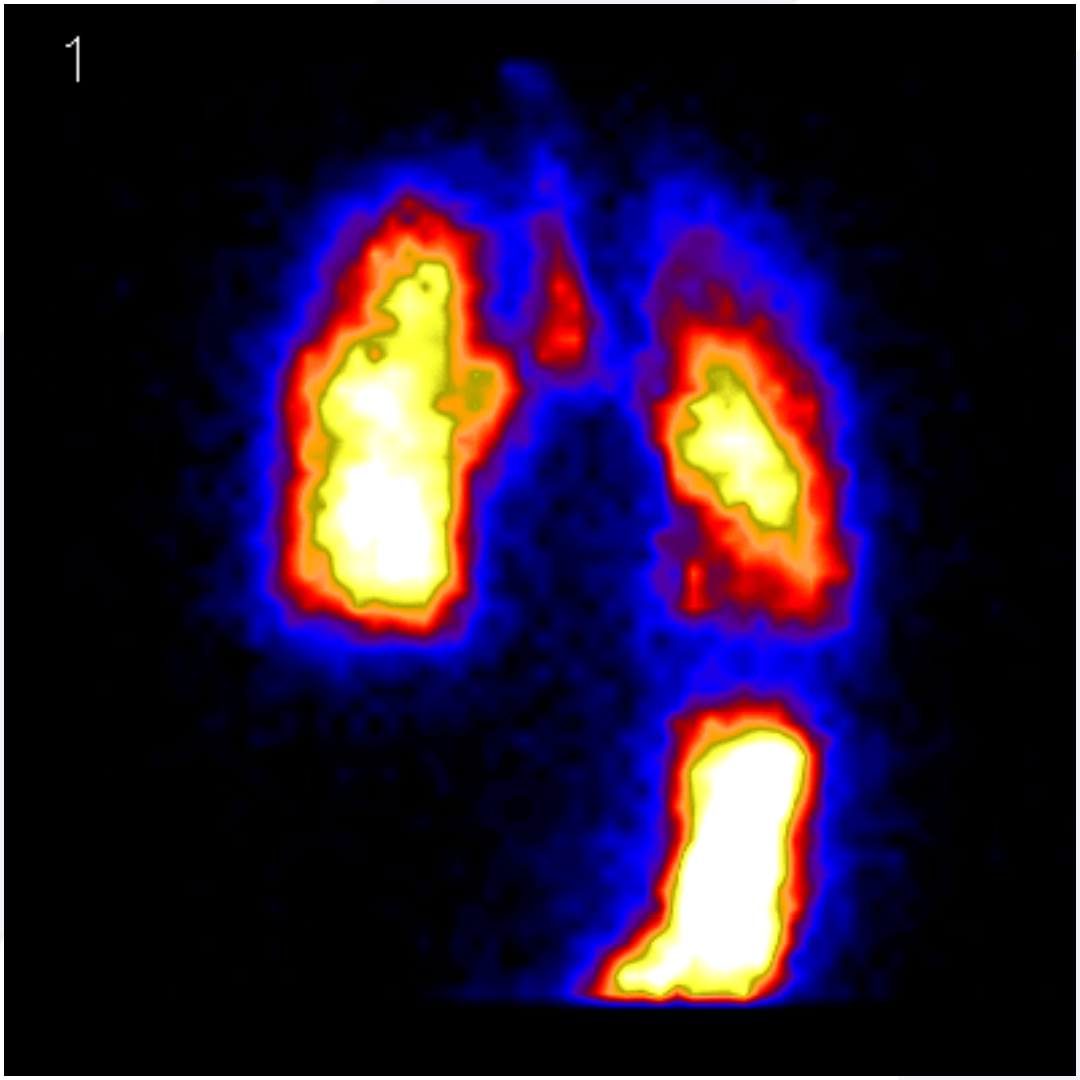
Bronchitol in the clinic…….

Chronic bronchitis – without Bronchitol



Bronchitol in the clinic…….

Chronic bronchitis – with 400 mg Bronchitol



Aridol™

- Identifies airway reactivity (active airway **inflammation**) which helps physicians in the diagnosis and management of **asthma**

- An **easy-to-use test kit** provides rapid results and doesn't require specialised equipment

International regulatory status - Aridol

- **Australia**
  - First market to launch
  - 50% penetration in 2 years — June 2006
- **Europe**
  - Approved European Union (MRP) — May 2007
  - Regional marketing partners appointed
  - Launches underway
- **South East Asia**
  - Approved for marketing – Korea — Jan 2008
    - Pricing approval expected mid-2009
  - Marketing application filed in Singapore
- **USA**
  - NDA submitted. Expected PDUFA date — Dec 2009

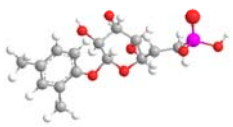
Aridol – growth markets

	USA	KOREA	GERMANY
Existing Market size	200,000 tests p.a.	120,000 tests p.a.	660,000 tests p.a.
Pricing	+++	+	++
Market drivers	Physician reimbursement	Physician reimbursement	Physician reimbursement
	Private physician market.		Private physician market
Entry route	Pharmaxis	Distributor	Distributor

Steroid Management

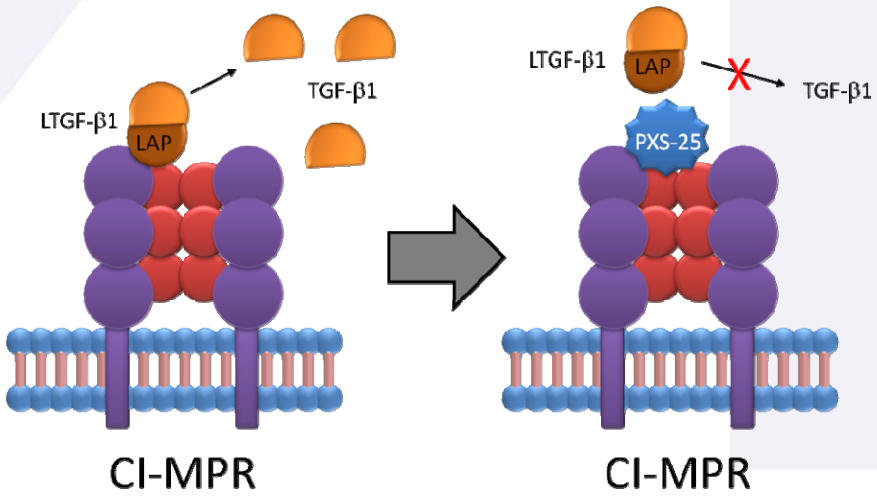
TRIAL	Data
ACRN 'BASALT' study	Q1 2009, Q1 2010
EU steroid response	Q4 2009
EU steroid titration	Q4 2009

R&D - Status (PXS-25)



- Inhibits cleavage of latent TGFβ to active TGFβ
  - anti-fibrotic agent with anti-inflammatory properties
    - Small molecule with robust pharmaceutical profile
    - Clinical focus is pulmonary fibrosis

- IND enabling toxicology complete
  - phase 1 trial to commence 1H09



Major near term catalysts ahead

Milestone	2Q-09	3Q-09	4Q-09	1Q-10
Bronchitol – cystic fibrosis				
P III trial (CF301) data available				
File MAA in EU (centralised)				
P III trial (CF302) fully enrolled				
P III trial (CF302) data available				
Bronchitol – bronchiectasis				
MAA decision (Aus)				
Start 2nd P III trial enrollment				
Complete 2nd PIII enrollment				
Aridol				
U.S. NDA complete response				
Facilities				
New factory complete (building)				
PXS25				
Commence Phase 1 program				

Financial Statements

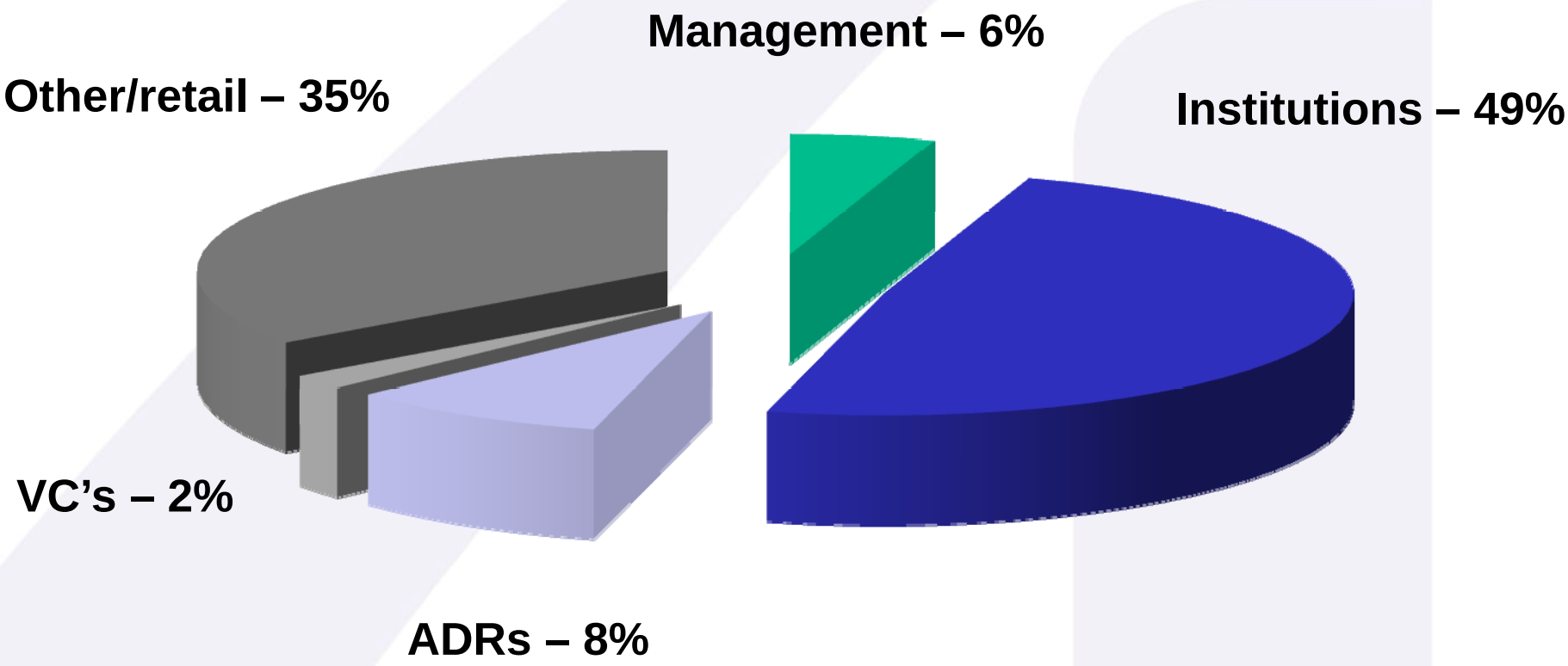
Income Statement Data	Three months ended		Nine months ended	
('000 except per share data)	31-Mar-09	31-Mar-08	31-Mar-09	31-Mar-08
	A$	A$	A$	A$
Revenue from sale of goods	144	136	453	330
Cost of sales	(35)	(30)	(113)	(82)
Gross profit	109	106	340	248
Interest	927	2,108	4,584	5,169
Other income	132	689	276	923
Expenses				
Research & development	7,193	4,370	20,780	14,010
Commercial	1,449	1,154	4,339	3,105
Administration	1,336	1,321	4,258	3,785
Total expenses	9,978	6,845	29,377	20,900
Loss before income tax	(8,810)	(3,942)	(24,177)	(14,560)
Income tax expense	(1)	2	27	18
Loss for the period	(8,809)	(3,944)	(24,204)	(14,578)
Basic and diluted earnings (loss) per share - $	(0.045)	(0.020)	(0.124)	(0.078)
Depreciation & amortisation	271	253	789	772
Fair value of options issued under employee plan	650	923	1,801	2,604

Financial Statements

Balance Sheet Data	As at	
('000 except per share data)	31-Mar-09	30-Jun-08
	A$	A$
Cash and cash equivalents	85,832	111,842
Plant & equipment	18,128	5,878
Total assets	107,457	125,049
Net assets	96,767	119,121

Cash Flow Data	Three months ended		Nine months ended	
('000 except per share data)	31-Mar-09	31-Mar-08	31-Mar-09	31-Mar-08
	A$	A$	A$	A$
Cash flows from operating activities	(4,461)	(4,363)	(16,343)	(16,674)
Cash flows from investing activities	(3,658)	(275)	(9,742)	(2,826)
Cash flows from financing activities	-	31	11	59,571
Net increase (decrease) in cash held	(8,119)	(4,607)	(26,074)	40,071

Share Capital
(including options)



31 March 2009: 194.5m shares; 13.6m options