



pharmaxis

Therapeutic products for respiratory diseases

September 2008

Forward Looking Statements






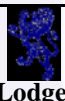
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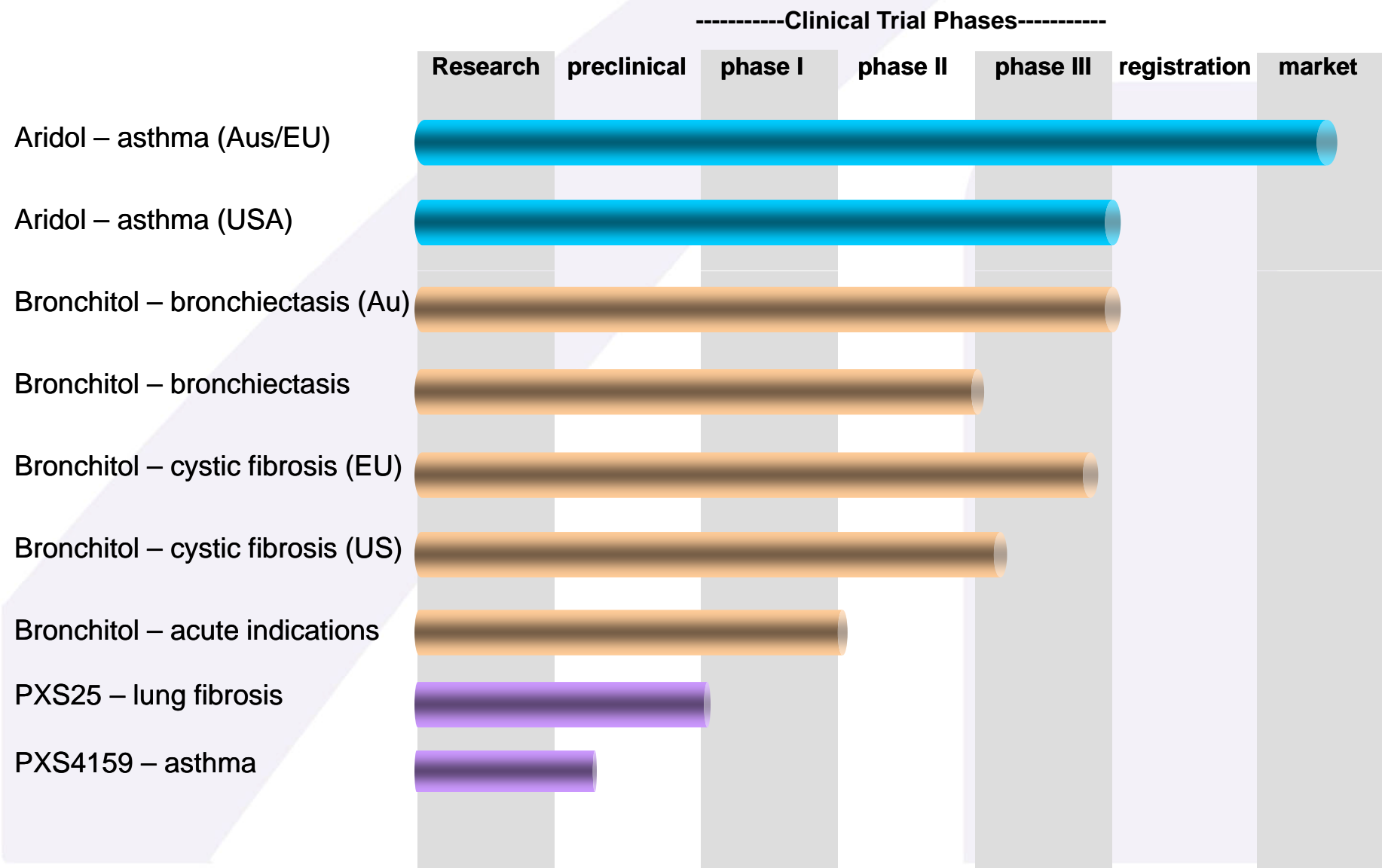
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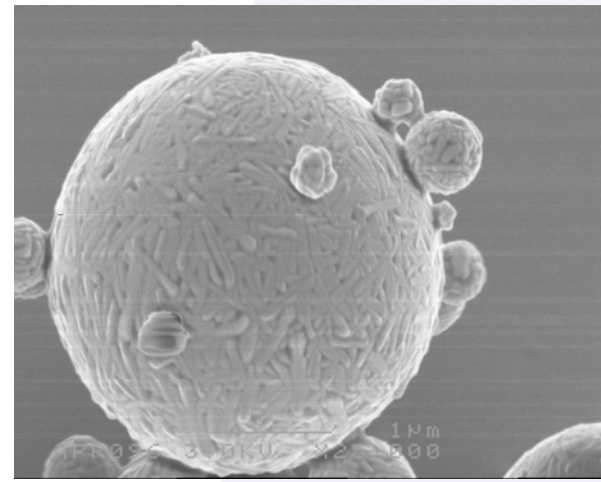
Summary.....

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 (IGFII antagonist). PXS4159 (VAP1 inhibitor)
Listings	ASX (Nov 2003): PXS; NASDAQ (Aug 2005): PXSL
Location	Sydney, NSW, Australia
Facility	GMP Manufacture of lead products
Employees	86
Cash (30/06/08)	\$112 million
Shares outstanding	195m (12.9m ADS)
Options outstanding	13.0m
Key patents	Aridol & Bronchitol granted in USA, Australia, Asia, Canada, Japan; pending in EU, Japan.
Analyst coverage	     

Development Pipeline



Bronchitol

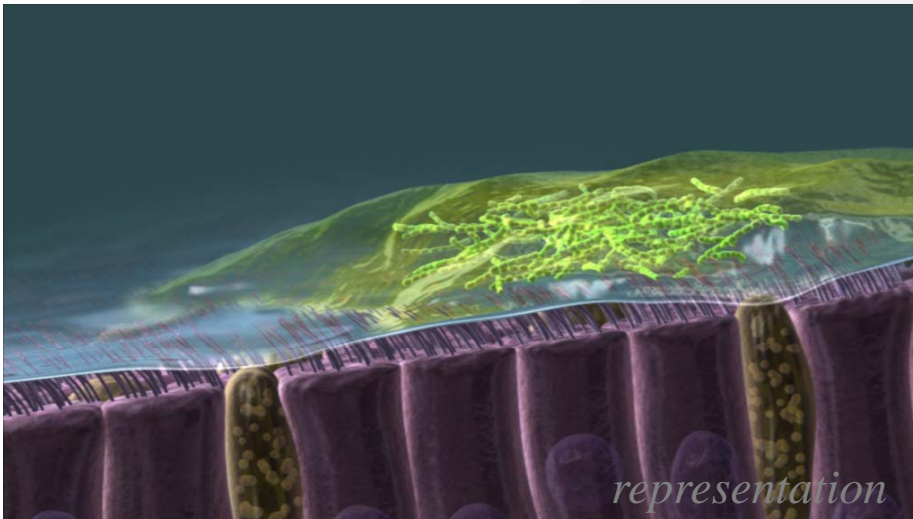


Mucus clearance:

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

Osmotic clearance of abnormal mucus.....

Before treatment

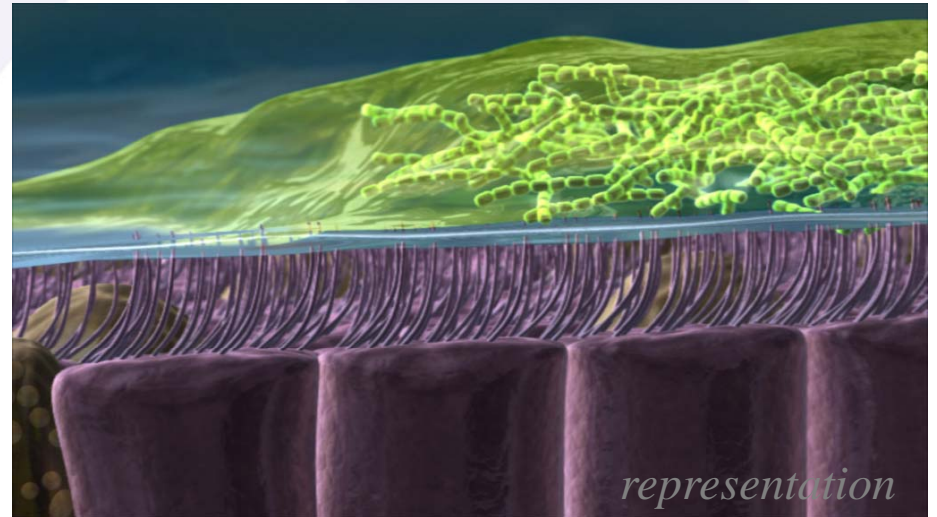


Lung surface dehydrated

Airway surface fluid layer impaired

Lung defense and hygiene compromised

After Bronchitol administration



Lung hydrated

Airway surface liquid restored

Normal lung clearance

Bronchitol – 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 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 programme.....

- Study 1

- Crossover, multicentre study in 39 CF subjects
- Randomised **2 week** treatment twice per day
- Reported
 - FEV₁ improvement of 7% (p=0.008)



- Study 2

- Crossover, 2 site study in 20 subjects
- Randomised **3 month** treatment including comparison with pulmozyme
 - FEV₁ improvement of 7%



- Study 3

- Randomised crossover **2 week** treatment including comparison of 4 doses of Bronchitol (38 subjects)
- 400 mg: FEV₁ increased 8.6% (p=0.0006 vs 40 mg)
- 240 mg: FEV₁ increased 4.6%
- 120 mg: FEV₁ increased by 3.7%
- 40 mg: FEV₁ decreased by -1.6%



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

- **1st Pivotal Phase III trial**



- Multicentre, double blind, comparator controlled
- 325 subjects enrolled (aged 6 and over)
- 6 month dosing, 400mg twice per day
- Primary endpoint: lung function (FEV1)
- Secondary endpoint: exacerbation frequency
- Top line efficacy data expected 1H 09

- **Orphan Drug designation in the EU**

- **European marketing application via centralised procedure**

- Earliest first approval expected: 2010

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



- **2nd Pivotal Phase III trial**

- Protocol review through Special Protocol Assessment (FDA)
- Double blind, comparator controlled
- 250 subject 6 years and older
- 400 mg, twice per day for 6 months
- 1^o endpoint - lung function by spirometry (FEV1)
- 2^o endpoints – antibiotic use, exacerbations, lung function

- To commence enrolment

2H 2008

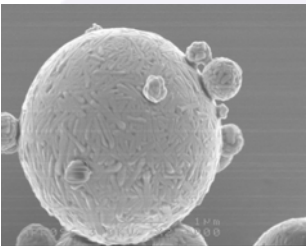
- First data

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)...

- 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 $\uparrow 30\%$, $p < 0.001$ versus placebo
- antibiotic use reduction $p < 0.05$ versus placebo
- adverse events (52 wks) cough 9%, sore throat 5%
no SAE attributed to treatment



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- First marketing application to be filed – Q3 08

Bronchitol – bronchiectasis registration (II)....



- **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
- Target commencement
- Data



USA
Q4 2008
2010

Bronchitol – acute clearance of lung secretions



ICU, hospitalized patients and ventilated patients

- Currently supplied on request to patients with life threatening condition
- Feedback encouraging for proof of concept study
- Clinical conditions include: asthma, COPD, cystic fibrosis, secondary respiratory disease, neurogenic disorder

Objective

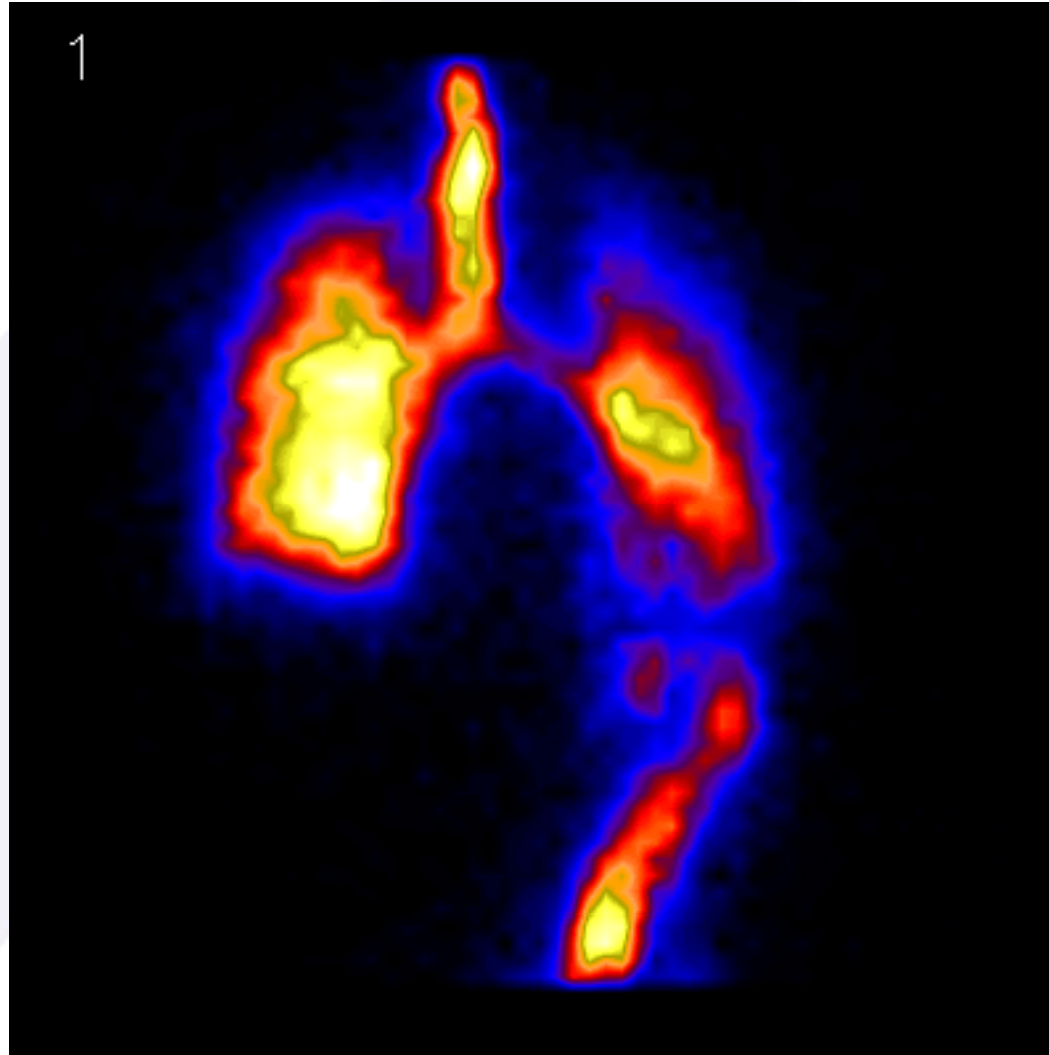
- acute care pilot study Q2 2009?
- study in ventilated patients Q2 2009?

Market opportunity

- 1 million U.S. emergency room visits every year (COPD alone)
- 60,000+ ICU beds worldwide 80 - 90% occupancy rates
- 75% patients ventilated / 75% have serious mucus problem

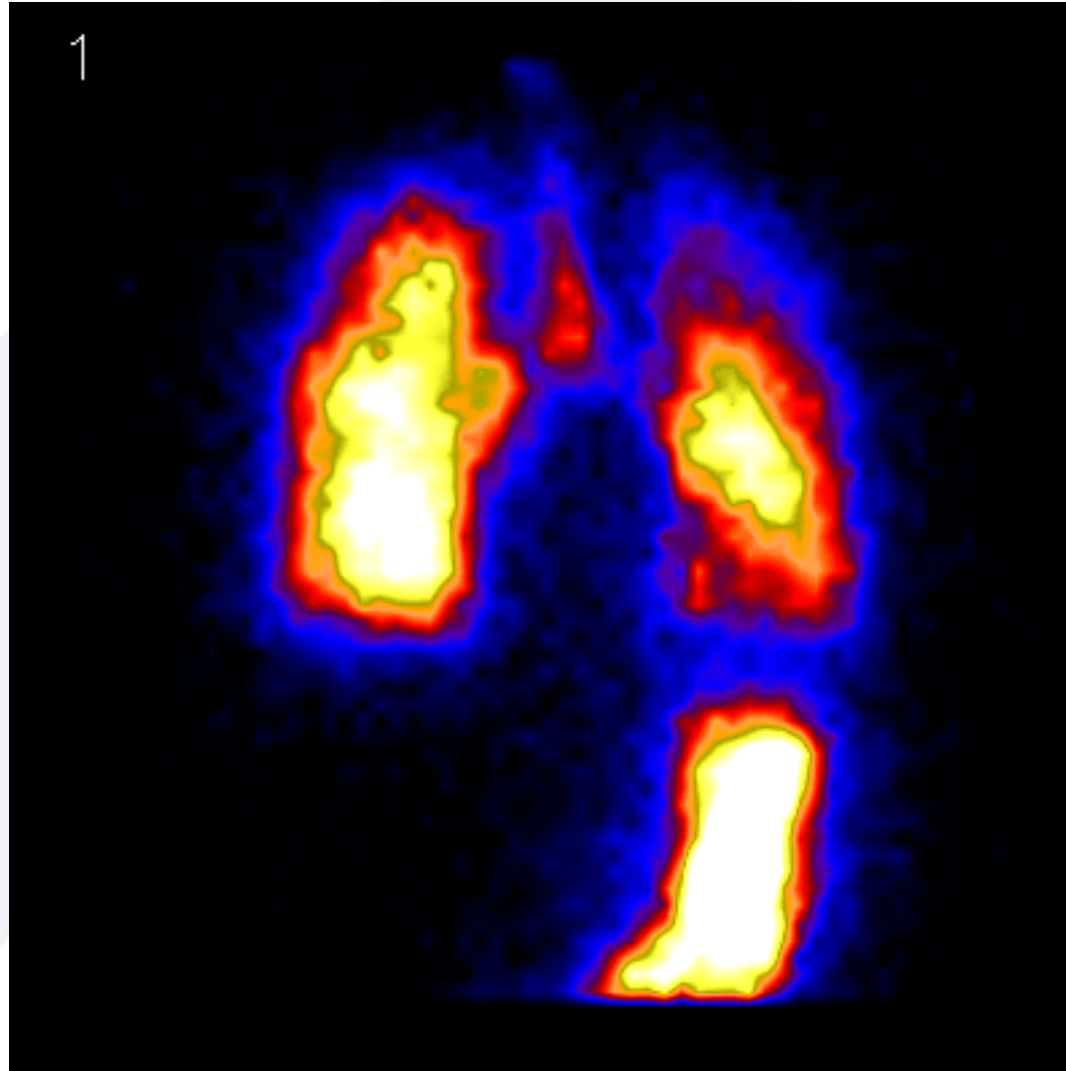
Bronchitol in the clinic.....

Chronic bronchitis – without Bronchitol



Bronchitol in the clinic.....

Chronic bronchitis – with 400 mg Bronchitol



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 European Union (MRP)
 - Launch in 1st countries
 - Regional authorizations almost complete
- Regional marketing partners appointed

May 2007

September 2007

- **South East Asia**

- Approved for marketing – Korea
 - Pricing approval expected

January 2008



early 2009

- **USA**

- Phase III trials completed
- New Drug Application being assembled



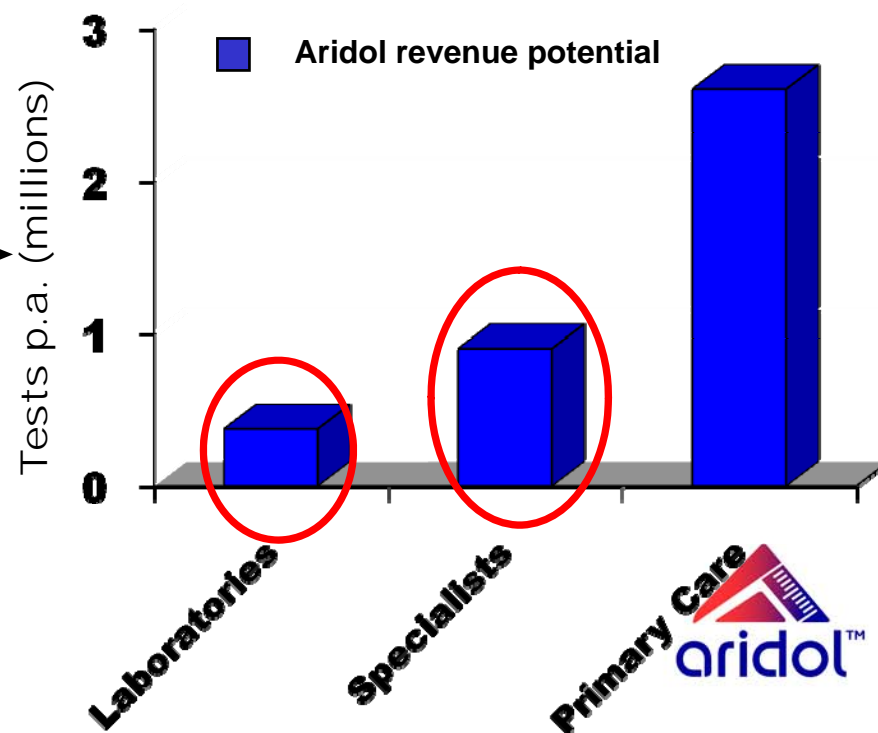
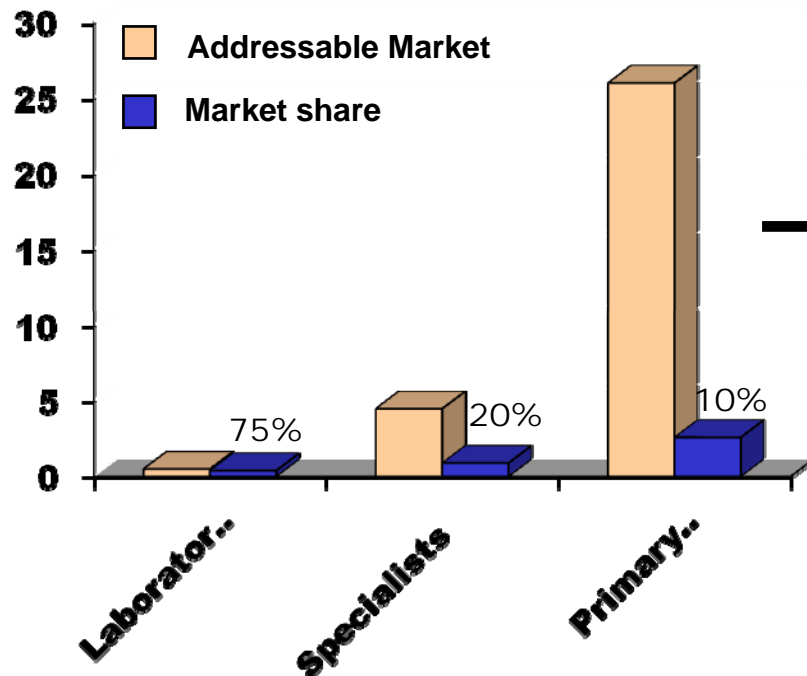
Aridol: current distribution agreements...

	Country	Partner	Regulatory	Status
	• Sweden	Nigaard	approved	launched
	• Finland	Nigaard	approved	launched
	• Germany	to be advised	approved	pricing
	• Ireland	Pharmaxis	approved	launched
	• Norway	Nigaard	approved	launched
	• Portugal	Pulmocor	approved	launched
	• UK	Pharmaxis	approved	launched
	• France		approved	planning
	• Greece	Allertec	approved	launched
	• Italy	Italchimici	MRP	
	• Holland	Romedic	approved	launched
	• Spain	Aldo-Union	MRP	
	• Denmark	Nigaard	approved	launched
	• Belgium		MRP	
	• Switzerland	Trimedal	approvable	
	• Korea	BLH	approved	pricing

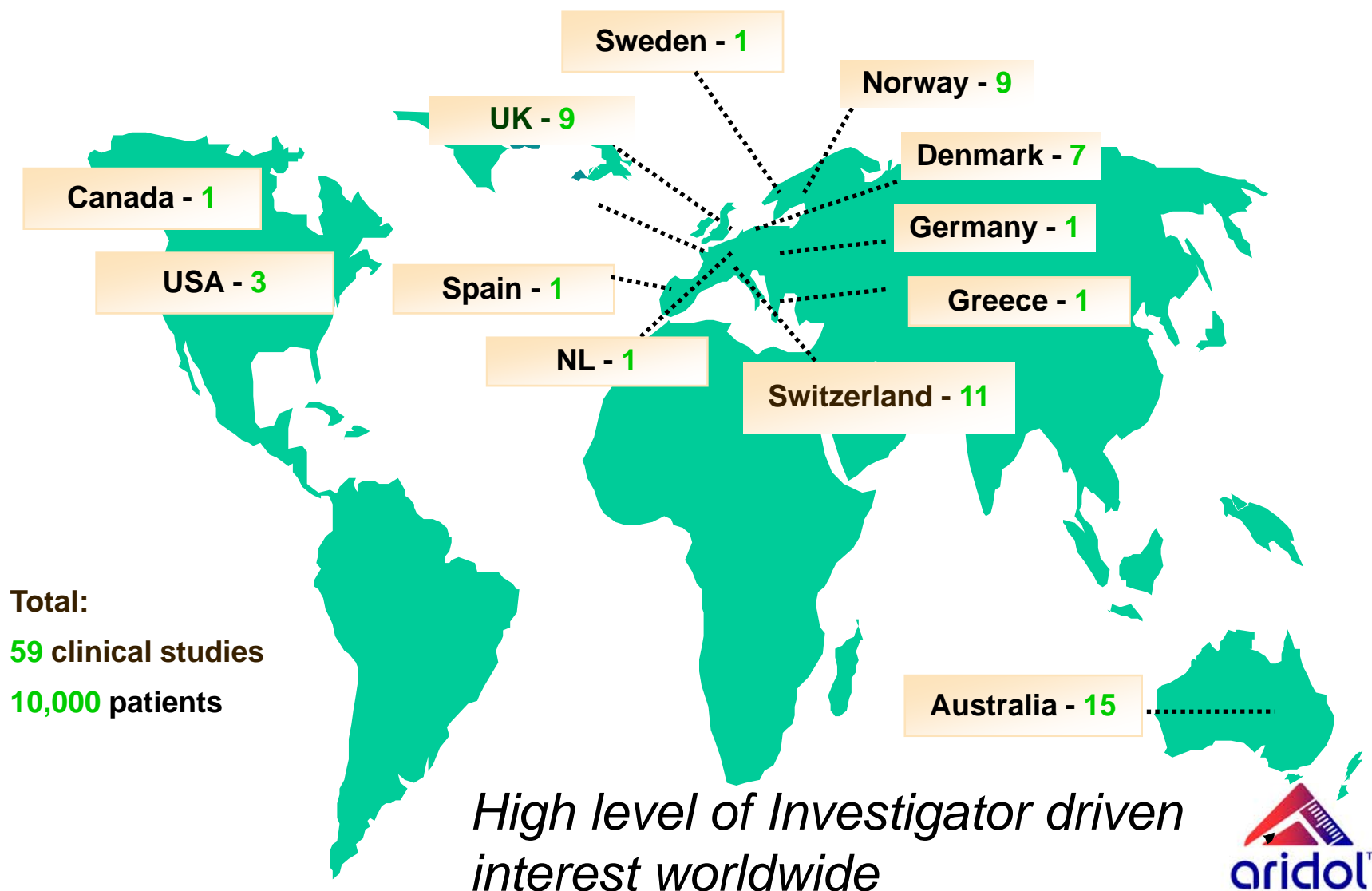
Growth Opportunities ahead: Aridol

	Timing
Portugal, Finland, Norway, Spain, Germany	Q3 2008
France, Italy, Korea	Q1 2009
USA	Q3 2009
New data – Asthma management	Q1 – Q4 2009

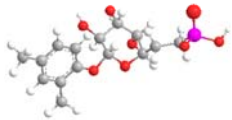
Patient Numbers in Millions



Worldwide development of Aridol.....



R&D - Status (PXS-25)



☐ M6P receptor antagonist inhibiting TGF and CTGF function

- both implicated in fibrotic disorders
- preclinical toxicology complete
- Phase 1 trial to commence end 2008



☐ Development plan and partnering strategy

- develop PXS-25 for pulmonary indication
- out-license PXS-25 for non-core indications / territories













R&D - Status (PXS-4159A)



- ❑ Selective and potent inhibitor of SSAO/VAP-1
 - Protein implicated in inflammation
 - potential indications include, asthma, diabetes, ocular inflammation
- ❑ Highly orally bioavailable
- ❑ Preclinical development commenced
- ❑ Phase 1 trial expected mid-2009

- ❑ **Development plan and partnering strategy**
 - ❑ develop PXS-4159 for pulmonary indication
 - ❑ out-license PXS-4159 for non-core indications / territories

Near term catalysts ahead.....

Milestone	3Q-08	4Q-08	1Q-09	2Q-09
Bronchitol – cystic fibrosis Finish 1 st P III trial enrollment PIII trial first data Start 2 nd P III trial enrollment PII trial data (dosing)	  			
Bronchitol – bronchiectasis Safety data from 1 st PIII (52w) Start 2nd P III trial enrollment File marketing application (Aus)	  			
Aridol File NDA (US)				
Facilities New facility complete				
PXS25/64 Commence Phase 1 program				

Financial Statements

Income Statement	Three months ended		Year ended	
	30-Jun-08	30-Jun-07	30-Jun-08	30-Jun-07
	A\$	A\$	A\$	A\$
Revenue from sale of goods	197	46	527	205
Cost of sales	(47)	(10)	(129)	(49)
Gross profit	150	36	398	156
Other income				
Interest	2,233	1,219	7,402	5,278
Grant income	562	569	1,358	2,152
Other	91	-	218	-
Expenses				
Research & development	5,986	4,856	19,996	23,840
Commercial	1,452	778	4,557	3,240
Administration	1,446	1,409	5,231	4,666
Total expenses	8,884	7,043	29,784	31,746
Net loss before tax	(5,848)	(5,219)	(20,408)	(24,160)
Income tax expense	14	7	32	19
Net loss after tax	(5,862)	(5,226)	(20,440)	(24,179)
Basic and diluted earnings (loss) per share - \$	(0.030)	(0.029)	(0.108)	(0.136)
Depreciation & amortisation	252	246	1,024	939
Fair value of options issued under employee plan	830	397	3,434	1,488

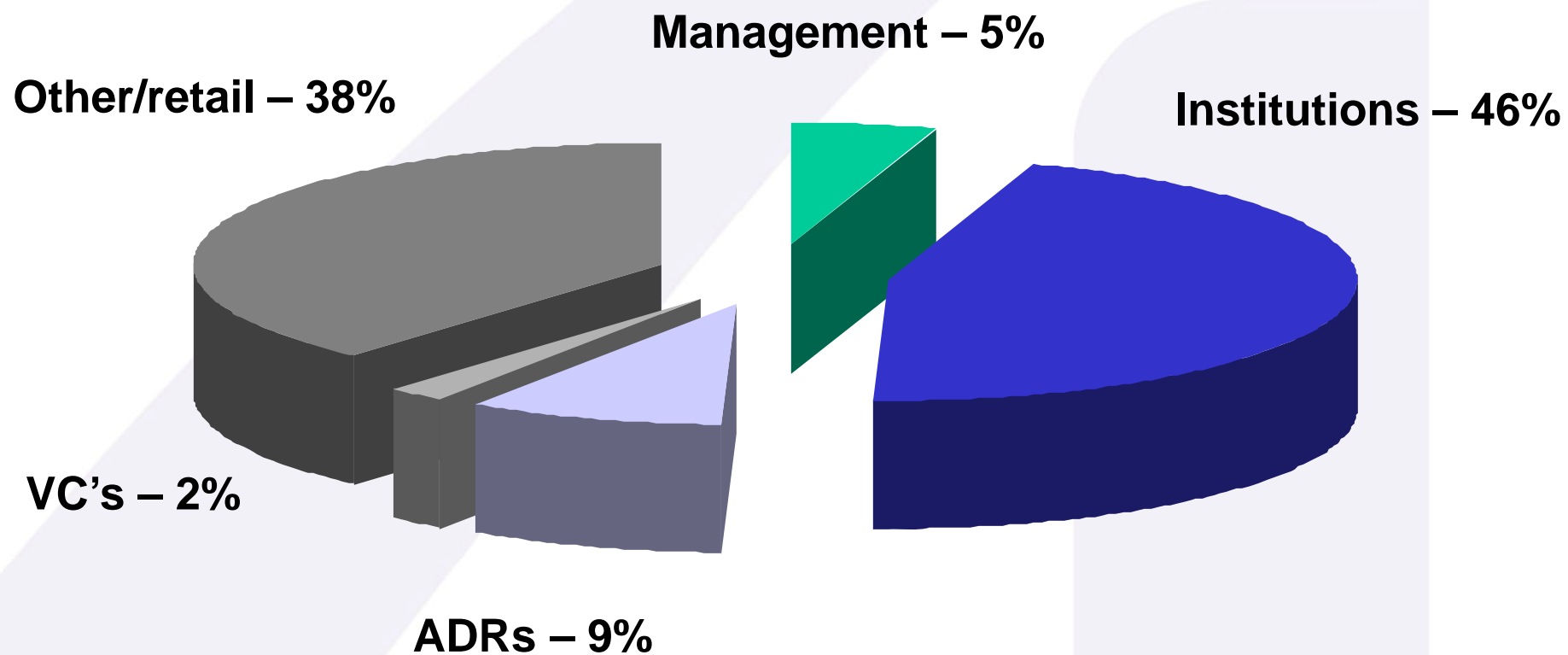
Financial Statements

Balance Sheet Data	As at	
	30-Jun-08	30-Jun-07
	A\$	A\$
Cash and cash equivalents	111,842	76,182
Plant & equipment	3,668	3,521
Intangible assets	1,227	1,239
Total assets	125,049	82,648
Total liabilities	(5,928)	(6,089)
Total shareholders' equity	119,121	76,559

Cash Flow Data	Three months ended		Year ended	
	30-Jun-08	30-Jun-07	30-Jun-08	30-Jun-07
	A\$	A\$	A\$	A\$
Cash flows from operating activities	(3,673)	(3,608)	(18,850)	(20,697)
Cash flows from investing activities	(736)	(295)	(5,059)	(1,322)
Cash flows from financing activities	1	171	59,572	363
Net increase (decrease) in cash held	(4,408)	(3,732)	35,663	(21,656)

Share Capital

(including options)



30 June 2008: 194.5m shares; 11.5m options