

Therapeutic products

tot

chronic respiratory

and autoimmune

diseases

November 2004





#### Chairman's Overview

#### Business

- International pharmaceutical business
- Retain product rights and fund development
- Multiple routes to harvest value

#### Infrastructure

- Management team with successful/relevant experience
- Board with appropriate skills and strong governance framework
- Solid investors
- Effective shareholder communications

#### Delivering

- Clinical success
- Manufacturing capability
- Government support
- Investor interest Australia and US
- Market Value







## Reducing Risk/Increasing Value

Product	Target Application	Market Size	Stage
Aridol	Management of asthma & COPD	A\$2.0 billion	Registration
Bronchitol	Bronchiectasis	A\$1.5 billion	Phase III
Bronchitol	Chronic Bronchitis	A\$4.0 billion	Phase I
Bronchitol	Cystic Fibrosis	A\$1.0 billion	Phase II
PXS25/64	Multiple sclerosis	A\$3.5 billion	Preclinical
PXS2076	Rheumatoid arthritis	A\$3.6 billion	Research



#### The Business.....





**Frenchs Forest** 



Aridol



**Bronchitol** 



Autoimmune disease

- Maximise value by funding product development through to registration
- Launch products in accessible markets
- Diagnosis and management of asthma and chronic obstructive pulmonary disease

 Treatment of cystic fibrosis and chronic obstructive pulmonary disease

 Research into new treatments for multiple sclerosis and rheumatoid arthritis





### The Pipeline....

#### -----Clinical Trials-----

#### research preclinical phase I phase II phase III registration market Respiratory diseases Aridol™ – airway function Mid -2005 Late -2007 Bronchitol<sup>™</sup> - bronchiectasis Bronchitol<sup>™</sup> – cystic fibrosis Early -2008 Bronchitol<sup>™</sup> - chronic bronchitis Late -2008 **Autoimmune diseases** PXS25 - multiple sclerosis PXS2076 – multiple sclerosis PXS2030 - rheumatoid arthritis

3-5 years 15 months 15 months 18 months 18 months 12 months

indicative time to complete







## The Economic Opportunity.....

Product	Target Application	Patient Population (million)	Market Size (A\$ million)	First Revenue
Aridol	Management of asthma	52	\$1,600	2005
Aridol	Management of COPD	30	\$400	2006
Bronchitol	Bronchiectasis	0.6	\$1,500	2007
Bronchitol	Chronic Bronchitis	30	\$4,000	2008
Bronchitol	Cystic Fibrosis	0.1	\$1,000	2008
PXS25/64	Multiple sclerosis	1	\$3,500	n.a.
PXS2076	Rheumatoid arthritis	6	\$3,600	n.a.







#### The Progress.....

#### Second half - 2003

- Commenced P II bronchiectasis trial with Bronchitol
- Commenced P III asthma trial with Aridol

#### First half - 2004

- PII cystic fibrosis trial commenced
- Role for Aridol in COPD management discovered
- Recipient of \$6 million government grant
- PXS2076 discovered for rheumatoid arthritis

#### Second half - 2004

- Asthma AND bronchiectasis trial completed
- Bronchitol (bronchiectasis) trial results positive
- Aridol trial results positive
- Share placement raises >\$16.5 million for Bronchitol development





### The People.....



Alan Robertson PhD

CEO

Inventor/developer of Zomig



David McGarvey CA

CFO/Secretary

CFO at Memtec



Brett Charlton PhD

CMO

Clinical research at Stanford



Gary Phillips MBA

Commercial

CEO at Novartis Australia



John Crapper MBA

COO

Managing Director of Memcor



William Cowden PhD

cso

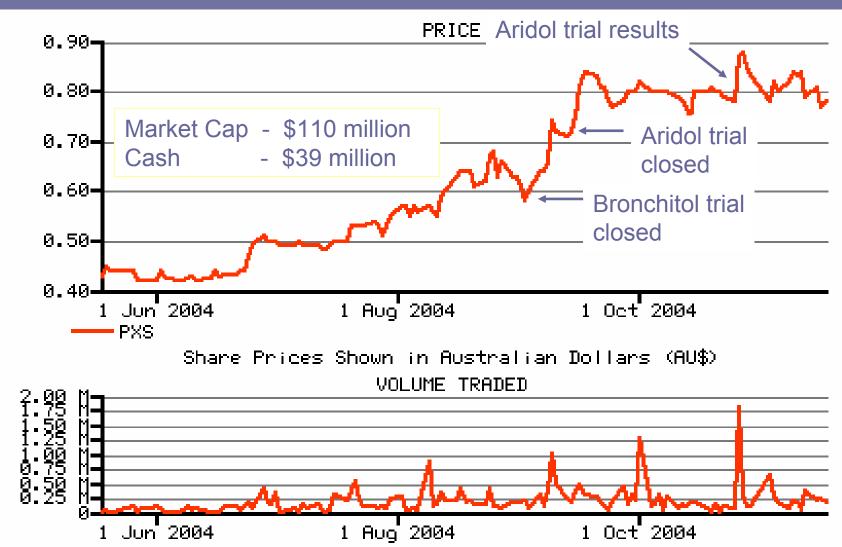
Co-inventor of TNF antibodies





#### The Market.....

#### Pharmaxis has hit all Major Milestones since Listing





### The year ahead.....

- 1. International launch of Aridol
- 2. Expansion of manufacturing capacity
- 3. Commence final Bronchitol trials for bronchiectasis
- 4. International opinion leading trials with Aridol
- 5. First human clinical study with PXS25





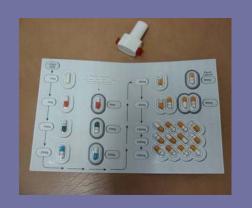
#### Aridol

asthma
asthma management
chronic obstructive pulmonary disease





#### Aridol





- New product for the diagnosis and management of Asthma and COPD
- Phase III completed
- Preparing for Aust/European market launch
- Accurately measures level of ongoing inflammation
- Quick and easy to use ideal for general practice
- Supported by international opinion leaders in respiratory medicine







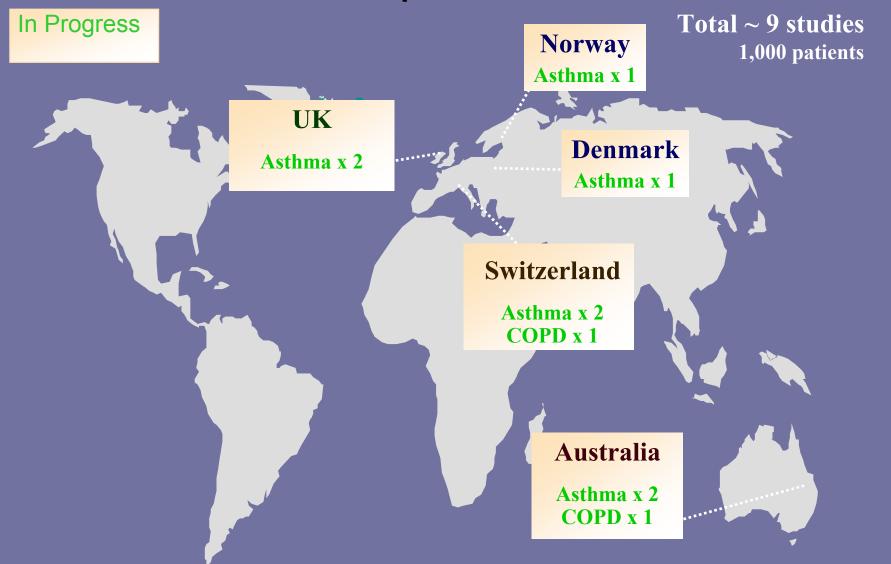
#### Positive Phase III trial results...

- Accurately identifies asthma
- Effective at identifying clinical mis-diagnosis (7%)
   ⇒140,000 Australians
- 20% of subjects over treated and over diagnosed
   ⇒ 400,000 people in Australia
- 25% of subjects not well controlled
  - ⇒ 500,000 Australian asthmatics
- Outcome marketing approval submission





### Worldwide development of Aridol





### Worldwide development of Aridol

In Progress Planned

Sweden

Asthma x 1

Norway

Asthma x 1

Asthma x 1

Total ~ 18 studies 3,500 patients

**USA** 

Asthma x 1

UK

Asthma x 2 Asthma x 1

Greece

**Denmark** 

Asthma x 1

Asthma x 2

**Switzerland** 

Asthma x 2 COPD x 1 Asthma x 2

#### Multi National Studiesx 2

- Asthma (GPs) in 7 countries
- COPD in 3 countries

Australia

Asthma x 2 COPD x 1 Asthma x 1 COPD x 1





#### Aridol<sup>TM</sup> - a significant revenue opportunity

Market	Patients (millions)	% Penetration	\$
Lung Tests Specialists	0.4	75	20
Asthma Mgmt Specialists	3.1	30	50
COPD Diag + Mgmt	4.0	15	50
Asthma Diag GPs	6.0	10	50
Asthma Mgmt GPs	17.3	10	100

Total opportunity = \$250m+







### Next steps for Aridol (2005)......

- Lodge marketing application Australia and Europe
- Prepare for product launch
- Complete US trial
- Lodge New Drug application with FDA
- Prepare for US launch





#### **Bronchitol**

cystic fibrosis
bronchiectasis
chronic obstructive pulmonary disease





#### **Bronchitol**<sup>TM</sup>

- Treatment for cystic fibrosis and chronic obstructive pulmonary disease
- Completed Phase II bronchiectasis
- Commenced Phase II cystic fibrosis
- Commence Phase III
  - Bronchiectasis H1 2005
  - Cystic fibrosis H2 2005
- Product Launch 2007







#### How Bronchitol works.....





# Bronchitol in the clinic......

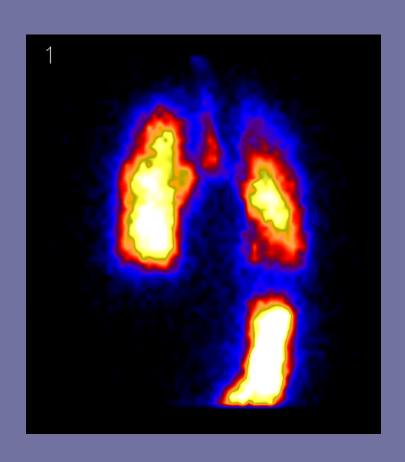






#### Bronchitol in the clinic......

chronic bronchitis - with Bronchitol - 400mg







### Phase II bronchiectasis trial positive.....

**Objective** 

**Quality of life** 

**Symptoms** 

Clinical improvement target

All patients

Severe patients (43/60)

Results

Statistically significant

improvement

Statistically significant

improvement

>4.0

4.8

6.8

Adverse events

None serious







### Trial participants response......

"It has been some weeks since my part of the trial finished and to be honest I have not felt as well as when I was on the Bronchitol."

Trial participant 1

"Thank you for any help that you can give and I wish you well with the Bronchitol project as it has made such a difference to my health."

Trial participant 2

"This patient has been on the Phase II clinical trial of Bronchitol for bronchiectasis. This has revolutionised her life, she would benefit and would be greatly relieved of her daily symptoms if she could continue this treatment."

Physician

"Healthy people take the ability to breathe very much for granted..... To have something to make our declining years a lot more comfortable is something we could only dream about previously."

Trial participant 3





### Next steps for Bronchitol

- © Commence international Phase III study 2005
- First product launch expected 2007
- Expand indications 2005



#### Autoimmune diseases

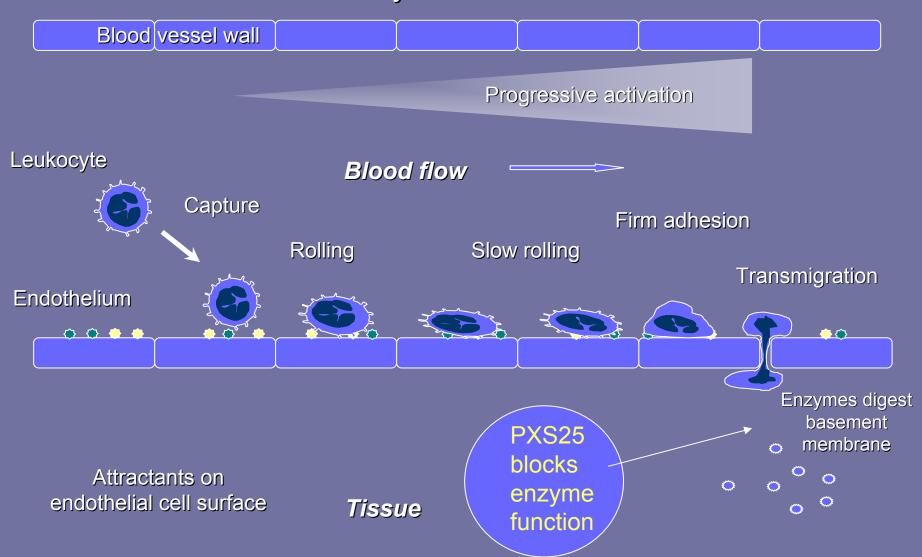
multiple sclerosis rheumatoid arthritis



#### Autoimmune Disease



Inflammation: the leukocyte activation cascade









#### Autoimmune Disease

- PXS25
  - Selective inhibitor of T cell migration
  - Novel mechanism of action
  - Effective in MS and RA models
  - Complementary with existing treatments
- Competitive Edge
  - Delivery by oral route
  - Approach clinically validated
- Status
  - Preclinical
  - Human studies 2005

- PXS2076
  - Inhibitor of TNF
  - Novel mechanism of action
  - Effective in RA models
- Competitive Edge
  - Delivery by the oral route
- Status
  - Research

Very large market opportunities







### Financials

	Year ended 30 June 2004	Year ended 30 June 2003	Quarter ended 30 Sept 2004	Quarter ended 30 Sept 2003
	<u> A\$'000</u>	<u>A\$'000</u>	<u> A\$'000</u>	<u>A\$'000</u>
Income Statement				
Revenues				
Grants	1,105	976	323	434
Interest	1,075	284	321	80
Other	48	43	-	17
	2,228	1,303	644	531
Expenditures				
Research & development	(6,047)	(1,790)	(2,377)	(978)
Commercial	-		(200)	
Administration	(2,182)	(981)	(903)	(427)
Net loss before and after tax	(6,001)	(1,468)	(2,836)	(874)
Depreciation & amortisation	490	256	137	117
EBITDA	(6,586)	(1,496)	(3,020)	(837)
Capital Expenditure	(406)	(1,652)	(275)	(50)





#### Financials

	<u>30-Jun-03</u> <u>A\$'000</u>	30-Sep-03 <u>A\$'000</u>	30-Jun-04 <u>A\$'000</u>	30-Sep-04 <u>A\$'000</u>	ProForma after Placement A\$'000
Balance Sheet					
Cash & bank accepted bills	7,384	6,246	25,217	22,932	38,632
Total assets	10,495	9,651	28,261	26,555	42,255
Long term debt	-	-	-	-	-
Shareholders' Equity	9,890	9,016	26,780	23,978	39,678

P3 Grant outstanding: \$6m 2005 to 2008





### Share Capital

#### **Shares**

108,304
24,964
130.304

#### **Options**

Options on Issue	10,463
Vested	7,399
Escrowed to 10 November 2005	6,720
Options Currently Exercisable	1.779

Level One ADR Program Effective 12 November 2004

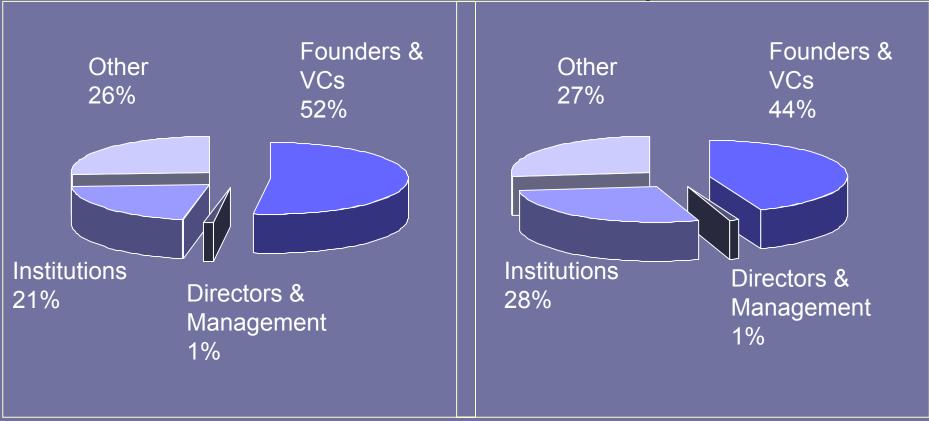




### Share capital.....



#### Post placement









### Summary

- Well resourced to execute Business Plan
- Aridol asthma launch 2005
  - Annual revenue potential >\$250 million
- Integrated business
  - All marketing rights retained
- Bronchitol in Phase III for bronchiectasis
  - Market launch expected 2007
  - Very large market potential
- Bronchitol in Phase II for cystic fibrosis
- Pipeline of earlier stage products
  - Targeting large market potential

