



4 November 2004

Pharmaxis Ltd ACN 082 811630



#### **AGENDA**

- Welcome & Introduction of Directors
- Formal Business:
  - Procedures for the Passing of Each Resolution
  - Item 1: Financial Report 30 June 2004
  - Item 2: Re-elect Mr Denis Hanley
  - Item 3: Re-elect Ms Brigitte Smith
  - Item 4: Re-elect Dr Brett Charlton
  - Item 5: Re-appoint PricewaterhouseCoopers as auditors
- Chairman's Address
- Report by Chief Executive Officer
- Report by Chief Financial Officer
- Close





"To receive and consider the financial report of the Company for the year ended 30 June 2004 and the related Directors' Report, Directors' Declaration and Auditors' Reports"

No shareholder vote is required in respect of this item





"To re-elect a Director. Mr Denis Hanley retires in accordance with the Company's Constitution and, being eligible, offers himself for re-election"

32,426,045 proxy votes in favour

No proxy votes against

No proxy votes abstaining

892,133 proxy votes to be voted by the chair in favour

14,728,734 proxy votes able to be voted by other persons





"To re-elect a Director. Ms Brigitte Smith retires in accordance with the Company's Constitution and, being eligible, offers herself for re-election"

32,443,278 proxy votes in favour

14,267 proxy votes against

No proxy votes abstaining

892,133 proxy votes to be voted by the chair in favour

14,697,234 proxy votes able to be voted by other persons





"To re-elect a Director. Dr Brett Charlton retires in accordance with the Company's Constitution and, being eligible, offers himself for re-election"

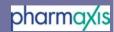
32,436,045 proxy votes in favour

No proxy votes against

No proxy votes abstaining

892,133 proxy votes to be voted by the chair in favour

14,718,734 proxy votes able to be voted by other persons





"To re-appoint the auditor, PricewaterhouseCoopers in accordance with section 327 of the Corporations Act 2001."

32,253,836 proxy votes in favour

12,209 proxy votes against

No proxy votes abstaining

892,133 proxy votes to be voted by the chair in favour

14,883,734 proxy votes able to be voted by other persons







**Denis Hanley** 

4 November 2004



# Pharmaxis Ltd 2004 Annual General Meeting Chairman's Address

My fellow Shareholders, 2004 has been a year of great achievement.

The shareholders, management and staff of Pharmaxis are on an important mission to commercialise Australian Scientific expertise in medicine. For a long time, Australia has performed well on the global stage from a scientific standpoint with a number of Nobel Prize winners - but has not always derived sufficient financial reward for this fine work.

The risk reward equation is directly proportional to the reduction of the technical risk associated with an invention. Pharmaxis is researching and identifying an invention. Then we take the invention, develop a clinical compound from it and then develop a manufacturing process for it. We then progress the clinical compound through Phase 1 clinical trials to understand the performance of the compound in healthy volunteers, then conduct Phase 2 trials in patients with the target disease to understand the utility and effectiveness of the compound and then move forward to do the pivotal work of a Phase 3 clinical trial to get registration of the product and approvals to market.

At each stage, as we are successful, we increase the value of our company by reducing the technical risk for the compound and increasing our chances of success in the marketplace.

After developing and acquiring some promising compounds as a research company financed by Australian private equity for a number of years, this time last year, Pharmaxis had achieved sufficient technical progress with its lead compound, Aridol to move into its Phase 3 clinical trial. The outcome of this study was designed to support the registration of Aridol for clinical use as a test for asthma. To fund that clinical work Pharmaxis listed successfully on the ASX.

It is now on the record that the Phase 3 Aridol clinical trial was successful and so your company is now preparing to file for the approval to market Aridol in Australia, Europe and a little later in the USA.

Your Company also funded, or supported in other ways, a number of other trials around the world and in particular a Phase 2 clinical trial in patients for our second product, Bronchitol.

The Bronchitol trial was successful also. This trial prepared the way for Bronchitol's first patient Phase 3 clinical trial, which will be designed to lead to registration of this compound for clinical use in the treatment of bronchiectasis.

To fund this new clinical work, your company has just completed successfully the placement of shares with Australian institutional shareholders to replace the money we have spent over the last 12 months on our successful trials and so not interfere with the development of the Aridol marketing plan.

We intend to follow up this placement with a Share Purchase Plan for all shareholders at the same price as the institutional placement so that all have the opportunity to expand their participation in your company's success.

Your Managing Director, Dr Alan Robertson in his presentation will be providing a more expansive presentation on Pharmaxis operations over the last 12 months and some insight into the scope of the opportunity in front of us.

Your CFO, Mr. David McGarvey will give an overview of the company's financial position.

On your behalf, I want to thank your Board for their oversight and strategic Direction of our company. Also on your behalf, I would also like to thank your Management and staff for delivering the success we are enjoying.

Denis M Hanley

4 November, 2004



Therapeutic products

for

chronic respiratory and autoimmune diseases

**CEO Presentation** 

Alan Robertson

#### 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					<b></b>		Mid -2005
Bronchitol <sup>™</sup> - bronchiectasis							Late -2007
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 Revenue Opportunity.....

Product	Target Application	Patient Population (million)	Market Size (A\$ million)	Revenue Opportunity (A\$ million)	First Revenue
Aridol	Management of asthma	52	\$1,600	\$200	H2 05
Aridol	Management of COPD	30	\$300	\$50	H1 06
Bronchitol	Bronchiectasis	0.6	\$1,500	\$400	H2 07
Bronchitol	Chronic Bronchitis	30	\$40	\$900	2008
Bronchitol	Cystic Fibrosis	0.1	\$1,000	\$350	2008
PXS25/64	Multiple sclerosis	1	\$3,500	n.a.	n.a.
PXS2076	Rheumatoid arthritis	6	\$3,600	n.a.	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 CE

CEO at Novartis Australia



John Crapper MBA

COO Managing Director of Memcor



William Cowden PhD

cso

Co-inventor of TNF antibodies

pharmaxis



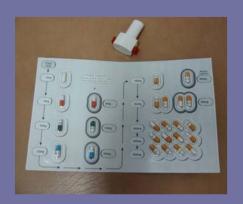
### Aridol

asthma
asthma management
chronic obstructive pulmonary disease





#### Aridol





- New product for the diagnosis and management of Asthma and COPD
- Phase III completed
- Preparing for 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







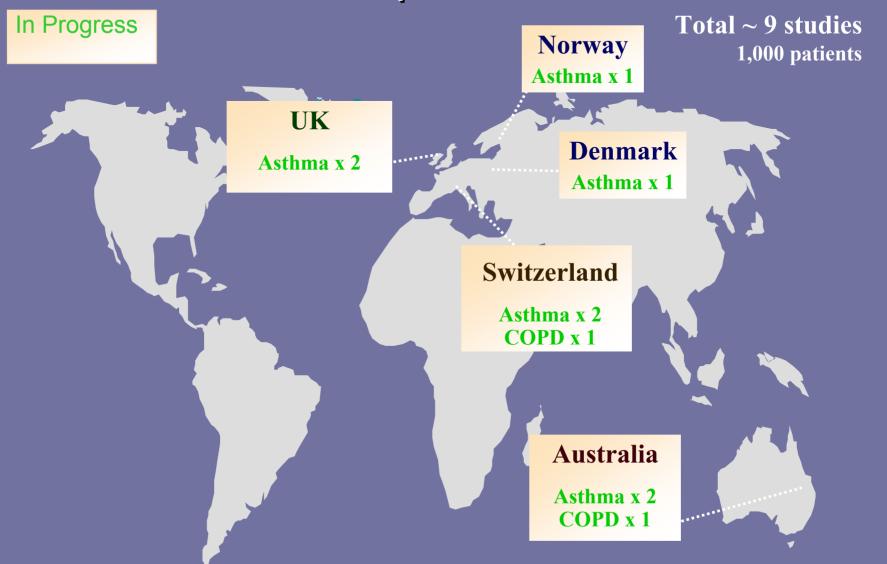
#### Positive Phase III trial results...

- 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

USA

Asthma x 1

Sweden

Asthma x 1

Norway Asthma x 1

Asthma x 1

Total ~ 18 studies 3,500 patients

UK

Asthma x 2 Asthma x 1 Denmark

Asthma x 1
Asthma x 2

Greece COPD x 1

**Switzerland** 

Asthma x 2 COPD x 1 Asthma x 2

Multi National Studies X 2

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

Australia

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





#### **Bronchitol**

cystic fibrosis
bronchiectasis
chronic obstructive pulmonary disease





### Bronchitol<sup>™</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





### Phase II trial results

**Objective** 

Quality of life

**Symptoms** 

///

1111

Clinical improvement target

All patients

Severe patients (43/60)

>4.0

4.8

6.8

**Side effects** 

None serious







### **Trial Participants**

"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





#### Autoimmune diseases

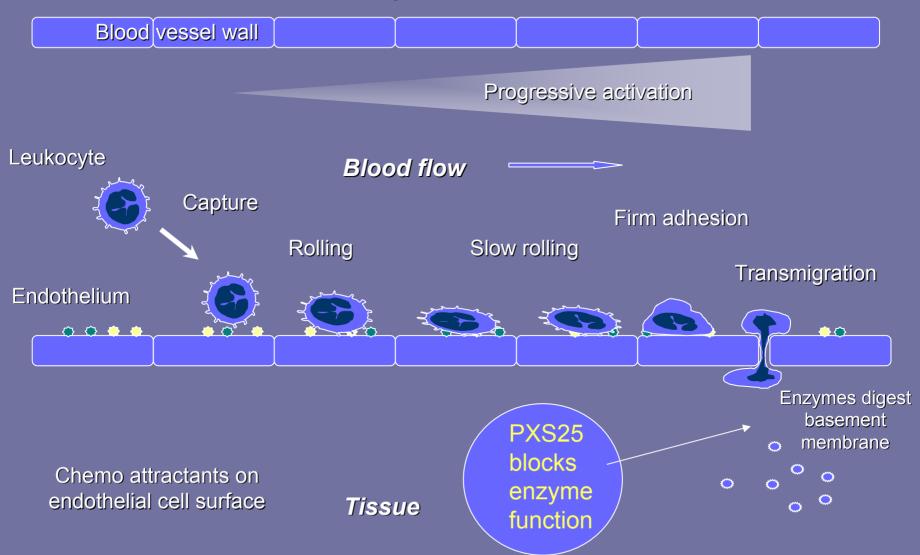
multiple sclerosis rheumatoid arthritis



#### 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





### The year ahead.....

- 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





Financial Report

**David McGarvey** 

Chief Financial Officer



### Financials

			<u>Quarter</u>	<u>Quarter</u>
	Year ended	Year ended	ended 30	ended 30
	30 June 2004	30 June 2003	Sept 2004	<b>Sept 2003</b>
	A\$'000	A\$'000	A\$'000	A\$'000
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





### **Share Capital**

	<u>31-Uct</u>
Shares on Issue ('000)	108,304
Escrowed to 10 November 2005	24,964
<b>Options</b>	
Options on Issue	10,463
Vested	7,399
Escrowed to 10 November 2005	6,720

**Level One ADR Program Effective November 2004** 

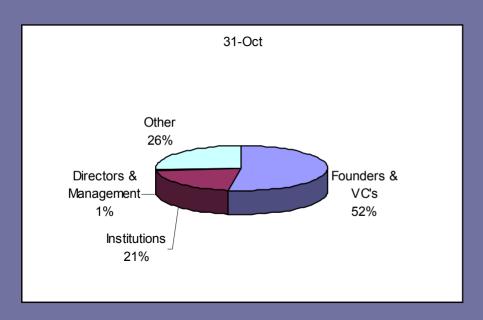
**Options Currently Exercisable** 

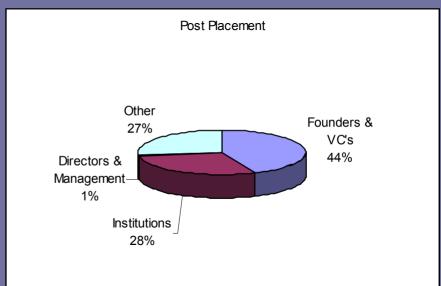


1,779



## **Share Capital**









### Summary

- Well resourced to execute Business Plan
- Aridol asthma launch 2005
  - Annual revenue potential >\$250 million
- Integrated business
  - All marketing rights retained
- Bronchitol entering 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

