

pharmaxis

Innovative products for respiratory diseases

Annual General Meeting
November 2011

Company Overview

Objective	The development of products for respiratory diseases	
Lead products	Aridol:	<ul style="list-style-type: none"> •assessment of asthma •approved & launched in major markets
	Bronchitol for cystic fibrosis:	<ul style="list-style-type: none"> •approved in Australia •recommended for approval in EU •US NDA in preparation
	Bronchitol for bronchiectasis:	•Phase III trial in progress
	ASM8 for asthma:	•Phase II trial in progress
Discovery	PXS25	M6P receptor blocker
	PXS4686	SSAO / VAP-1 inhibitor
Listing	ASX (Nov 2003): PXS	
Locations	Sydney, Australia • Philadelphia, USA • London, UK	
Facility	Manufacture of Aridol & Bronchitol	
Employees	132 (31/10/11)	
Cash	A\$34 million (30/9/11)	
Shares & Options	Shares outstanding: 229m; Options outstanding: 12m (30/9/11)	

Bronchitol - Cystic Fibrosis

• Background



- Genetic disorder affecting ~40,000 in Western Europe, ~30,000 in US and ~3,000 in Australia
- Poorly hydrated, tenacious, thick mucus
- Median predicted age of survival approximately 35 years (2009 – US and UK)

• Main Therapeutics

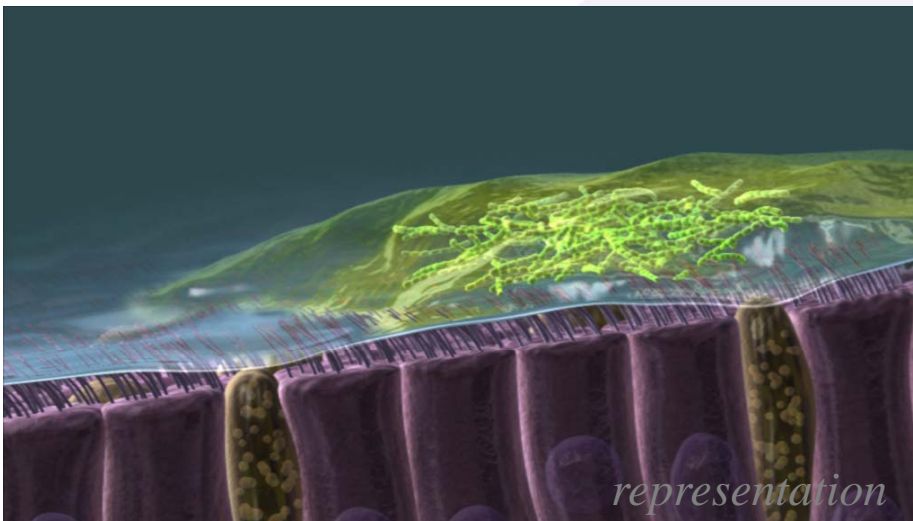


- Mostly delivered by nebulizer (preparation, sterilization)
- rhDNase (Pulmozyme®): global sales ~CHF 513m (2010)
- Tobramycin (Tobi®): global sales ~US\$ 279m (2010)
- Aztreonam (Cayston®): approved EU: 09/09; US: 02/10

Bronchitol - Clearance of Thick Mucus

Mechanism of Action

Before treatment

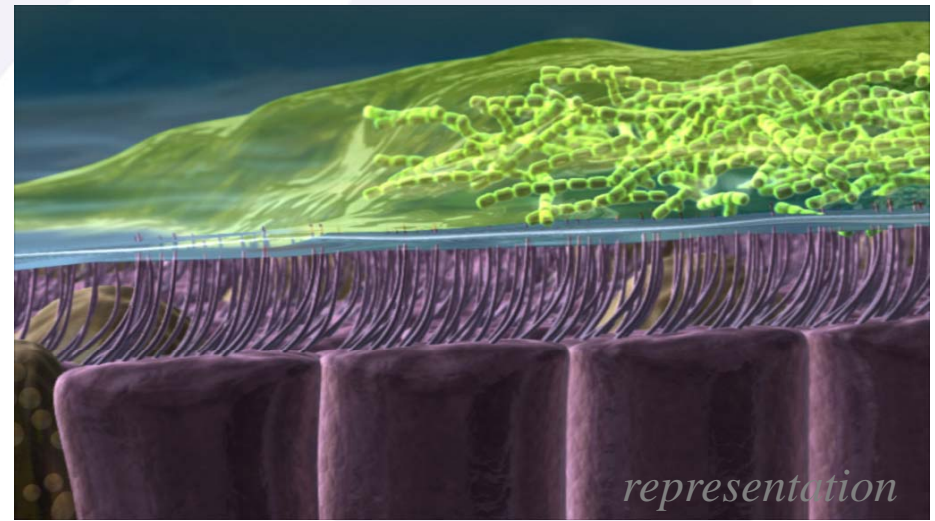


Lung surface dehydrated

Airway surface fluid layer impaired

Lung defense and hygiene compromised

After Bronchitol administration



Lung hydrated

Airway surface liquid restored

Improved lung clearance

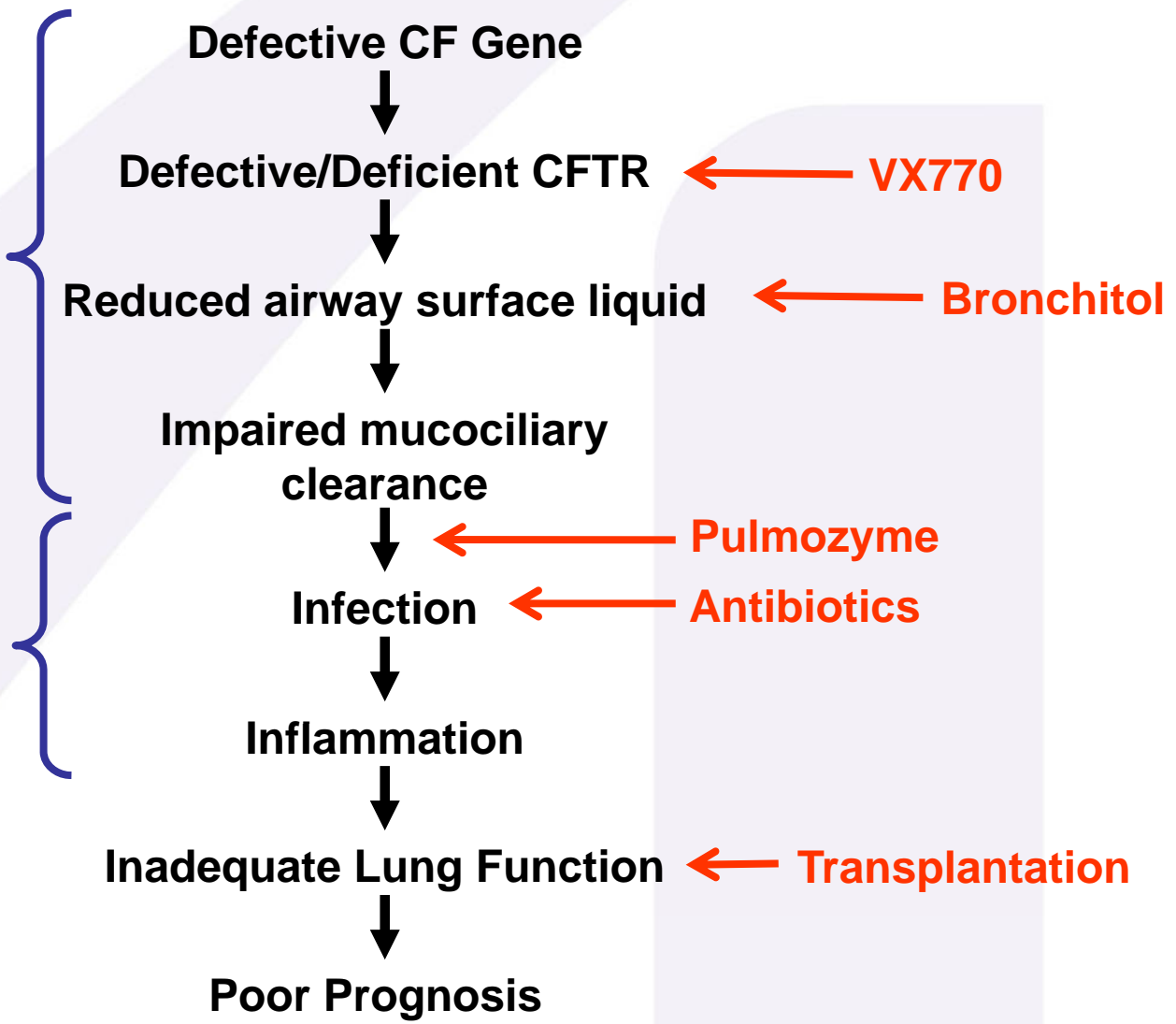
Bronchitol - Progression of CF Lung Disease



New Therapies



Current Therapies



Bronchitol - Cystic Fibrosis Clinical Program



Two Pivotal Phase III trials – same design

- Multicentre, double blind, controlled
- Approx 300 subjects greater than 6 years old per trial
- 6 month treatment, 400mg twice per day followed by 6 month open label
- Primary endpoint:
 - lung function (FEV₁)
- Secondary endpoints:
 - Other lung function measures
 - Mucus clearance
 - Exacerbations
 - Antibiotic use
 - Quality of life
- CF301: 40 centres in UK, Ireland, Australia & New Zealand
- CF302: 53 centres in US, Canada, Argentina, Germany, France, Belgium, & Netherlands
- Subjects remain on existing best standard of care



Bronchitol - Improvements in Lung Function

Change in lung function after 6 months Bronchitol treatment

Results of Clinical Trials CF301 and CF302 - Combined

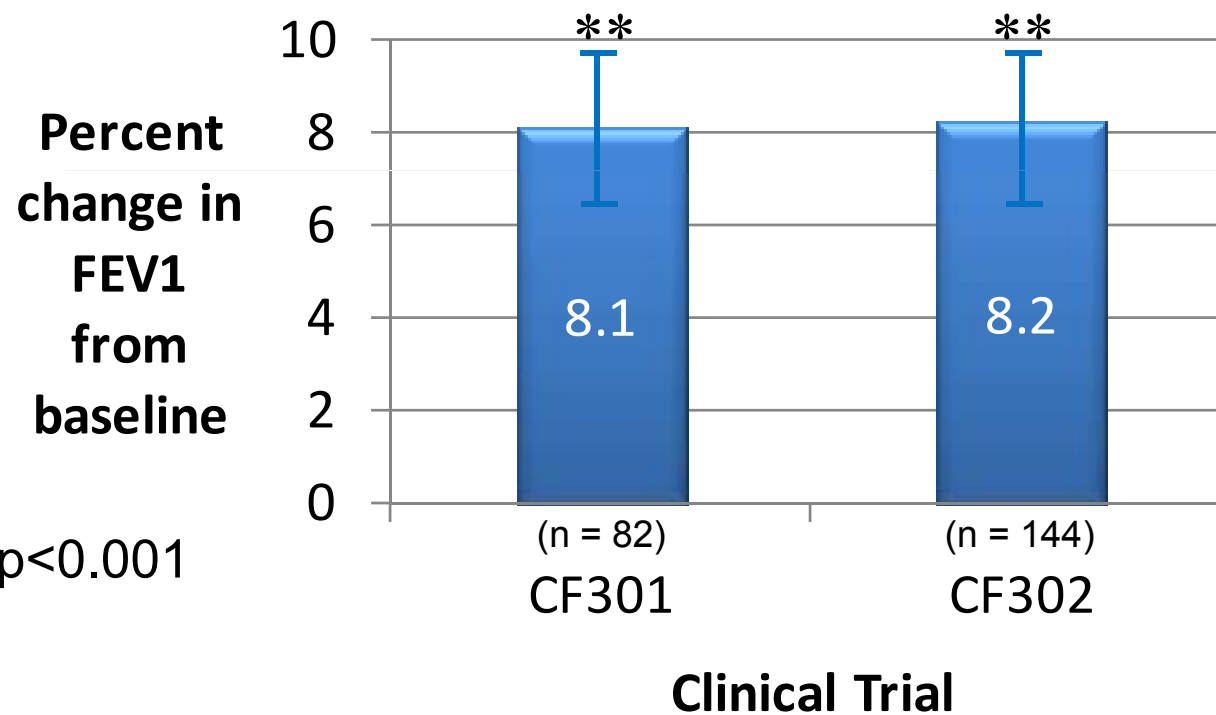
	Paediatric (6-11yrs)	Adolescents (12-17 yrs)	Adults (≥18 yrs)	Overall (n = 569)	
	FEV ₁	FEV ₁	FEV ₁	FEV ₁	p value
% difference versus control (mL)	4.16*	1.25*	4.88	3.80	<0.001
% change from baseline (mL)	13.19	8.41	4.68	7.32	<0.001

Overall treatment response (FEV₁) over 26-weeks – all age groups (Pooled Data)

* not statistically significant

Bronchitol - Sustained Treatment Effect

Change in lung function after 12 months Bronchitol treatment



CF301 and CF302 – Double Blind for 6 months followed by Open Label for 6 months

Bronchitol - Exacerbation Incidence Reduced

Percentage reduction in exacerbation incidence after 6 months Bronchitol treatment

CF301	35%	p=0.045
CF302	20%	p>0.05
CF301 +CF302 combined	29%	p=0.039

Bronchitol - Cystic Fibrosis (Europe)

30,000 CF Patients in Top 5 EU Countries

● First two launch markets: UK and Germany

- Revenues from Qtr 2 2012
- Free pricing on approval
- NICE to review pricing / effectiveness post launch (UK)
- 110 CF clinics in Germany and 50 in UK

● Next three: France / Italy / Spain

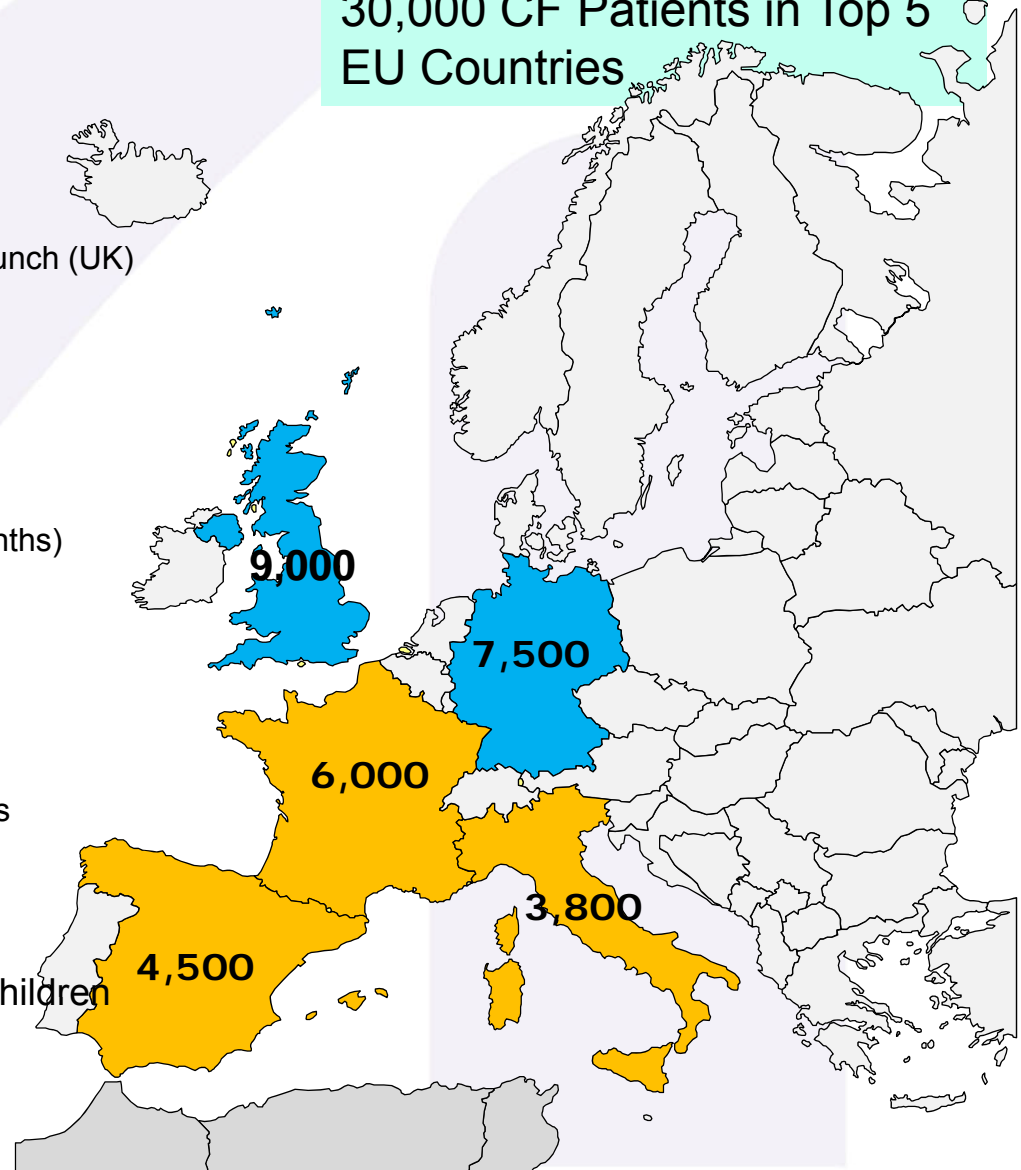
- To be launched after reimbursement (6-12 months)
- 110 additional clinics

● Remaining EU countries

- Subsequent rollout on country-by-country basis

● Label expansion to include adolescents and children

- Short clinical trial required
- Represents one third of total market



Bronchitol - Cystic Fibrosis (USA)

Regulatory



- NDA scheduled submission H1 2012
- Earliest FDA review completed H1 2013
- Orphan drug provides 7 years market exclusivity from date of FDA approval

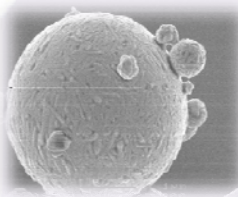


Marketing

- ~150 to 180 CF centres
- Anticipated requirement for 20 - 25 person field force
- ~30,000 people in the US with CF
- Pulmozyme price ~ US\$22,000 per patient per annum

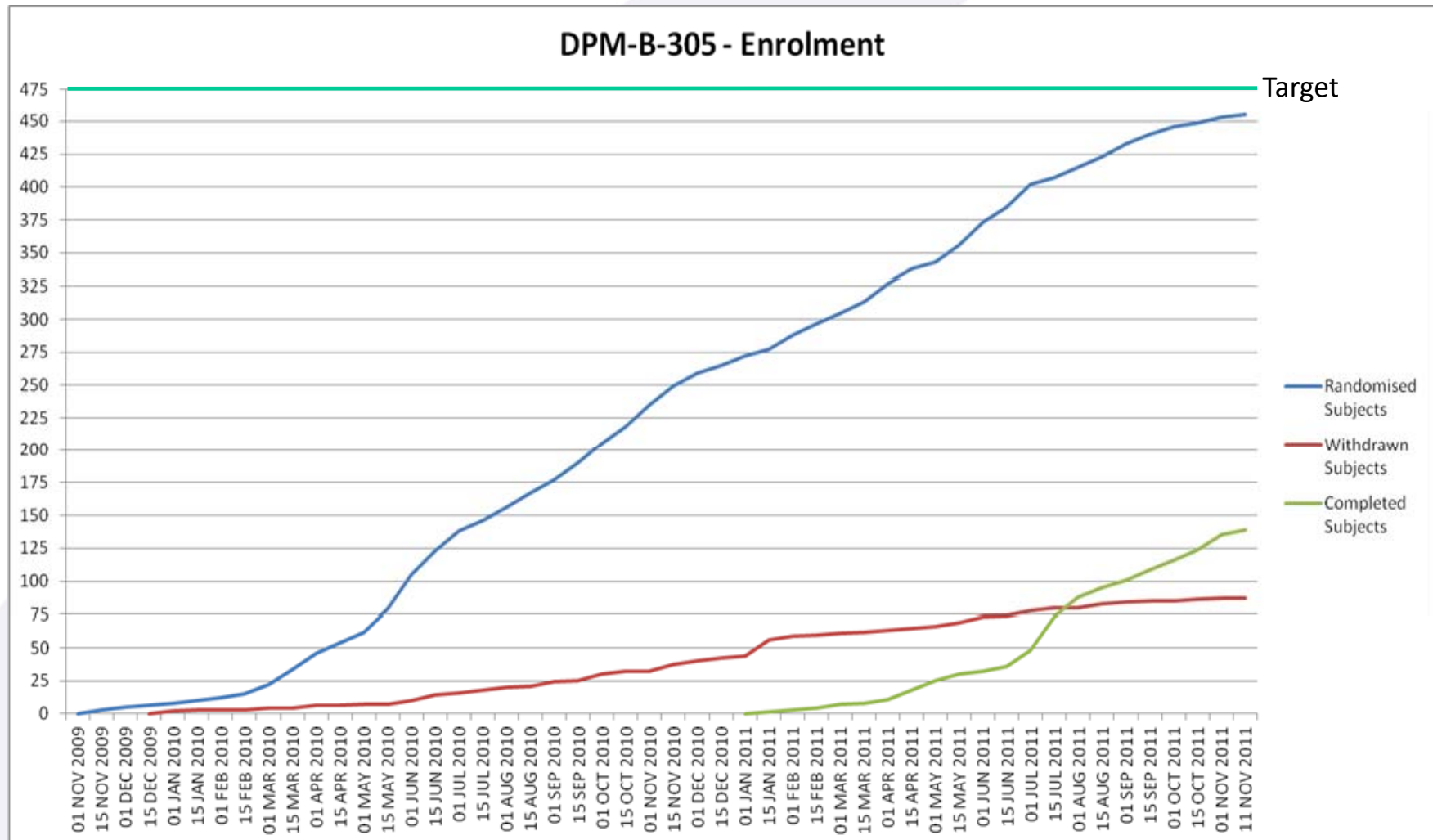


Bronchitol - Bronchiectasis



Indication	Bronchiectasis (non Cystic Fibrosis)
Target Product Profile	<ul style="list-style-type: none">- Effective clearance of mucus- Reduction in exacerbation incidence
Market Size	Approximately 110,000 people in the US and 210,000 in the EU are seeking treatment
Competitors	Antibiotics & CF drugs; lack of targeted clinical development in this disease state
Status	Phase III trial (B305) recruitment ongoing
Next Milestones	Phase III trial closed to recruitment – Q4 2011 Data – 1H 2013

B305: Phase III Trial in Bronchiectasis – Status Mid Nov 2011



Aridol®

- Identifies airway hyperresponsiveness which helps physicians in the overall assessment of **asthma**
- An **easy-to-use test kit** provides rapid results and doesn't require specialized equipment



Aridol – commercialisation status



Financial years ending 30 June			2008	2009	2010	2011
Sales (A\$'000)						
Australia	Launched 2006	Direct	216	232	268	253
Europe	Staggered launch from 2006	Individual country distributors; UK – direct	137	267	398	398
South Korea	Launched 2009	Distributor	-	32	162	205
Clinical trials		Direct	174	64	-	-
US	Launched Feb 2011	Direct	-	-	-	54
			527	595	828	910

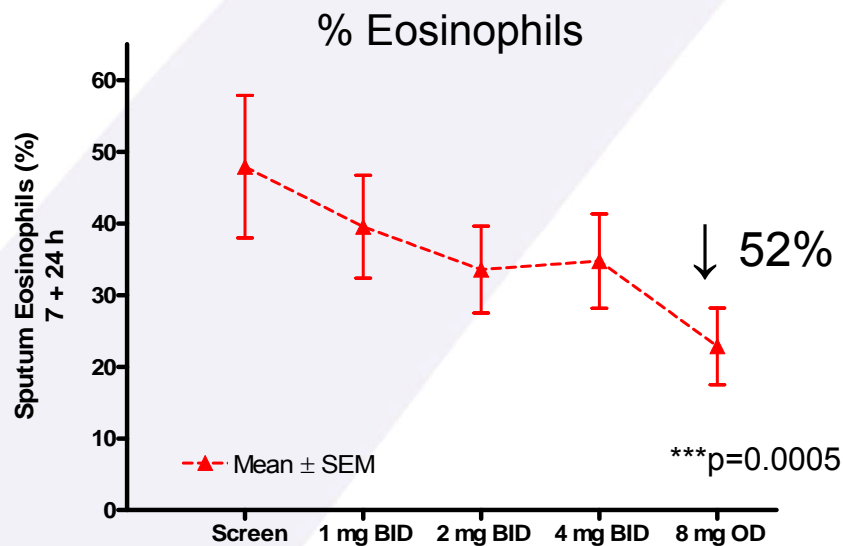
Potential growth

- US and South Korea – full reimbursement for procedure and product
- Asthma management – recent investigator initiated trial published
- COPD – recent investigator initiated trial published

ASM8 – Asthma



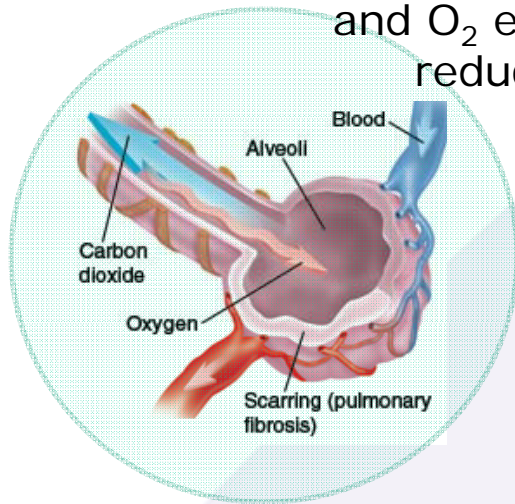
Phase IIa dose profiling trial



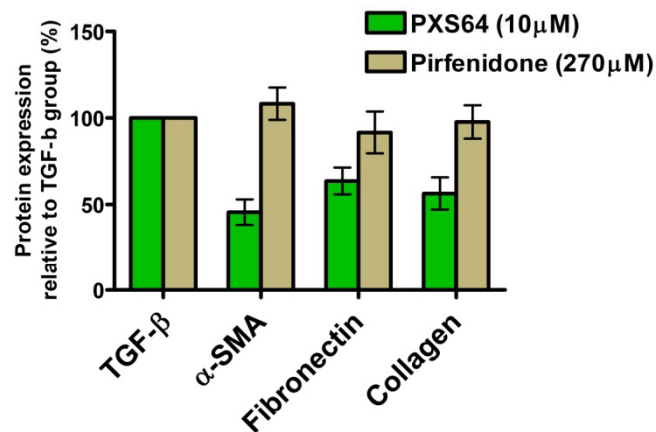
Indication	Moderate to severe asthma for patients who do not respond to inhaled steroids or cannot tolerate high doses
Target Product Profile	<ul style="list-style-type: none"> -Greater efficacy through multi-targeting -Better tolerability & convenience compared with current treatments -Once daily nebulisation
Market Size	Affects ~12 million people worldwide
Competitors	Xolair (US\$369M, 2010)
Status	Phase II trial fully recruited
Next Milestone	Phase II trial results – Q2 2012

PXS25 / PXS64 – Idiopathic Pulmonary Fibrosis

alveoli thickening
and O₂ exchange
reduction

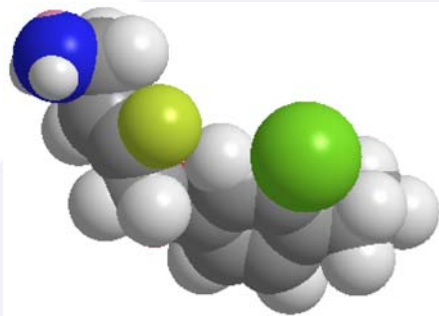
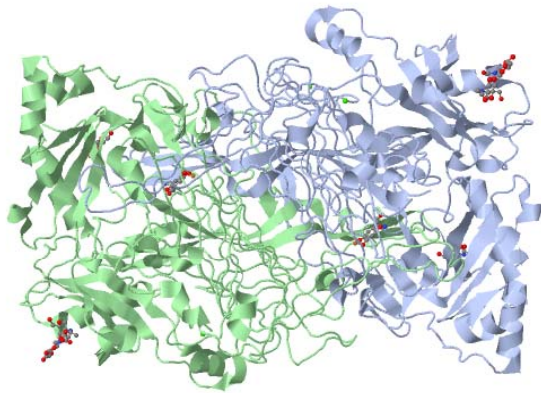


The effect of PXS64 vs pirfenidone in primary derived human lung fibroblasts



Indication	Idiopathic Pulmonary Fibrosis (IPF)
Target	M6P receptor blocker
Target Product Profile	-Inhibition of fibrosis and inflammation to lung tissue -Local administration to the lung -Safe & well tolerated in humans
Market Size	Affects ~200,000 people in the USA
Competitors	Pirfenidone (just launched in EU), immunosuppressives & steroids
Status	Initial Phase I trial (intravenous) completed
Next Milestone	Confirmatory in-vivo data Clinical plan in development

PXS4686 – Lung Inflammation



small molecule inhibitor of SSAO

Indication	Treatment of inflammatory disease, such as asthma
Target	SSAO / VAP-1 inhibitor
Target Product Profile	-Neutrophilic asthma -Once daily oral dosing
Market Size	Affects ~23 million people worldwide
Competitors	Significant clinical activity amongst pharmaceutical companies
Status	Pre-clinical development
Next Milestone	Lead development candidate – Q4 2011

Summary

- **Respiratory company with approved products and strong pipeline**

- **Aridol**

→ Approved in Australia, South East Asia, Europe and USA

→ Fully reimbursed in USA and South Korea

- **Bronchitol**

→ Approved in Australia for cystic fibrosis

→ Recommended for approval in Europe

- First launch expected 1H 2012

→ USA marketing application to be filed 1H 2012

→ Clinical trials in progress to extend reach into Bronchiectasis

- **ASM8 for asthma**

→ Phase IIb trial results due 1H 2012

- **PXS 25 for Idiopathic Pulmonary Fibrosis**

→ Phase I trial completed with IV formulation





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Chief Financial Officer

David McGarvey

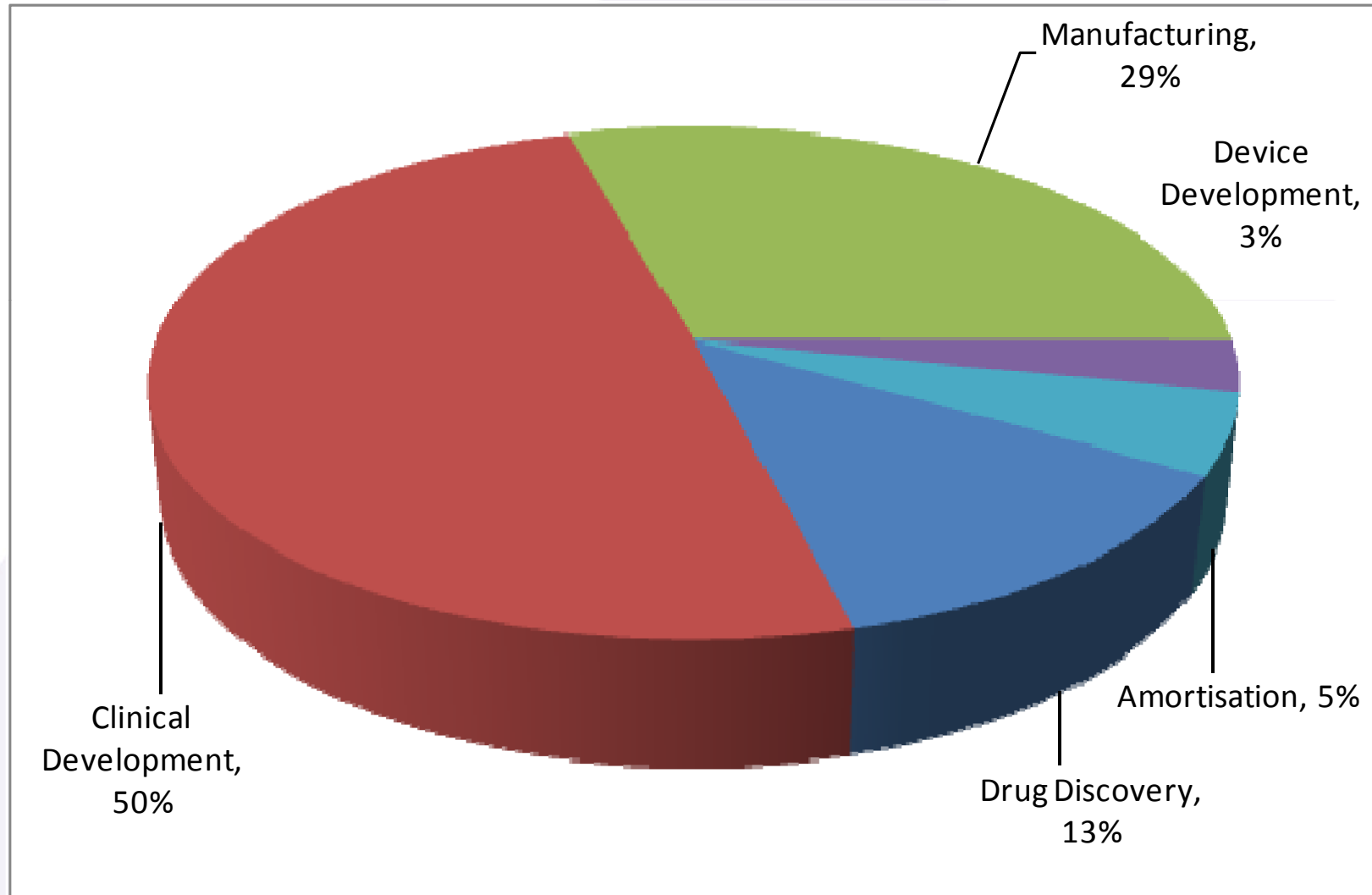
Annual General Meeting

November 2011

Financial Statements

Year ended 30 June	<u>2011</u>	<u>2010</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
	A\$	A\$	A\$	A\$	A\$	A\$
Income Statements						
Revenue from sale of goods	910	828	595	527	205	8
Gross profit	568	521	442	398	156	6
Interest	3,083	3,935	5,347	7,402	5,278	4,282
Other income	465	616	523	1,576	2,152	1,299
Expenses						
Research & development	(34,632)	(35,140)	(29,308)	(19,996)	(23,840)	(16,978)
Commercial	(9,163)	(5,657)	(6,202)	(4,557)	(3,240)	(1,946)
Administration	(5,171)	(9,715)	(5,800)	(5,231)	(4,666)	(4,391)
Finance expenses	(859)	(854)	(122)	-	-	-
Total expenses	(49,825)	(51,366)	(41,432)	(29,784)	(31,746)	(23,315)
Loss before income tax	(45,709)	(46,294)	(35,120)	(20,408)	(24,160)	(17,728)
Income tax expense	(49)	(51)	(51)	(32)	(19)	(5)
Loss for the year	(45,758)	(46,345)	(35,171)	(20,440)	(24,179)	(17,733)
Depreciation & amortisation	4,767	2,783	1,242	1,024	939	947
Fair value of securities issued to employees	1,567	2,495	2,432	3,434	1,488	1,124

Research & Development 2011- \$35m



Europe - Direct Sales Resources Required

Country		Targeted Launch Sequence	Sales Force Personnel	Centres/Sales Person
TOP 5	United Kingdom	Q2 2012	6	8
	Germany	Q2 2012	5	22
	France	Q4 2012	5	13
	Italy	Q1 2013	4	9
	Spain	Q1 2013	3	12
	Rest of Western Europe	Q3 2012 – Q3 2013	7	N/A
	Central & Eastern Europe	From Q3 2012 onwards	Distributor strategy	Distributor strategy

European Commercial Infrastructure

- UK – Pharmaxis UK subsidiary and sales force in place (currently promoting Aridol)
- Remainder Western Europe (13 countries) – Quintiles:
 - Recruit and manage dedicated Pharmaxis sales force
 - Local market knowledge to speed access
 - Full back office support
 - Satellite model leveraging PXS Top 5 country management infrastructure
- European CF market support – Pharmaxis UK subsidiary
 - Marketing
 - Pricing
 - Medical information and pharmacovigilance
- Build to total ~40 people in EU for CF
- Logistics infrastructure by 3rd party

Financial Statements

As at 30 June	<u>2011</u>	<u>2010</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
Balance Sheet Data						
Cash and cash equivalents	44,343	85,787	124,993	111,842	76,182	97,840
Plant & equipment	30,570	32,537	32,698	3,668	3,521	3,205
Intangible assets	15,954	17,702	1,193	1,227	1,239	1,195
Total assets	94,572	140,767	163,997	125,049	82,648	104,267
Total liabilities	(23,742)	(25,751)	(26,306)	(5,928)	(6,089)	(5,379)
Total shareholders' equity	70,830	115,016	137,691	119,121	76,559	98,888
Share Data						
Ordinary shares on issue	228,290	225,410	217,659	194,515	177,949	176,904
Options over ordinary shares on issue	12,727	13,155	15,075	11,536	9,836	9,692

Frenchs Forest Facility ~ \$33million

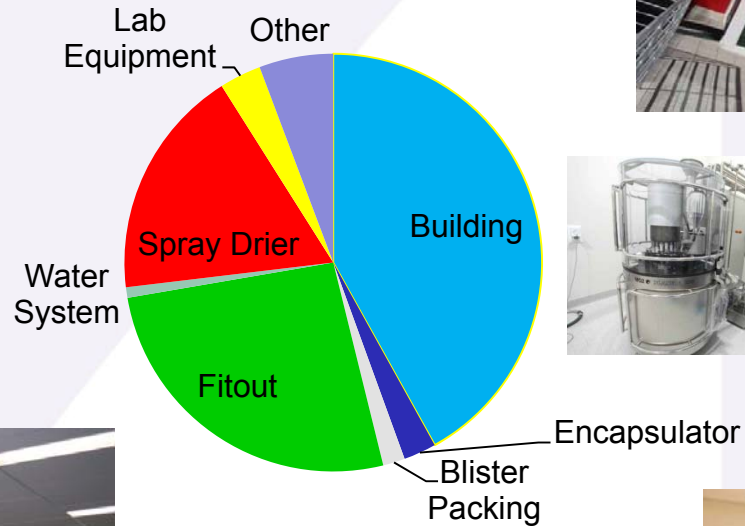


Initial capacity - 1 spray drier:

- 40,000 patients p.a.

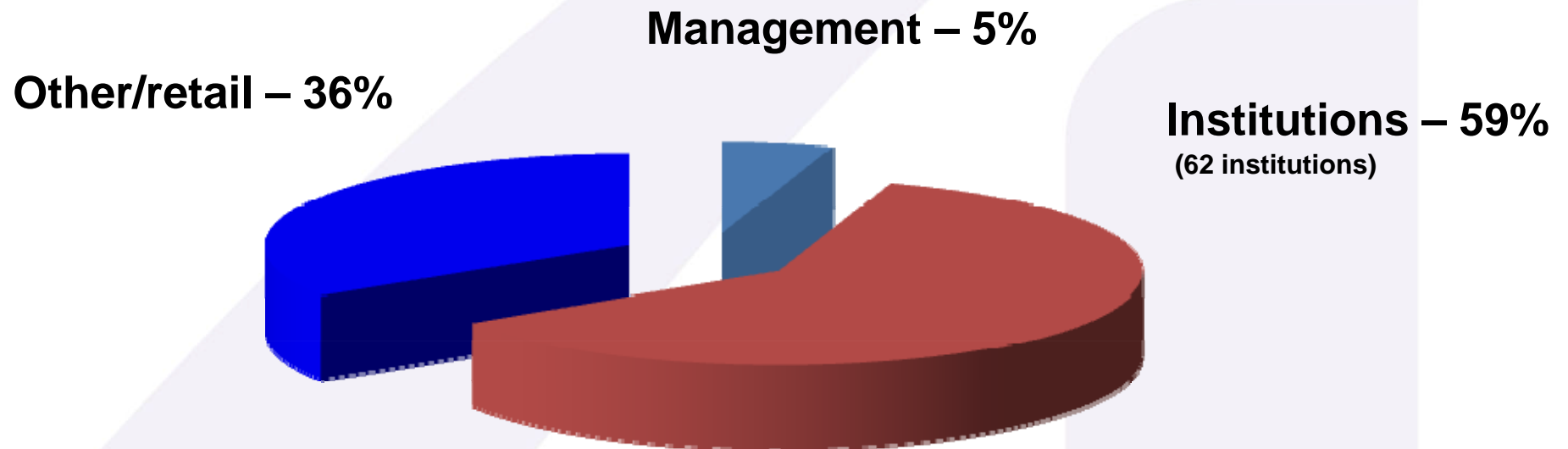
Expanded capacity - 2nd spray drier:

- 80,000 patients p.a.



Share Capital

(including options)



Institutions – 59%
(62 institutions)

30 September 2011: 229m shares; 12m options

Key Terms of the Offer

Entitlement Offer Structure and Size

- 1 for 3 accelerated pro-rata non-renounceable entitlement offer to raise approximately \$80 million, comprised of:
 - Institutional Entitlement Offer and Retail Entitlement Offer
 - Initially underwritten to \$40m by Merrill Lynch International (Australia) Ltd and Wilson HTM Corporate Finance Ltd, now fully underwritten to \$80m
- Record date is 7pm (Sydney time) on 21 November 2011

Offer Price

- A\$1.05 per new share
- 19.2% discount to Pharmaxis' closing price of A\$1.30 on 15 November 2011
- 15.2% discount to the theoretical ex-rights price (TERP)⁽¹⁾

Institutional Entitlement Offer⁽²⁾

- Institutional Entitlement Offer from 16 November 2011 to 17 November 2011

Retail Entitlement Offer⁽²⁾

- Retail Entitlement Offer from 24 November 2011 to 8 December 2011

Ranking

- Shares issued under the Entitlement Offer will rank equally with existing shares

Notes:

1. The theoretical ex-rights price is the price at which Pharmaxis shares should trade immediately after the ex-date for the Entitlement Offer assuming 100% take-up of the Entitlement Offer. The theoretical ex-rights price is a theoretical calculation only and the actual price at which Pharmaxis shares trade immediately after the ex date for the Entitlement Offer will depend on many factors and may not be equal to the theoretical ex-rights price. The theoretical ex-rights price is calculated by reference to Pharmaxis' closing price of \$1.30 on 15 November 2011

2. Dates are indicative only and subject to change. All times refer to Sydney time



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Living with Cystic Fibrosis

Annual General Meeting

November 2011



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Shareholder Questions

Annual General Meeting

November 2011



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Formal Business

Annual General Meeting

November 2011

Resolution 1 – Financial Report, Directors' Report and the Auditor's Report

- **No shareholder vote is required**

Resolution 2: Remuneration Report

Resolution:

“That the remuneration report of the Company for the year ended 30 June 2011 is adopted.”

Remuneration Framework

	Senior executive officers	Non-executive directors
Contract	Three year fixed term contracts with 3 months notice	Retire by rotation at AGM as per constitution and Listing Rules
Salary	Base salary, plus <ul style="list-style-type: none"> • Superannuation of 9% of base • Variable cash incentive component, average of 20% of base salary in 2011. Achieved less than 50%, paid nil • Equity remuneration 	Fixed fee No variable component Fees reviewed by external advisors when last increased
Salary review	Annual and on promotion	Last adjustment 2006
Equity Remuneration	Annual grant of performance rights by Board. Nil re FY 2011	Once only sign-on grant of 30,000 restricted shares
Vesting/ Restrictions	Vest after 3 years, restricted for additional year, Board approval to sell	Vest after 3 years, Board approval to sell

Resolution 2: Remuneration Report

The Company has received:

- 115,897,193 proxy votes in favour of the resolution;
- 868,211 proxy votes against the resolution;
- 599,340 proxy votes abstaining from the resolution;
- 1,790,421 proxy votes prohibited from voting;
- Nil proxies able to be voted by the chair which the chair intends to vote in favour of the resolution.

Resolution 3: Re-election of Mr Denis Hanley as a Non Executive Director

Resolution:

“That Mr Denis Hanley is re-elected as a non executive director of the Company.”

Resolution 3: Re-election of Mr Denis Hanley as a Non Executive Director

The Company has received:

- 118,300,431 proxy votes in favour of the resolution;
- 604,583 proxy votes against the resolution;
- 141,173 proxy votes abstaining from the resolution;
- 409,222 proxies able to be voted by the chair which the chair intends to vote in favour of the resolution.

Resolution 4: Re-election of Mr William Delaat as a Non Executive Director

Resolution:

“That Mr William Delaat is re-elected as a non executive director of the Company.”

Resolution 4: Re-election of Mr William Delaat as a Non Executive Director

The Company has received:

- 118,599,064 proxy votes in favour of the resolution;
- 303,168 proxy votes against the resolution;
- 143,955 proxy votes abstaining from the resolution;
- 409,222 proxies able to be voted by the chair which the chair intends to vote in favour of the resolution.

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**Thank You for Your
Participation**

Annual General Meeting
November 2011