Pharmaxis Business Review

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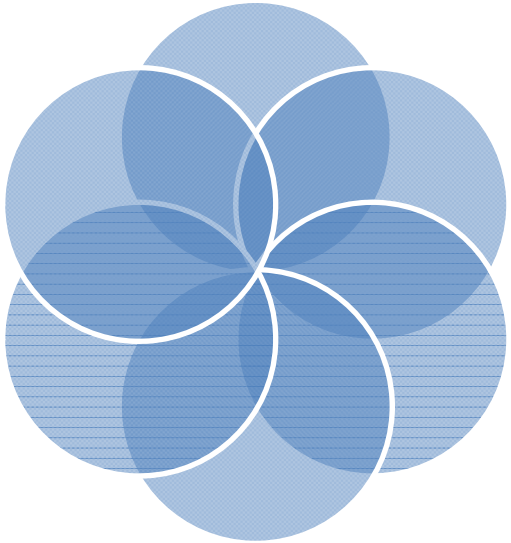
Pharmaxis

A speciality Pharma Company with a global interest in CF and other specialist respiratory diseases

Direct commercial interest in EU and Australian CF markets



Strategic interest in an innovative pipeline of early stage compounds

Seeking to partner assets for CF and bronchiectasis in USA and other markets of interest

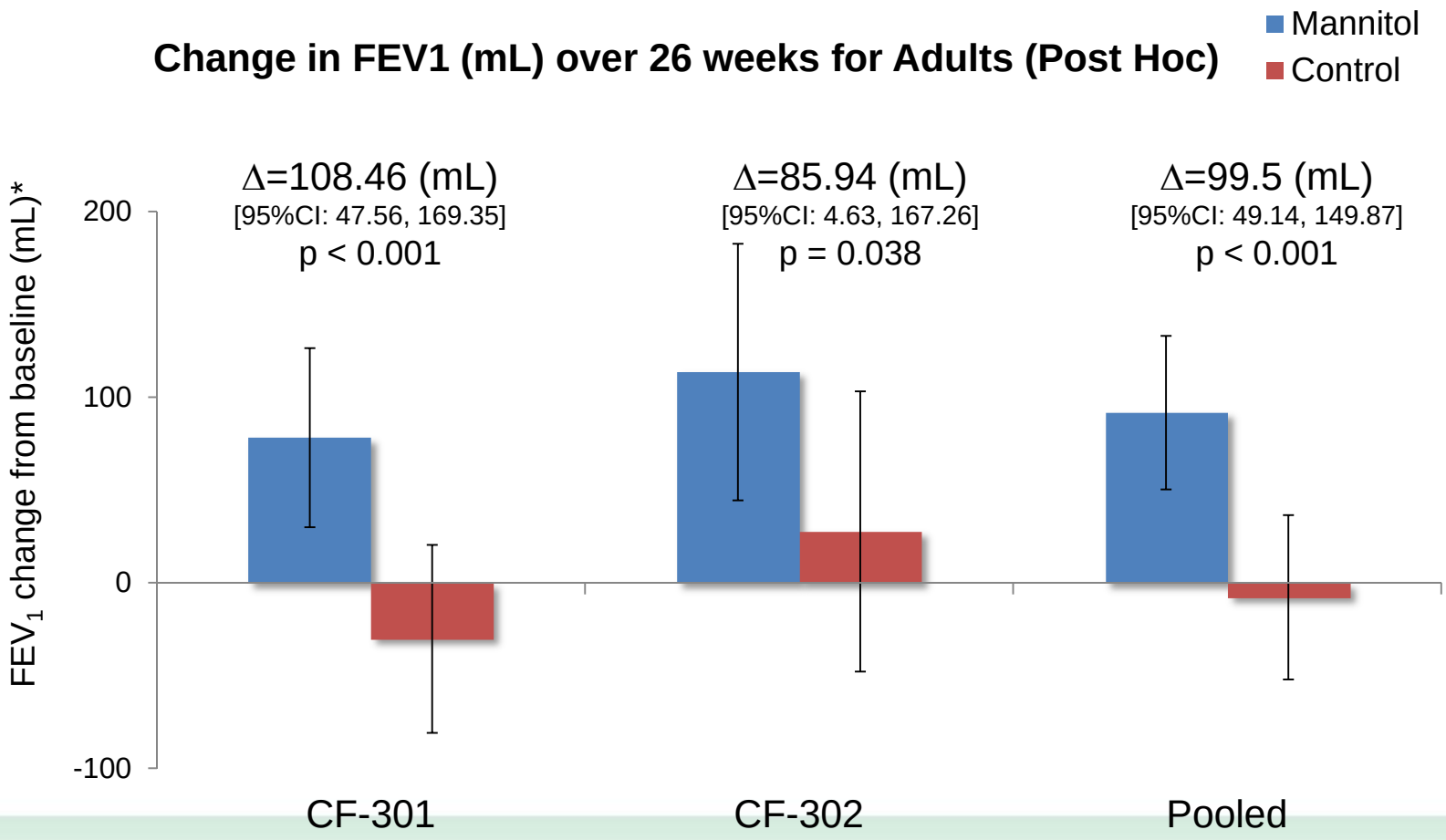
A fresh assessment of Bronchitol

Assets	Estimated revenue opportunity p.a.	Actions to unlock value

Bronchitol approvable for CF in the US for adults with one study by 2H 2016	$160m	• One phase 3 study
		  • 300 patients
		  • <$15m / 2 years
		• Seek partnering opportunities

Bronchitol approvable for CF in the US / EU for children	$130m	• CF 204 study underway • US pathway TBD • Seek partnering opportunities for US
Bronchitol works in bronchiectasis (estimate 20% of US and EU patients)	$800m	• Explore sub group data • Clinical path TBD • Seek global partnering opportunities
Bronchitol approved for treatment of CF in EU and Australia	$75m	• Invest selectively in commercial infrastructure • Complete CF204
Bronchitol approvable for CF in ROW (ex US)	$70m	• Leverage Australian / EU label • Use distributors

Predictable results in adult CF patients



*Post Hoc analysis

CF-301		CF-302		Pooled	
n = 101	n = 72	n = 87	n= 57	n= 188	n= 129

Bilton D, Robinson P, Cooper P, et al. *J Cystic Fibrosis* 2011, Suppl 20 (A78) and Data on File Pharmaxis

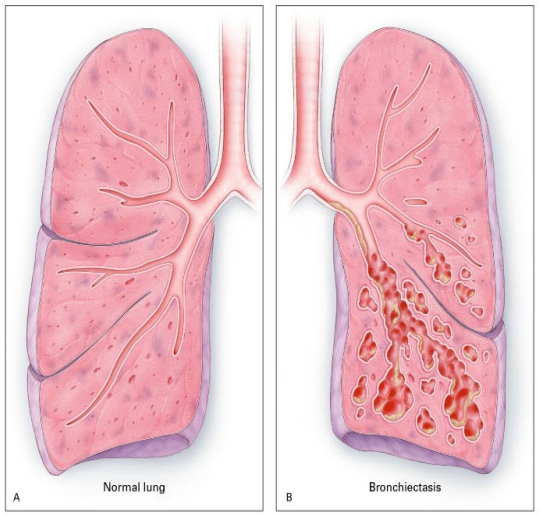
B-305: Significant 2° endpoints

Primary endpoint	Difference in the rates of graded pulmonary exacerbations (rate ratio)	Reduced 8%	Not significant
Secondary endpoints	• Time to first exacerbation (Hazard ratio) • Days of antibiotic use – duration (rate ratio) • Quality of life: Change in SGRQ • Sputum weight: 24 hour collection (g) • Spirometric lung function • Epworth Sleep Score • Hospitalisations for exacerbations rate ratio)	Improved 28% Improved 24% Improved 28% Improved 29% Not achieved Not achieved Improved 39%	0.78 (p=0.022) 0.76 (p=0.0496) -2.4, (p=0.046) +2.8 (p=0.036) Not significant Not significant Not significant
Safety	• Similar overall rates of AE's and SAE's between treatment groups • Acceptable safety profile		

The Bronchiectasis opportunity

Permanently dilated airways due to chronic bronchial inflammation[1]

- Underlying inflammation and damage leads to impaired mucocilliary clearance of micro-organisms and recurrent or chronic infection[1]



Dr.Bashir Ahmed Dar, Chinkipora Sopore Kashmir

US Bronchiectasis

- In US over 190,000 are reported to have non-CF Bronchiectasis[2]

Global opportunity

- 660,000 patients globally[3]
- 29-50% of COPD cases have associated Bronchiectasis[4]

Competition

- Macrolide antibiotics; effective but long term drug resistance issues
- Hypertonic saline; long term studies show no difference to normal saline
- Pulmozyme: Proven to be detrimental in phase 3 studies

References:
1. Bilton, D, Update on non-cystic fibrosis bronchiectasis. Curr Opin Pulm Med 2008; 4. King P, Holmes P. www.australindoctor.com.au 2005

Bronchitol partnering strategy

Deal Structure

1. Classic license deal; upfront plus milestones and royalties
2. Timing options
   a) Partner takes responsibility for clinical development / regulatory submissions / commercialisation
   b) PXS part funded by partner to complete phase 3 trial with option to purchase rights on approval
   c) PXS funds phase 3 trial and licenses post approval

Process Q2- Q4 2013

1. Maximise valuation
   a) Agree development path
   b) Finalise trial protocol and feasibility
2. Shortlist potential partners
3. Marketing and due diligence
   a) CF
   b) Bronchiectasis
4. Assess value

Support

- NovaQuest $20m drawdown option to complete clinical trial before partnering
- Barclays appointed to advise on value accretive alternatives including partnering arrangements for Bronchitol

Key initiatives to drive Bronchitol sales growth in Europe and RoW (ex US)

- Leverage existing EU/Australian approvals
  - Leverage success in larger German clinics
  - Initiatives to improve adherence
  - Continue pricing approvals in EU; improve pricing approval in Australia
  - Enter new countries via distributors

Market	Patients	Distributer	Approval status
Brazil	3,500	United Medical Ltda	File Q3
Poland	7,000	PharmaSwiss	Approved
Israel	3,000	Q3	Filed Q2
Russia	10,000	H2	File H2
Others	9,000	tba	tba

- Leverage existing sales & marketing infrastructure
  - In-license other CF therapeutics

Unlocking value in R&D pipeline

Assets	Actions to unlock value	Potential indication
SSAO inhibitor	• Complete pre clinical development • Phase 1 study • Phase 2 study	• Lung inflammation
LOXL2 inhibitor	• Complete pre clinical development • Phase 1 / 1b study	• Lung fibrosis • Liver fibrosis • Cancer?
Oligonucleotide portfolio ASM8; PXS2200	• Phase 2b study in ASM8	• Asthma • COPD
Orbital – High payload device	• License out to companies for non CF / bronchiectasis use	• Lung conditions requiring high payload device

R&D funding strategy

1. Strategic options

a) Pharmaxis to fund focussed single target initiative – LOXL2

b) Grants and Pharma research collaborations (process commenced)

c) VC / Pharma invested spin out (project commenced)

2. Timetable

a) 2H 2013 – continue to invest selectively in proof of concept

b) Q1 2014 – Target for external funding structures in place

Timetable for key value milestones

Time	2013	2014	2015	2016
Direct commercial interests –				
Bronchitol – EU, Aust, RoW				
Aridol				
Partnering – milestone payments				
CF				
Bronchiectasis				
Orbital				
Early stage compounds				
Oligo's				
SSAO				
LOXL2				

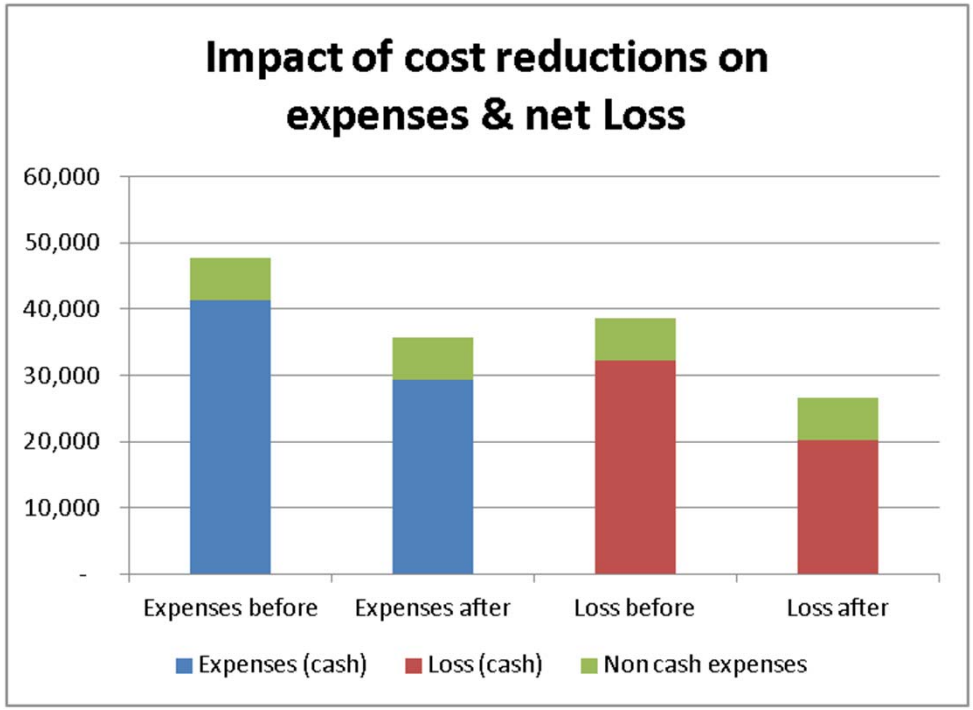
Funding: ⟷ **Value point:** ⟷

Ongoing investment:

- **Short term investment to consolidate value:**
  - Completing the analysis and close out of the clinical study B305
  - Consolidation of production into one facility
  - Marketing and contracting activities associated with the various partnering initiatives

- **Long term investment to grow asset value:**
  - CF commercialisation teams in Australia and the EU
  - Regulatory teams to support the extension of Bronchitol approvals to new territories
  - Clinical management of the soon to commence EU paediatric study CF204
  - Manufacturing capability for Bronchitol and Aridol
  - Management of ongoing partnering performance

Proforma impact of cost reductions



- Cost reduction ~$12m p.a., 29% of cash costs / 37% of cash loss
- Reductions will be fully implemented by 31 Dec 2013
- Reductions are across the board with overall headcount reducing by ~30% to 110 people
- Restructuring costs of ~$2m will be booked in FY13
- Total costs reduced to ~$36m, with cash costs reducing to ~$29m
- Net cash out-goings are reduced further to $20.3m after taking into account current annualised revenue/interest of ~$9m

March 2013 quarter costs annualised

Function (A$'m)	March Qtr Costs		Non-cash		Cash	
	Qtr	Annual	Qtr	Annual	Qtr	Annual
Sales & marketing	3.5	13.9	0.0	0.0	3.5	13.9
Safety, medical & regulatory affairs	1.1	4.2	0.0	0.2	1.0	4.0
Cost of sales	0.3	1.2	-	-	0.3	1.2
R&D - new drug development	1.0[1]	3.9	0.3	1.3	0.6	2.6
R&D - Bronchitol	4.2[2]	16.8	0.7	2.7	3.5	14.0
Finance & administration	2.0	7.8	0.5	2.2	1.4	5.6
Total expenses	11.9	47.8	1.6	6.4	10.3	41.4

Total annual costs ~$47.8m

- Cash expenses ~ $41.4m
- Non-cash expenses consist of depreciation, amortisation & share plan ~ $6.4m

1. Net $0.7m after R&D tax credit of ~$300k for March quarter
2. Net $3.7m after R&D tax credit of ~$500k for March quarter

Future capabilities required & cost reduction initiatives

Function	Required capability	Change / cost reductions
Sales & marketing	USA • CF team not required • Aridol - only require sales team of 2.6 FTE • Office facility not required	• CF capability removed Q2 • Aridol staff reductions Q2 • US office closure Q2/3

	CF: EU & Australia
	• Invest for sales growth returns
	  • New countries
	  • Improved patient compliance
	  • Leverage sales infrastructure
	• Funded from sales growth
		• Australia: maintain
		• CF – Europe: invest in line with country pricing approvals
		• Monitor level of investment vs returns

	Aridol – Rest of world • Sales capability of 1.4 FTE	• Maintain
	• Focus on revenue generation	• CF: 95% of sales costs • CF in Europe: 90% • Aridol: 5%

Future capabilities required & cost reduction initiatives

Function	Required capability	Change / cost reductions
Clinical (included in Bronchitol R&D)	• Execution of EU paediatric trial • Plan US CF clinical trial • Complete analysis of B305 and support publication of results	• Reduce headcount Q2 and Q3/4

Manufacturing (included in cost of sales and Bronchitol R&D)	• Production for commercial sales & US clinical trial
	• Complete transfer to #20
		• Exit 10 Rodborough Road Q3/Q4
		• Capacity limit of minimum staffing:
		  • sufficient for sales ~$20m
		  • double capacity by +6 employees
		  • triple capacity by +5 employees

R&D – Bronchitol	• Orbital device	• Nominal Orbital investment while seeking external funding

Future capabilities required & cost reduction initiatives

Function	Required capability	Change / cost reductions
Safety, medical & regulatory affairs	• Support approved products – compliance, registration, pricing approvals • Support approvals in RoW (eg Brazil, Eastern Europe) • Regulatory review of US CF trial • Publication of B305 results • Support Bronchitol partnering project	• US regulatory efforts managed directly from Australia with US advisors - ceased US based resource Q2 • Transfer medical resource to EU
R&D – drug development	• Targeted at business development value milestones	• External funding of early pipeline by end of CY 2013
Finance & administration	• CEO, COO, finance & accounting, HR, IT, project coordination	• COO role assumed into CEO role and consulting costs reduced

Cash & available funds

- Cash at 30 April 2013: $70.5m
- Additional US$20m available under NovaQuest agreement
  - Precondition: Commencement of US CF trial
  - 4 equal instalments
  - NovaQuest facility is not debt – only payments are % of CF sales in US and EU within term of agreement
- At current revenue levels the current cash balance represents over 3 years of reduced net cash outgoings of $20.3m

The way forward

1. Reduce cash burn on non essential capabilities
2. Retain / invest in capabilities that are fundamental to value generation
3. Partnership strategy to mitigate short term risk on cash intensive activities
4. Alternative funding to maintain progress in R&D programs

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