

CYCLOPHARM (CYC)

FNN Presentation

4th September 2018
James McBrayer



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CYCLOPHARM OVERVIEW



Profitable & Growing MedTech
underlying business is cash positive and issuing dividends



First in class
Technegas technology is available in 57 countries and named as the agent of choice in the EANM Guidelines



Recurring revenue
from high margin consumable sales similar to an annuity model



USFDA approval
set to more than quadruple the existing CYC sales from Pulmonary Embolism (PE)



Optionality
expanding into indications beyond PE could dwarf the near term USA opportunity

Cyclopharm – an established company



1986

Technegas
launched in
Australia



57 countries

via 1,500
Technegas
customers



4M Technegas

patient scans
completed in 2018



80% recurring

revenue via high
margin single-
patient consumable
sales

Pulmonary Embolism



~3 million cases of PE p.a.

but could be much higher



30%

of pulmonary embolisms are fatal if left untreated



Symptoms

are varied with diagnosis confirmed either through CTPA or a nuclear medicine ventilation-perfusion study



Nuclear Medicine

using 3-D imaging is the most accurate method of diagnosis

Technegas world's best functional lung ventilation imaging agent



Patient inhales
Technegas, carbon
particles labeled
with Tc99m.



Clinician can visualize
functional ventilation
using Technegas through
to the alveolus: the site
of gas exchange

cyclopharm 

Benefits of using Technegas



Easy
to prepare and
administer



Only need
3 to 4 breaths



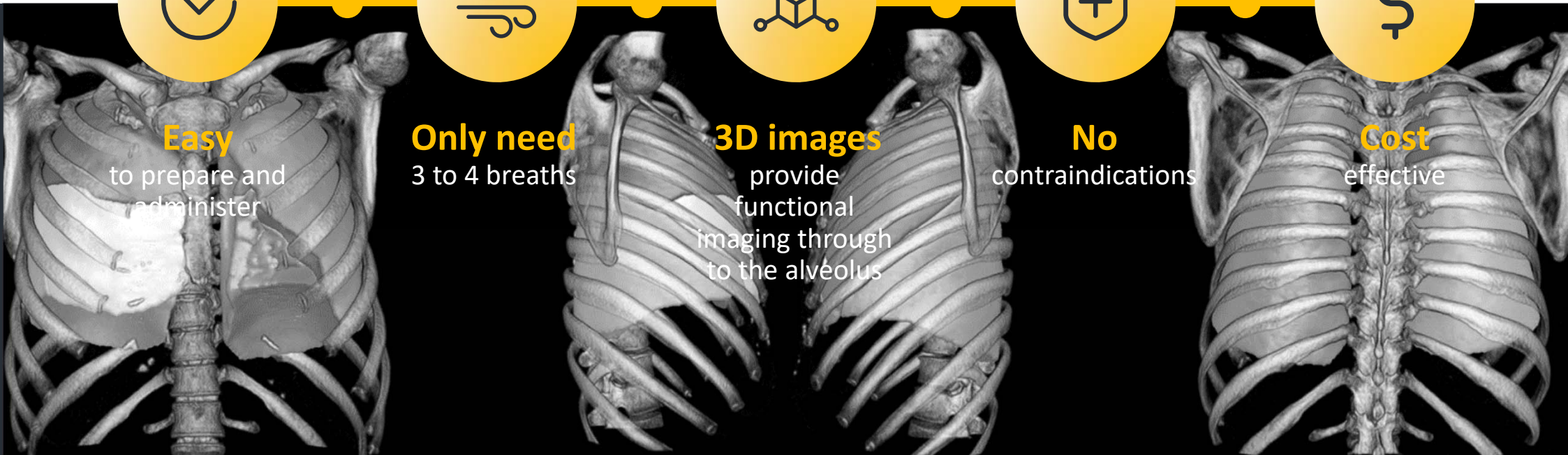
3D images
provide
functional
imaging through
to the alveolus



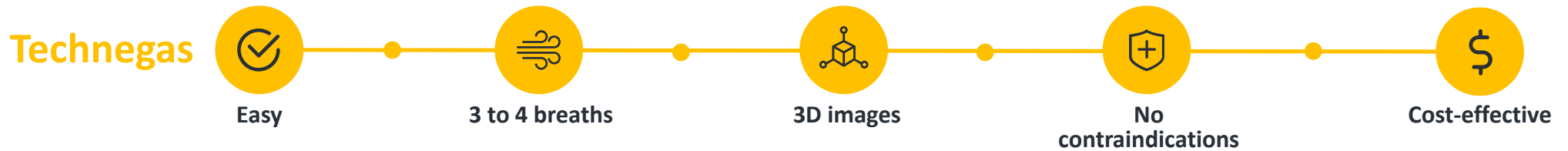
No
contraindications



Cost
effective



Superior to competitive nuclear medicine products



Xenon - 133



True radioactive gas inhaled with full face mask



Constant inhale -exhale breathing for 15 mins



No 3D images limited to planar imaging resulting in inferior clinical outcomes



Requires special rooms to contain radioactive gas in the event of a release

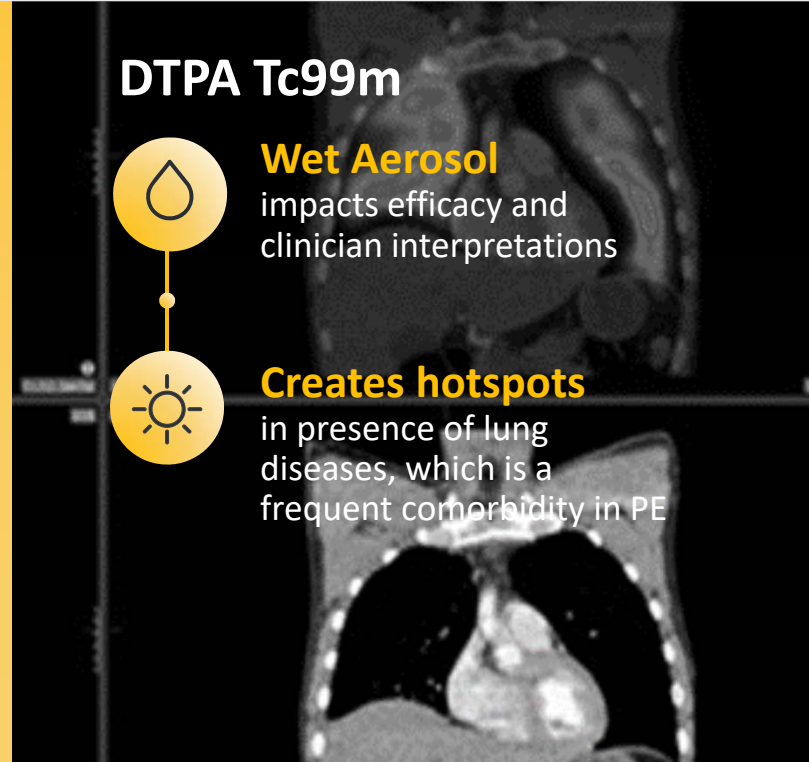
DTPA Tc99m



Wet Aerosol impacts efficacy and clinician interpretations



Creates hotspots in presence of lung diseases, which is a frequent comorbidity in PE



Diagnosing Pulmonary Embolism in the USA

USA = 4 million studies p.a.
to rule out PE

**Nuclear
Medicine**
Predominantly
Planar Imaging

15%

85%
CTPA
radiology

\$90m USD

nuclear medicine
ventilation imaging
market (Planar)

OPPORTUNITY TO DISPLACE CTPA:



High radiation burden
CTPA delivers at least 27 times
more radiation to the breast as
compared to V/Q SPECT



Contraindications
CTPA should not be performed
with pregnancy, renal impairment,
contrast media allergy, diabetes



AKI
Acute Kidney Injury
occurs in up to 13%
of CTPA cases



Lower Clinical Sensitivity
Planar = 67%
CTPA = 82%
SPECT = 93%

Technegas USFDA Phase 3 clinical trial underway



Special Protocol Assessment (SPA)

–advanced finding from the USFDA has been received that de-risks potential issues when filing our NDA



Interim 40 patient read

results submitted with a face-to-face meeting scheduled for 11 October 2018 at USFDA Headquarters



240 patient “all-comer” Protocol

– wide cross section of diseases

70 patients imaged as at 30/08/2018



USFDA approval

targeting 2H 2019

Building from a strong & well established foundation

Near term opportunities providing significant growth potential beyond PE toward patient management



USA Market

nuclear medicine
ventilation imaging
market to diagnose PE
equal to \$90m USD with
reimbursement already
in place



Targeting USA CTPA PE market

opportunity to convert
CTPA to nuclear
medicine imaging by
shifting market to SPECT
imaging



Half billion

combined sufferers
of Asthma and
Chronic Obstructive
Pulmonary Disease
globally.

Trials underway

Clinical Study Strategy Beyond PE Underway



Hunter Medical Research Institute

100 patient trial targeting phenotyping and response to therapy in severe asthma. 56 patients enrolled as at 03/09/2018



Woolcock Institute

100 patient trial to commence Q4 2018 targeting the diagnosis of mild to moderate COPD and response to therapy



Other clinical trials initiated

Lung Volume Reduction, assessment of Lung Transplant patients and early detection of COPD and response to therapy



Protocol development underway

Clinical trial to determine the effectiveness of early detection of COPD in asymptomatic smokers



CYCLOPHARM BUSINESS CASE



Profitable & Growing MedTech
underlying business is cash positive and issuing dividends



First in class
proprietary product available in 57 countries with 4 million studies to date



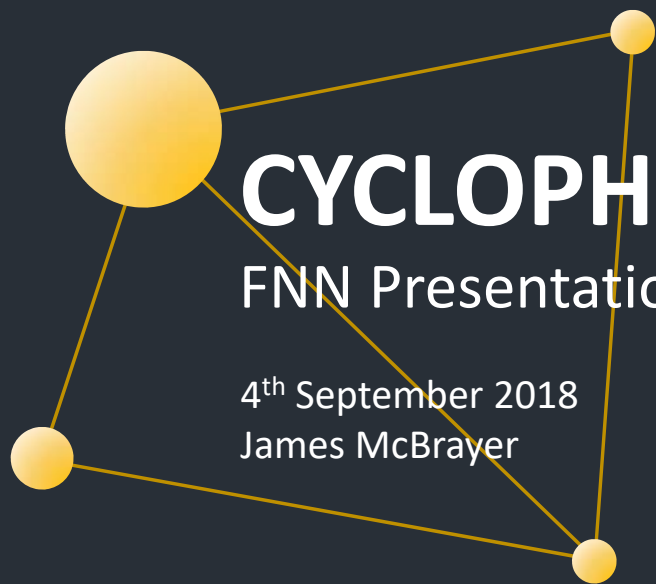
Recurring revenue
from consumables similar to an annuity model



USFDA approval
set to quadruple the size of the existing PE business and further leverage penetration into the CTPA market



Optionality
into indications beyond PE into chronic respiratory disease management could deliver exponential growth



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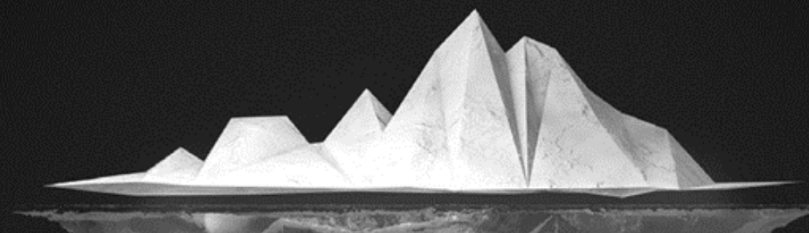
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Company Overview



Cyclopharm Limited (CYC) is a leading diagnostic lung imaging company

A world leader in functional lung ventilation imaging technology

Recurring consumables , service and capital equipment revenue streams

A profitable and growing company with a history of dividend payments

Lead nuclear medicine product Technegas is currently available in 57 countries with significant opportunity to expand into USA with USFDA approval expected in H2 2019

Opportunity to broaden Technegas applications beyond pulmonary embolism diagnosis into exponentially larger addressable markets such as COPD and Asthma



Share Price (as at 31 August 18)	\$0.925
Shares on Issue	68.8 million
Market Capitalisation	\$64 million
Cash (30 Jun 18)	\$7.6 million

1H2018 Results Highlights

Group Sales Revenue

\$6.34 million

Gross Margin

\$5.00 million

Net Loss After Tax

(\$0.68) million including USFDA investment

Interim Dividend

0.5 cents per share

Underlying Technegas EBITDA¹

\$459,000

FDA Trial expenses

(\$1.46) million

Strong balance sheet

\$7.61 million of cash reserves

Guidance Affirmed

The Board expects continuing modest growth in underlying Technegas volumes for FY18

Note 1: Underlying Results represent results from the division excluding realised and unrealised foreign exchange gains and losses, FDA Expenses and net expenses for Almedis Altmann GmbH

Technegas

FDA Clinical Trial Process and Design

Study Specifics

- Non-inferiority structural ventilation study comparing Xe133 vs. Technegas
- Special Protocol Assessment Granted
- Total estimated trial cost \$7.5 million USD with \$4.7m AUD spent to date
- Assumes 240 patient study at up to 15 clinical sites
- CYC completed a preliminary 40 patient trial submitted to the FDA
- 70 Patients enrolled as at 31 August 2018
- Face to Face meeting scheduled with the FDA on 11 October 2018 to discuss trial to date and explore opportunities to expedite the clinical trial program



Timeline

1H 2018

Finalise
Trial Site
Recruitment

1H 2018

Submit Preliminary
Trial Results
for FDA Review

Q2 2019

Complete US
Clinical Trial
& Submit NDA

Q4 2019

Commence US
Commercialisation

2018 Strategic Priorities and Outlook

Strategic Goals & Guidance	Activity	Timeframe
United States FDA Approval	Continue patient recruitment	Ongoing
	Expand clinical trial sites	Ongoing
	Complete Extended Technegas particulate study	Completed
	Submit preliminary 40 patient report to the USFDA	Completed
	Finalise paediatric plan and submit to USFDA	Under review
	Finalise patient recruitment	1H 2019
	Complete internal review of pharmaceutical and device manufacturing requirements to comply with USFDA requirements	2H 2018
	Submit New Drug Application to the USFDA	1H 2019
Indication Expansion	Continue UoN-HMRI-JHH clinical trial	Ongoing
	Commence new pilot trials in Canada and Australia	2H 2018
	Initiate Woolcock Institute – Sydney University clinical trial	2H2018
New Product – Ultralute™	Registration as a medical device technology	2H 2018
	First meaningful sales of Ultralute™	1H 2019
	Initiate multi-centre multi-country trial design with the IAEA	1H 2019
Expand Product & Service Offering	Identify and evaluate business prospects targeting growth, product extension, diversification, improved distribution models, accretion and enhanced returns	Ongoing
	Integrate acquired nuclear medicine distributor covering BeNeLux region	Ongoing
	Complete restructuring of German operations including new distribution model	2H2018
	Integrate new acquisitions in BeNeLux and Scandinavia markets	Ongoing
2018 Full Year Guidance	Technegas sales and underlying earnings growth supported by additional sales in China and France Expenditure of approximately AUD \$5.3 million on FDA approval process and regulatory / operational readiness for US launch Finalise operational and regulatory readiness for USFDA launch Ongoing investment in trials to support expanded use of Technegas supported by AusIndustry R&D grants	FY 2018