#### Cyclopharm Limited Appendix 4D - Half Year Report For the half year ended 30 June 2020



То	COMPANY ANNOUNCEMENTS		
Company	Australian Securities Exchange	No of Pages	41 incl. cover
Date	25 August 2020		
From	James McBrayer		
Subject	Appendix 4D		

Please see attached 30 June 2020 Half Year Report for Cyclopharm Limited (ASX - CYC).

This announcement is made pursuant to Listing Rule 4.2A.3.

For all enquiries please contact

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#### 1. Company details

#### Name of entity

#### CYCLOPHARM LIMITED

ABN or equivalent company reference

Half year ended ('current reporting period')

Half year ended ('previous corresponding period')

74 116 931 250

30 June 2020

30 June 2019

The information contained in this report is to be read in conjunction with Cyclopharm Limited's 2019 Annual Report and any announcements to the market by Cyclopharm Limited during the half year ended 30 June 2020 and up until the date of this Appendix 4D.

#### 2. Results for announcement to the market

2.1 Revenues from ordinary activities	Down 11%		to	5,766,657	
2.2 Loss from ordinary activities after tax attributable to members	Up 87% (larger loss)		to	(5,649,881)	
2.3 Loss for the period attributable to members	Up 87% (larger loss)		to	(5,649,881)	
2.4 Dividends	Amount per security		Franked amount per security		
Final dividend proposed	Not applicable		Not a	applicable	
Interim dividend	0.5 cents per share		0 ce	nts per share	
2.5 Record date for determining entitlements for the final dividend		eptember 2020			



#### 2. Results for announcement to the market (continued)

## 2.6 Brief explanation of any of the figures in 2.1 to 2.4 above necessary to enable the figures to be understood.

Key highlights of Cyclopharm's financial results for the half year ending 30 June 2020 included:

- Group revenue of \$5,766,657 (1H2019: \$6,502,894),
- Net loss after tax of \$5,649,881 (1H2019: \$3,024,510),
- Technegas Division Underlying EBITDA<sup>1</sup> of (\$1.57 million loss) (1H2019: \$0.33 million profit), and
- Net cash balance of \$8.064 million.

The following table outlines Cyclopharm's sales, gross margin and reconciles Technegas' underlying EBITDA performance<sup>1</sup> on a comparative half year basis:

HALF-YEAR ENDED 30 JUNE (AMOUNTS IN \$000'S)	2020	2019
SALES - TECHNEGASTM,	4,912	6,503
SALES - NON-TECHNEGAS™	854	-
CONSOLIDATED SALES	5,766	6,503
GROSS MARGIN	4,554	5,385
GROSS MARGIN % SALES	79.0%	82.8%
UNDERLYING EBITDA	(1,570)	329
INCOME		
CPET DIVISION EBITDA	145	(42)
EXPENSES		
OTHER NON-OPERATING (EXPENSES) / INCOME*	(281)	130
FDA EXPENSES	(2,358)	(2,060)
QUALITY SYSTEM INVESTMENT	(182)	(987)
ACCOUNTING SYSTEM UPGRADE	(231)	-
REDUCTION IN ADMINISTRATION EXPENSES ARISING FROM THE ADOPTION OF AASB16 LEASES	-	173
LITIGATION (EXPENSES) / RECOVERIES	(649)	178
REPORTED CONSOLIDATED EBITDA	(5,126)	(2,279)

<sup>\*</sup> Realised and unrealised foreign exchange gains and losses, finance revenue and Jobkeeper grant.

Cyclopharm recorded sales revenue of \$5,766,657 (1H2019: \$6,502,894) and a net loss after tax of \$5,649,881 (1H2019: NLAT \$3,024,510) for the half year ending 30 June 2020. Revenue was impacted by the COVID-19 pandemic with a deferral of Patient Administration Set (PAS) consumable orders from the scheduled 2Q France order valued at \$1.26 million and generally lower PAS volumes in most markets. Technegas™ generator revenue was 9% lower at \$712k. Sales of Individual PAS sets were down \$1.42 million and service revenue decreased by \$100k offset by \$700k sales from new third party products and \$154k income from Cyclotek NSW Pty Ltd. Excluding France, consolidated sales revenue increased 14% compared to the previous period.

Gross sales margins for the period however narrowed to 79.0% after accounting for lower margin third party products.

<sup>&</sup>lt;sup>1</sup> Underlying Results represent results from the TechnegasTM Division excluding realised and unrealised foreign exchange gains and losses, FDA Expenses, system upgrades and quality improvements expenses, reduction in administration expenses arising from the adoption of AASB 16 Leases and net effects from litigation.

## Cyclopharm Limited Appendix 4D - Half Year Report

For the half year ended 30 June 2020



On an underlying basis (adjusting for USFDA expenses and foreign exchange gains and losses), Technegas<sup>TM</sup> division's EBITDA for the half year was a loss of \$1.57 million. This EBITDA result includes a ramp up in expenditure to ensure compliance with USFDA guidelines as well as the new International Medical Device Single Audit Program (MDSAP). Including FDA and FOREX expenses, the Technegas<sup>TM</sup> Division incurred a loss before tax of \$5.77 million in the First Half compared to a loss before tax of \$2.73 million in the pcp.

In addition to the \$736k decrease in revenue, the EBITDA result for the half year was driven by increased costs associated with investments in implementing quality improvements and systems upgrades across the business. Ongoing investment in manpower to improve the company's quality processes, systems and management depth in anticipation of entry into the US market and upcoming compliance with European Medical Device Regulations (MDR) that will be effective as of 2021 boosted wages cost by \$980k to \$3.11 million and will position the business strongly for its next growth phase, post the anticipated USFDA Technegas<sup>TM</sup> approval.

Cyclopharm's net cash at the end of the period of \$8.064 million.

#### **OUTLOOK**

Technegas is established in 60 countries around the world with over 4.2 million procedures completed to date. Technegas<sup>TM</sup> is extensively documented in hundreds of peer reviewed papers and clinical guidelines as the functional ventilation imaging agent of choice in determining PE<sup>2</sup>. Furthermore, particularly during this time of pandemic where concerns of infection control is heightened, Technegas<sup>TM</sup>, with its unique product characteristics and method of administration, is considered to be the safest ventilation imaging agent in its class. Given this exceptional clinical support and strong safety profile, we believe demand for Technegas<sup>TM</sup> will continue to grow in our existing markets.

Developing additional Technegas<sup>TM</sup> indications, particularly for COPD, remains a key priority as they have the potential to significantly expand Technegas<sup>TM</sup>'s revenue and profitability over the medium to longer term in indications valued at \$900 million per annum.

The Directors are excited by the near-term major opportunity to significantly expand Cyclopharm's sales and profitability that USFDA approval to market Technegas<sup>™</sup> into the US market provides. We look forward to the completion of our Phase 3 clinical trial program in late 2020. We anticipate approval by the USFDA to commence sales in 2021 and are investing in the systems, infrastructure, personnel and inventory required to introduce Technegas to the United States market.

<sup>&</sup>lt;sup>2</sup> European Association of Nuclear Medicine Guidelines for Ventilation/Perfusion Scintigraphy Part 1. Pulmonary imaging with ventilation/perfusion single photon emission tomography. Eur J Nucl Med Mol Imaging (2009) 36:1356–1370 DOI 10.1007/s00259-009-1170-5



#### 3. Net tangible assets

	30 June 2020	30 June 2019
Net Tangible Assets per security	\$0.15	\$0.13

4.	Entities over	which contro	l has	been ga	ined or	lost d	uring th	e period
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4. Entities over which control has be	een gained or lost during the period
Control over entities	
Name of entity (or group of entities)	None
Loss of control over entities	
Name of entity (or group of entities)	None
5. Dividends	
An unfranked dividend of 0.5 cents per sha 2020 for the year ended 31 December 202 unfranked interim dividend of 0.5 cents pe	19. The Directors have declared an
6. Dividend reinvestment plans	
Not applicable	



#### 7. Details of associates and joint venture entities

The share of the associate's loss for the period was \$nil (2019: \$nil).

8. For Foreign Entities, which accounting standards were used in compiling this report

International Financial Reporting Standards (IFRS)

9. If the accounts have been audited or subject to review and are subject to dispute or qualification, details are described below

The accounts have been subject to review.

# Cyclopharm Limited Half Year Report 2020

Cyclopharm Limited and its Controlled Entities ABN 74 116 931 250

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## **Highlights**

## Cyclopharm is a globally recognised market leader in lung health and nuclear medicine technology

- Technegas<sup>™</sup> is on track to enter US market in 2021
- Solid 1H performance with sales in 60 existing markets
- Technegas<sup>™</sup> products approved for sale in Russia and first orders secured.
- European 3rd party distribution strategy delivers new revenues stream
- New Cyclotek NSW joint venture makes first profit contribution
- Beyond PE strategy substantially expands Technegas addressable market - study into the use of Technegas<sup>™</sup> in Asthma/COPD completes recruitment and prepares to publish initial findings

During the half year to 30 June 2020, we continued to successfully execute the Company's growth strategy of leveraging its significant intellectual property, technology and technical expertise to broaden sales into new countries and expand end-use device applications and complementary businesses. While COVID-19 interrupted many customers' activities, Cyclopharm continued to prioritise employee safety and welfare and execute on our own growth strategy.

#### Our strategic priorities remain:

- Expanding Technegas<sup>™</sup> sales into new markets including attaining USFDA approval to distribute Technegas in the USA
- 2. Expanding the use of Technegas<sup>™</sup> beyond the traditional diagnosis of Pulmonary Embolism (PE) into significantly broader scope applications including Chronic Obstructive Pulmonary Disease (COPD) and Asthma, Lung Cancer, Lung Volume Reduction and Pulmonary Hypertension for both diagnosis and patient management
- 3. Leveraging our core global regulatory strengths, fiscal discipline, strong balance sheet and well-developed expertise in nuclear medicine and pulmonary healthcare to seek out complementary technologies and businesses

#### **Financial Performance**

During the period, Cyclopharm generated revenues of \$5.77 million with gross margins declining to 79.0% of sales (vs 1H19: 82.8%) driven by a change in revenue mix. Net loss after tax for the period was \$5.65 million, which includes \$2.36 million of pre-tax expenses associated with the Group's United States Food and Drug Administration (USFDA) clinical trial of Technegas<sup>TM</sup>.

The 11% decline in 1H revenues was impacted by factors relating to the COVID-19 pandemic and a consequential deferral of Patient Administration Set (PAS) consumable orders from predominantly a delay in the scheduled late 2Q France order valued at \$1.26 million.



## First half highlights continued

The Company anticipates sales orders from France will resume in the second half of this financial year along with rebound in volumes to the rest of the world.

Excluding sales to France, consolidated revenue increased by approximately 14% on the prior corresponding period (pcp). New revenue streams from the distribution of third-party products in Europe, contributing approximately \$700k in revenue and \$154k from the new Cyclotek NSW Pty Ltd collaboration, when combined with favourable sales mix to more profitable regions, more than offset the impact of lower volumes, ex France.

On an underlying basis (adjusting for USFDA expenses and the impacts of foreign exchange), Cyclopharm's core Technegas<sup>TM</sup> division's EBITDA was a loss of \$1.57 million. This result includes expenditure to ensure compliance with USFDA guidelines as well as the new International Medical Device Single Audit Program (MDSAP). Including USFDA and FOREX expenses, the Technegas Division incurred a loss before tax of \$5.77 million in the First Half compared to a loss before tax of \$2.73 million in the pcp.

TechnegasPlus generators revenue was marginally lower by \$72k at \$712k, principally reflecting lower sales of generators which were largely offset by an increase in the unit price compared to the previous half year.

The decrease in higher margin PAS sales, due to the challenges presented by the COVID-19 pandemic, more than offset the positive influence from improving new third-party revenue streams in our European operations, to keep margins under pressure in the short term. We anticipate that gross margins will improve as the restrictions imposed from the COVID-19 pandemic ease.

At 30 June 2020, cash balances equalled \$8.06 million. The Company's balance sheet remains strong following the completion of a \$9.8 million capital raising in December 2019, and ongoing positive cash flows from its core operations. This balance sheet strength also continues to support delivery of Cyclopharm's other strategic priorities, including expanding the use of Technegas<sup>TM</sup> beyond pulmonary embolism (Beyond PE) and product and system enhancements.

#### **USA Market Entry**

During the period the Company made significant progress in its efforts to attain approval, from the USFDA, for Cyclopharm to sell Technegas<sup>™</sup> in the USA. The US market accounts for around half of the total nuclear medicine departments in the world. The US market for nuclear medicine ventilation imaging estimated to be approximately US\$90 million annually. This represents approximately 600,000 individual procedures per annum.

Based on the Group's Canadian experience, Cyclopharm believes that Technegas<sup>™</sup> can achieve a 50% share of the USA market over 2 to 3 years, post market entry, with an 80% share representing around 480,000 procedures per annum achievable over a 5 to 7 year period.

In the first half of 2020, through its wholly owned subsidiary Cyclomedica Australia Pty Ltd, Cyclopharm lodged a New Drug Application (NDA) submission with the USFDA; received a full application fee waiver; and Approval to File status for its NDA.

Over recent months, the Company has been actively responding to questions and requests for information from the USFDA. Based on our feedback from and interactions with the USFDA to date, the Board remains highly confident of a positive outcome to the approval process.



## First half highlights (continued)

In the United States, infectious control concerns relating to the risks associated with the provision of competitors' nuclear medicine ventilation imaging procedures have dramatically impacted the utilisation of this important diagnostic tool in that market. In response to this concern, Cyclopharm has been made aware that 77 United States Nuclear Medicine Clinicians in late June 2020 co-signed a letter to the USFDA requesting an expedited evaluation or emergency approval of Technegas<sup>TM</sup>. <sup>1</sup>

The positive response from US physicians gives your Board great confidence to initiate an increase in Technegas<sup>TM</sup> inventory in the 3<sup>rd</sup> Quarter of 2020, with a target of manufacturing 200 Generators to ensure the company is operationally ready for rapid market entry upon USFDA approval.

#### Beyond PE - Substantially expanding Technegas™'s addressable market

Technegas<sup>™</sup> remains the recognised functional ventilation imaging agent used in diagnosing Pulmonary Embolism as referenced in both the recently published Canadian Association of Nuclear Medicine Guidelines<sup>2</sup> and the updated 2019 European Association of Nuclear Medicine Guidelines<sup>3</sup>. Both guidelines reinforce the superior use of Technegas<sup>™</sup> particularly in patients with COPD and the potential for nuclear medicine imaging.

Cyclopharm estimates the global COPD market is 30 times the size of the PE market and over 500 million patients suffering with COPD and Asthma could benefit from the use of Technegas<sup>TM</sup> in diagnosis and ongoing patient monitoring/management. These markets represent significant opportunities to expand sales of Technegas<sup>TM</sup> and drive shareholder value over the medium term.

Cyclopharm's commitment to the field of nuclear medicine is demonstrated by the several clinical research projects underway to expand the use of Technegas $^{\text{TM}}$  in a range of respiratory diseases we term 'Beyond PE'.

The Company's Beyond PE initiatives are linked to significant Research and Development activities, which are being impacted by COVID-19 as the rate of patient recruitment for trials slowed during the first half of 2020 and in some cases has been put on hold. Advancing these initiatives could expand the use of Technegas<sup>TM</sup> by improving the diagnosis and management of patients with COPD and other small airways diseases.

Study	Indication	Status	Reference(s)
CYC-009	Ventilation comparison of Technegas vs Xe133	On- hold 204 of 240 patients completed	https://clinicaltrials.gov/ct2/show/NCT03054870
HMRI	Asthma/COPD	Fully Recruited 100 patients First publication pending	https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=3 73490 https://hmri.org.au/news-article/nuclear-imaging-clear-airway-diagnosis
McMasters University	Lung Resection Surgery	On-hold 12 of 115 Patients Recruited	https://clinicaltrials.gov/ct2/show/NCT04191174
СНИМ	COPD	On-hold 5 of 30 Patients Recruited	https://clinicaltrials.gov/ct2/show/NCT03728712
Woolcock Institute	Asthma/COPD	1 <sup>st</sup> Patient Imaged 23/06/2020 1 of 100 Patients Recruited	http://investor.cyclopharm.com/site/PDF/1561_0/BetterDefiningAir waysDiseasewithTechnegas
Dalhousie University	Lung Transplant complications	On-hold 9 of 30 Patients Recruited	https://canm- acmn.wildapricot.org/resources/Documents/Documents%20- %20Web%20pages/Édition%20spéciale%202019.pdf

<sup>&</sup>lt;sup>1</sup> Cyclopharm confirms that none of the signatories have any professional or financial relationship with the Company or any of its affiliates.

<sup>&</sup>lt;sup>2</sup> Leblanc et. Al. CANM Guidelines for Ventilation/Perfusion (V/P SPECT) In Pulmonary Embolism. November 2018

<sup>&</sup>lt;sup>3</sup> Bajc et. Al. EANM guideline for ventilation/perfusion single-photon emission computed tomography (SPECT) for diagnosis of pulmonary embolism and beyond. European Journal of Nuclear Medicine and Molecular Imaging. July 2019. https://doi.org/10.1007/s00259-019-04450-0



## First half highlights (continued)

#### Commercialising New Technologies - Ultralute

Ultralute<sup>™</sup> is a proprietary technology, developed and owned by Cyclopharm, which extends the useful life of Molybdenum-99 (Mo-99) generators by up to 50%.

Cyclopharm is currently seeking to register Ultralute<sup>TM</sup>, in Europe, as a medical device to support better acceptance of this new first in class technology. As previously advised, following a change in European Union regulations requiring recertification of existing medical devices, there is now significant backlogs of medical device applications awaiting registration. Consequently, the Company does not anticipate Ultralute<sup>TM</sup> receiving registration in Europe in 2020 but remains confident of its ultimate revenue potential.

#### **Leveraging our Strengths**

Cyclopharm's strategy to leverage our core global regulatory strengths and well-developed expertise in nuclear medicine by seeing out complementary technology is beginning to gain traction. Following Cyclopharm's successful acquisitions of Technegas<sup>TM</sup>'s distributors in northern European markets, the Company is now focussed on capturing additional value by distributing third party products.

Revenue from third-party distribution agreements with TEMA and ROTOP totalled approximately \$700k during the first half of 2020. We expect second half 2020 revenues from distributing third-party products will exceed first half revenues as we continue to grow this new revenue stream.

#### Outlook

Over the full year, Cyclopharm expects ongoing growth in its core business in 2020 as well as further progress in the development of the company's key growth initiatives and opportunities. We are highly confident of securing USFDA approval to distribute Technegas in the US market with first commercial sales expected in 2021. We will continue to invest in expanding our addressable market Beyond PE, and look for ways to leverage our deep expertise and experience for the benefit of shareholders.

Having regard to the underlying financial results and the company's strong balance sheet position, for the half year period, the Directors have declared an unfranked interim dividend of 0.5 cents per share which will be paid on 14 September 2020 to shareholders on the register on 7 September 2020.



## First half highlights (continued)

Half Year ended 30 June		2020	2019	Inc / (Dec)	% Change
Sales Revenue	\$	5,766,657	6,502,894	(736,237)	(11%)
Loss before tax and finance costs	\$	(5,512,348)	(2,719,214)	(2,793,134)	(103%)
Net Loss after tax*	\$	(5,649,881)	(3,024,510)	(2,625,371)	(87%)
Loss Per Share	cents	(7.35)	(4.46)	(2.89)	(65%)



Total consolidated revenue, ex France, increased 14% on the prior corresponding period (PCP) as factors related to COVID-19 caused delays to order of consumables.



Process for United States Food and Drug Administration approval to distribute Technegas<sup>™</sup> in the United States market is on-track. First commercial sales expected in 2021.



Technegas<sup>™</sup> generator revenue was 9% lower at \$712k. Sales of Individual Patient Administration Set (PAS) were down \$1.42 million; service revenue decreased by \$100k and gross margins dropped to 79.0% reflecting lower margins recorded from the new revenue stream.



Loss before tax and finance costs was \$5.51 million for the half year. The loss was primarily attributable to the 11% decrease in total revenue, the USFDA trial expenses and an increase in ongoing costs to improve the company's quality processes, systems and management depth ahead of the anticipated USFDA approval to market Technegas<sup>TM</sup> in the USA.



Beyond PE Strategy advancing with first publication expected and new three-year, 100-patient study trial commencing at the Woolcock Institute for Medical Research in collaboration with The University of Sydney and the Northern Sydney Local Health District, to develop better tools to diagnose and manage patients suffering from Asthma and COPD using Technegas<sup>TM</sup>.



Cyclotek NSW Pty Ltd, the joint venture collaboration between Cyclopharm, Cyclotek (Aust) Pty Ltd and the Australian Nuclear Science and Technical Organisation ('ANSTO') made a \$154k positive contribution to the company's results.



New revenue stream commenced with the establishment of third party distribution agreements contributing \$700k in sales.



Investment in systems, processes and people in preparation for US market entry.



## **Managing Director's Review**

Cyclopharm recorded sales revenue of \$5,766,657 (1H2019: \$6,502,894) and a net loss after tax of \$5,649,881 (1H2019: NLAT \$3,024,510) for the half year ending 30 June 2020. Revenue was impacted by the COVID-19 pandemic with a deferral of Patient Administration Set (PAS) consumable orders from the scheduled 2Q France order and generally lower PAS volumes in most markets. Technegas<sup>TM</sup> generator revenue was 9% lower at \$712k. Sales of Individual PAS sets were down \$1.42 million and service revenue decreased by \$100k offset by \$700k sales from new third party products and \$154k income from Cyclotek NSW Pty Ltd. Excluding France, sales revenue increased 14% compared to the previous period.

Gross sales margins for the period however narrowed to 79.0% after accounting for lower margin third party products.

During the period, the company continued to invest in improving the company's quality processes, systems and management depth in anticipation of entry into the US market in 2021.

On an underlying basis (adjusting for USFDA expenses and foreign exchange gains and losses), Technegas<sup>TM</sup> division's EBITDA for the half year was a loss of \$1.57 million. This EBITDA result includes a ramp up in expenditure to ensure compliance with USFDA guidelines as well as the new International Medical Device Single Audit Program (MDSAP). Including FDA and FOREX expenses, the Technegas<sup>TM</sup> Division incurred a loss before tax of \$5.77 million in the First Half compared to a loss before tax of \$2.73 million in the pcp.

#### Cyclopharm's Underlying Results4:

The following table outlines Cyclopharm's sales, gross margin and reconciles Technegas<sup>TM</sup>'s underlying EBITDA performance on a comparative half year basis:

HALF-YEAR ENDED 30 JUNE (AMOUNTS IN \$000'S)	2020	2019
SALES - TECHNEGASTM	4,912	6,503
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FDA EXPENSES	(2,358)	(2,060)
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REDUCTION IN ADMINISTRATION EXPENSES ARISING FROM THE ADOPTION OF AASB 16 LEASES	-	173
LITIGATION (EXPENSES) / RECOVERIES	(649)	178
REPORTED CONSOLIDATED EBITDA	(5,126)	(2,279)

<sup>\*</sup> Realised and unrealised foreign exchange gains and losses, finance revenue and Jobkeeper grant.

<sup>&</sup>lt;sup>4</sup> Underlying Results represent results from the Technegas<sup>™</sup> Division excluding realised and unrealised foreign exchange gains and losses, FDA Expenses, system upgrades and quality improvements expenses, reduction in administration expenses arising from the adoption of AASB 16 Leases and net effects from litigation.

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## **Managing Director's Review**

Continued

In addition to the \$736k decrease in revenue, the EBITDA result for the half year was driven by increased costs associated with investments in implementing quality improvements and systems upgrades across the business. Ongoing investment in manpower to improve the company's quality processes, systems and management depth in anticipation of entry into the US market and upcoming compliance with European Medical Device Regulations (MDR) that will be effective as of 2021 boosted wages cost by \$529k. Wages have also increased in European markets by \$354k where the Company has established a direct market position rather than a dealership sales model. The direct market position is expected to yield greater margins for proprietary products and additional revenue streams from third party products. These additional resources in sales, quality, service and operations collectively will position the business strongly for its next growth phase as it delivers on its key strategic initiatives.

Our strategy to substantially expand Technegas<sup>TM</sup> addressable markets is showing good progress through new uses - "Beyond PE". In addition to the collaboration with the Hunter Medical Research Institute and the University of Newcastle, Cyclopharm is active in supporting four other clinical initiatives in Australia and internationally targeting the use of Technegas<sup>TM</sup> beyond PE. In the short-term, these initiatives are being impacted by COVID-19 as the rate of patient recruitment for trials slowed during the first half of 2020 and in some cases has been put on hold.

Sales in Germany have improved. Litigation expenses of \$649,422 were recorded during the period as compared to the previous period's gain from litigation of \$178,233 net of expenses. Whilst progress is being made to resolve this matter, legal proceedings are expected to continue throughout 2H 2020.

In December 2019, a business venture collaboration agreement between the Company, Pettech Solutions Limited a wholly owned subsidiary of the Australian Nuclear Science and Technical Organisation ('ANSTO') and Cyclotek was executed. The collaboration combines CycloPet and Pettech's cyclotron facilities under a single operating enterprise known as Cyclotek NSW Pty Ltd. The Company has benefited from eliminating an ongoing non-productive lease expense and gained access to an income stream from what was a suspended business. During the period, Cyclotek NSW Pty Ltd made a \$154k positive contribution to the Company's results.

The Group's net cash at the end of the period was \$8.064 million.

Expectations for the second half of the financial year 2020, include:

- 1. Continuing to advance the process for FDA approval of Technegas<sup>™</sup> in the US market
- 2. Supporting clinical trial programs targeting applications for Technegas<sup>TM</sup> in both the diagnosis and management of specific chronic respiratory disease states

#### **OPERATING REVIEW**

In many markets around the world, noncritical medical procedures were temporarily suspended, as part of broader strategies to contain the spread of COVID-19. Consequently, sales of PAS kits and Generators were depressed in many markets during the first half of 2020. Revenue from sales and service of Technegas<sup>TM</sup> products recorded a 24.3% decline in first half revenues to \$4.91 million compared to \$6.50 million in the pcp driven by:

- Decreased sales of Individual Patient Administration Set (PAS) of \$3.69 million delivering a \$1.42 million decrease in revenue;
- a decrease of \$100k in Technegas<sup>TM</sup> service revenues; and
- Decreased sales of Technegas<sup>TM</sup> generators contributing a \$72k decrease in revenues to \$712k

This was offset by a new revenue stream distributing third party radiopharmaceutical products in Europe, which contributed \$700k to Group sales and income of \$154k from Cyclotek NSW Pty Ltd.

Gross margins in the first half decreased from 82.8% to 79.0% with the inclusion of lower margined third party products.

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## **Managing Director's Review**

Continued

#### TECHNEGAS™ MARKET REVIEW

#### **Europe**

During the first half of 2020, Europe accounted for 52% of revenues from Technegas<sup>™</sup> products compared to 57% in the pcp, underscoring the region's continued importance. European sales revenue of \$2.55 million was \$1.13 million below the pcp with a delay in the scheduled order from France (2019: \$1.26 million).

Excluding the French market, European sales revenue increased by 14% during the period.

Historically, the majority of consumable and generator sales in Europe have occurred in the second half of the financial year. We expect this trend to continue.

#### **Americas**

Sales into the Americas, which includes predominantly Canada and to a lesser extent Latin America, generated \$0.97 million in revenue, representing 20% (2019: 19%) of revenue from Technegas<sup>TM</sup> products in the period.

Sales revenue in Canada was 23% lower than in the same period last year at \$0.90 million down from \$1.17 million. Cyclopharm views its success in Canada as a strong indicator of prospects for Technegas<sup>TM</sup> in the USA if, as anticipated, USFDA approval to market Technegas<sup>TM</sup> in the USA is obtained, and sales to that market commence in 2021.

#### **Asia Pacific**

Sales revenue in Asia Pacific during the period of \$1.37 million was 5% below the pcp of \$1.43 million.

#### Approval of Technegas<sup>™</sup> for sale in the US

Gaining approval to sell Technegas<sup>™</sup> in the USA is a priority for Cyclopharm. The US market is set to be the largest market for Technegas<sup>™</sup> globally, delivering a substantial increase in shareholder value.

Cyclopharm continues to make progress towards USFDA approval to commence marketing of Technegas<sup>TM</sup> in the United States. In the first half of 2020, through its wholly owned subsidiary Cyclomedica Australia, the company lodged a New Drug Application (NDA) submission; received a full application fee waiver of US\$2.90 million; received approval to file an NDA and the USFDA initiated a 10-month NDA review process.

Since receiving the Approval to File status in late May 2020, the Company has been participating in several conference calls along with actively responding to questions and requests for additional or clarifying information relating to our NDA from the USFDA.

In the United States, infectious control concerns relating to the risks associated with the provision of nuclear medicine ventilation imaging procedures using competitive products have dramatically impacted the utilisation of this important study in that market. In response to this concern, the Company was advised that 77 United States Nuclear Medicine Clinicians in late June 2020 co-signed a letter to the USFDA requesting an expedited evaluation of Technegas<sup>TM</sup>.

# cyclopharm Wuclear Medicine

## **Managing Director's Review**

#### Continued

The positive response from US physicians gives the Board of Cyclopharm great confidence to initiate an increase in Technegas<sup>™</sup> inventory in the 3rd Quarter of 2020, with a target of manufacturing 200 Generators to ensure the company is operationally ready for rapid market entry upon USFDA approval.

Notwithstanding any impact from the Covid-19 pandemic, the market for nuclear medicine, ventilation imaging in the USA is estimated to be approximately US\$90 million annually, representing approximately 600,000 individual procedures. Based on Cyclopharm's experience in the Canadian market, it remains confident that Technegas<sup>TM</sup> can achieve a 50% share of the USA market over 2 to 3 years, post US market entry, with an 80% share representing around 480,000 procedures per annum achievable over a 5 to 7-year period.

We have enrolled 204 patients as at 20 August this year, in our 240-patient study across 9 sites in the US. Unfortunately, because of the pandemic, it is not likely that we will be able to enrol the remaining 36 patients in the near future.

However, fortunately for the company, in 2018 we instigated an alternative drug approval pathway, known as a 505(b)2 application, to run in parallel with the clinical trial. This pathway allows Cyclopharm to include the positive historical outcomes from Technegas<sup>TM</sup> used in non-US markets as part of our submission. Based on feedback to date, we remain confident our 505(b)2 New Drug Application is sufficient for USFDA approval.

Expenditure on the USFDA trials will continue to be expensed until approval is achieved. For the half year, these expenses totalled \$2,358,178 compared to \$2,059,753 in the pcp.

#### **Litigation Update**

Cyclopharm continues to defend its valuable Intellectual Property vigorously and successfully. In 2019, the company successfully brought an initial civil case against its former employee in the German market, Mr Bjorn Altmann and Almedis Altmann GmbH ("Almedis"), resulting in Cyclopharm's subsidiary Cyclomedica, being awarded and receiving a payment of approximately \$340k which represents 100% of this claim. A bad debt provision of \$540k was raised in 2017 to cover this and other claims. The company is continuing with its efforts to recover the remainder of this bad debt provision.

Further actions were launched in both German and Australian courts with favourable progress being made. Last month the company successfully attained an injunction against a company related to Altmann pertaining to misleading conduct relating to servicing aspects on TechnegasPlus Generators in Germany.

The company expects decisions to be handed down in two additional actions in Germany in the coming weeks. When considering the separate Australian proceedings it is difficult to predict a timeframe for these to conclude, however, we are confident that we will achieve a successful outcome from these actions.

#### 'Beyond PE'

Cyclopharm believes the extension of Technegas<sup>TM</sup> into new applications such as the diagnosis and monitoring of COPD, asthma and other respiratory disease states will create opportunities to exponentially expand the market for Technegas<sup>TM</sup> beyond its traditional PE market.

Cyclopharm's strategy to expand Beyond PE is being delivered by targeting new applications through clinical studies; educating clinicians; and engaging directly with respiratory medicine referrers.



## **Managing Director's Review**

#### Continued

The University of Newcastle, Hunter Regional Medical Institute (HRMI) and John Hunter Hospital are conducting a study into the use of Technegas<sup>TM</sup> in patients with severe small airways disease.

The 100-patient study has now reached full recruitment. As part of the study, a 39-patient subset of the 100 underwent tests using Technegas<sup>™</sup> to determine response to therapy.

The overall study is designed to test two specific hypotheses:

- 1. There is ventilation heterogeneity among patients with severe obstructive airway diseases that can be assessed using Technegas<sup>TM</sup> functional lung ventilation imaging with quantification; and
- Technegas<sup>™</sup> functional lung ventilation imaging with quantification is responsive to change following intervention in patients with severe obstructive airway diseases.

Cyclopharm expects initial publications for the HRMI study in 2020.

In addition to the Newcastle study, Cyclopharm is active globally in supporting four other clinical initiatives targeting the use of Technegas<sup>™</sup> beyond PE. In the short-term, these initiatives are impacted by COVID-19 as the rate of patient recruitment for trials slowed during the first half of 2020 and in some cases has been put on hold.

The implication in advancing these initiatives could expand the use of Technegas<sup>TM</sup> by improving the diagnosis and management of patients with COPD and other small airways diseases. Cyclopharm estimates the global COPD market is 30 times the size of the PE market and over 500 million patients suffering with COPD and Asthma could benefit from the use of Technegas<sup>TM</sup> in diagnosis and ongoing patient monitoring/management. These markets represent significant opportunities to expand sales of Technegas<sup>TM</sup> and drive shareholder value over the medium term.

#### **ULTRALUTE™**

Ultralute<sup>™</sup> extends the useful life of Molybdenum-99 (Mo-99) generators by up to 50%. This technology potentially gives nuclear medicine departments the ability to dramatically improve operating efficiencies and health outcomes for patients.

The European Union (EU) is currently undergoing significant change in the regulatory regime. Authorised notified bodies are required to reassess and recertify the conformity of all existing medical devices in accordance with the new and more onerous Medical Device Regulation. The Company was advised that due to the enormity of the number of reassessment reviews in progress it is taking longer than would otherwise be the case to introduce new products within the region.

Since notifying shareholders of the delay earlier this year the COVID-19 pandemic has resulted in auditors not being able to conduct onsite audits and this delay has increased

We share shareholders' disappointment in this regulatory delay and, at this stage, we do not expect to see meaningful sales from Ultralute<sup>TM</sup> until 2022.

#### **MACQUARIE MEDICAL IMAGING**

Cyclopharm continues to maintain its 20% equity ownership in Macquarie Medical Imaging (MMI). It is anticipated that MMI will be de-registered in late 2020 upon the finalisation of its accounts payable and receivables.

## **Managing Director's Review**

Continued

#### **CYCLOPET**

During the period, Cyclotek NSW Pty Ltd made a \$154k positive contribution to the Group's results. Cyclotek NSW Pty Ltd is a collaboration between Cyclopharm, Cyclotek (Aust) Pty Ltd and the Australian Nuclear Science and Technical Organisation (ANSTO') set up, in part, to realise the inherent value of Cyclopharm's legacy Cyclotron assets both to generate profits and contribute to enhanced health outcomes for the Australian community.

Under the terms of the joint venture Cyclopharm will contribute \$40k per annum, over a period of 9 years, to fund the ongoing research activities of Cyclotek NSW and is entitled to receive a share of profits from the business venture collaboration.

#### COVID-19

The global impact of the COVID-19 pandemic is unprecedented and continues to evolve. Technogas<sup>TM</sup> is primarily used to diagnose the life-threatening condition Pulmonary Embolism (PE). Dyspnea or shortness of breath is a key symptom exhibited in both COVID-19 and PE.

In many markets around the world, imaging procedures were temporarily delayed. It appears that the delays in the use of Technegas<sup>TM</sup> have been short term and the Company is seeing volumes returning to pre-COVID-19 levels.

During this time of pandemic where concerns of infection control is heightened, Technegas<sup>™</sup>, with its unique product characteristics and method of administration, is considered to be the safest ventilation imaging agent in its class. Combined with its exceptional clinical support and strong safety profile, we believe demand for Technegas<sup>TM</sup> will grow in our existing markets where other competitive products are still in use.

#### OUTLOOK

Given the strong clinical support for Technegas<sup>TM</sup> as the functional ventilation imaging agent of choice in determining PE<sup>5</sup>, we believe demand for Technegas<sup>TM</sup> will grow in our existing markets. Additionally, we will continue to educate referring physicians on the clinical and safety superiority of our diagnostic capabilities compared with competing technologies.

Developing additional Technegas<sup>TM</sup> indications, particularly for COPD, remains a key priority as they have the potential to significantly expand Technegas<sup>TM</sup>'s revenue and profitability over the medium to longer term in indications valued at \$900 million per annum.

The Directors are excited by the near-term major opportunity to significantly expand Cyclopharm's sales and profitability that USFDA approval to market Technegas™ into the US market provides. We look forward to the completion of our Phase 3 clinical trial program in late 2020. We anticipate approval by the USFDA to commence sales in 2021 and are investing in the systems, infrastructure, personnel and inventory required to introduce Technegas to the United States market.

James McBrayer Managing Director

Sydney, 25 August 2020

Janes SMCBreyer

<sup>&</sup>lt;sup>5</sup> European Association of Nuclear Medicine Guidelines for Ventilation/Perfusion Scintigraphy Part 1. Pulmonary imaging with ventilation/perfusion single photon emission tomography. Eur J Nucl Med Mol Imaging (2009) 36:1356-1370 DOI 10.1007/s00259-009-1170-5



## **Directors' Report**

The Directors of Cyclopharm Limited ("Cyclopharm" or "Group") submit their half yearly report together with the financial report for Cyclopharm and its controlled entities for the half year ended 30 June 2020.

#### **DIRECTORS**

The names of the company's directors in office throughout and since the end of the half year are set out below.

Mr D J Heaney Non-Executive Chairman
Mr T A McDonald Non-Executive Director
Mr J S McBrayer Managing Director

#### **PRINCIPAL ACTIVITIES**

During the half year, the principal continuing activities of the consolidated entity consisted of the manufacture and sale of medical equipment and radiopharmaceuticals, including associated research and development. There were no significant changes in the nature of the consolidated entity's principal activities during the half year.

#### **OPERATING AND FINANCIAL REVIEW**

#### Operating results for the half year

For the reporting period, the consolidated entity recorded a half year loss before tax of \$5,631,498 (2019: loss before tax of \$2,856,817) impacted by \$0.74 million decrease in revenue, ongoing investment in manpower of \$3.11 million (2019: \$2.13 million) to improve the company's quality processes, systems and management depth in anticipation of entry into the US market and upcoming compliance with European Medical Device Regulations (MDR) that will be effective as of 2021 and higher FDA expenses incurred of \$2,358,178 (2019: \$2,059,753). The Molecular Imaging division recorded a profit before tax of \$143,986 (2019: loss before tax of \$129,351) with a \$153,717 contribution from Cyclotek NSW Pty Ltd.

Revenue for the period of \$5.77 million (2019: \$6.50 million) was impacted by factors relating to the COVID-19 pandemic and a consequential deferral of Patient Administration Set (PAS) consumable orders from predominantly a delay in the scheduled late 2Q France order and generally lower PAS volumes in most markets. The \$0.74 million decrease in revenue for the half year resulted from lower sales of Individual Patient Administration Set (PAS) (down \$1.42 million or 28%) while service revenue decreased by \$100k. TechnegasPlus generators revenue was lower by \$72k at \$712k. New revenue streams from the distribution of third-party products in Europe, contributed \$700k in revenue with \$154k income from Cyclotek NSW Pty Ltd.

#### **Financial position**

Net assets have decreased from \$23,203,945 as at 31 December 2019 to \$16,994,236 as at 30 June 2020 predominantly due to the net loss after tax of \$5,649,881 for the half year.

#### SIGNIFICANT CHANGES IN STATE OF AFFAIRS

#### Shares issued during the half year

1,045,000 Long Term Incentive Plan shares were issued on 4 May 2020 and 24,443 Long Term Incentive Plan shares were cancelled on 5 May 2020.

There were no other shares issued and cancelled and during the half year.

Other than as set out above, there were no significant changes in the state of affairs of the consolidated entity during the half year.



## **Directors' Report**

Continued

#### SIGNIFICANT EVENTS AFTER BALANCE DATE

#### **Shares issued**

1,015,500 Long Term Incentive Plan shares were issued on 24 July 2020.

No other matters or circumstances have arisen since the end of the financial period, not otherwise dealt with in the financial report, which significantly affected or may significantly affect the operations of the economic entity, the results of those operations, or the state of affairs of the economic entity in future financial periods.

#### DIVIDEND

The Directors are pleased to declare an unfranked interim dividend of 0.5 cents per share which will be paid on 14 September 2020. The record date for the interim dividend is 7 September 2020.

The Directors intend to continue to manage the capital of the Group efficiently to maximise financial returns to shareholders. The quantum and nature of future payments to shareholders will have regard to a number of factors, including the company's financial position, projected cash flows, capital expenditure and investment, share price and any proceeds or capital requirements of corporate actions.

#### COVID-19

Whilst overall sales of PAS kits and Generators have been depressed during the first half of 2020 as the pandemic left large numbers of hospital wards and departments at a virtual standstill globally, Cyclopharm's expectation is for sales of PAS kits and Technegas® Generators to rebound once Covid-19 restrictions are lifted.

Subject to no material change in financial affairs and having regard to the above factors, the Directors anticipate that they will declare dividends for each forthcoming half year period, and that the FY2020 final dividend will be an amount equal to the 2020 interim dividend.

#### **AUDITOR'S INDEPENDENCE DECLARATION**

A copy of the Auditor's Independence Declaration as required under section 307C of the Corporations Act 2001 follows the Directors' Report.

This report is made and signed in accordance with a resolution of the directors made pursuant to section 306(3) of the Corporations Act 2001:

James McBrayer

Managing Director & CEO

Janus & MCBryer

Sydney, 25 August 2020



To the Board of Directors of Cyclopharm Limited

#### Auditor's Independence Declaration under section 307C of the Corporations Act 2001

As lead audit director for the review of the condensed consolidated financial statements of Cyclopharm Limited for the half year ended 30 June 2020, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- (a) the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- (b) any applicable code of professional conduct in relation to the review.

Yours sincerely

**Nexia Sydney Audit Pty Ltd** 

**Andrew Hoffmann** 

Director

Sydney

Dated: 25 August 2020



# **Condensed Consolidated Statement of Comprehensive Income**

For the half year ended 30 June 2020

#### Consolidated

	Conso	iidated	
	30 June 2020	30 June 2019	
	\$	\$	
Notes	<b>S</b>		
CONTINUING OPERATIONS		***************************************	
Sales revenue 3	5,766,657	6,502,894	
Finance revenue	3,729	22,845	
Total Revenue	5,770,386	6,525,739	
Total Neverlue	3,770,300	0,323,733	
Cost of materials and manufacturing	(1,330,125)	(1,247,606)	
Employee benefits expense	(3,383,023)	(2,385,060)	
Advertising and promotion expense	(121,895)	(112,140)	
Depreciation and amortisation expense	(386,544)	(439,937)	
Freight and duty expense	(303,487)	(176,720)	
Research and development expenses*	(2,364,496)	(2,212,885)	
Administration expense	(2,747,602)	(2,547,243)	
Other expenses	(645,562)	(123,362)	
Loss before tax and finance costs	(5,512,348)	(2,719,214)	
Finance costs	(119,150)	(137,603)	
Loss before income tax	(5,631,498)	(2,856,817)	
Income tax	(18,383)	(167,693)	
Net loss for the period	(5,649,881)	(3,024,510)	
Other comprehensive loss after income tax			
Items that may be re-classified subsequently to profit and loss when specific conditions are met:			
Exchange differences on translating foreign controlled entities (net of tax)	(320,725)	106,741	
Total comprehensive loss for the year	(5,970,606)	(2,917,769)	
Loss per share (cents per share) 5	cents	cents	
-basic loss per share for continuing operations	(7.35)	(4.46)	
-basic loss per share	(7.35)	(4.46)	
-diluted loss per share	(7.35)	(4.46)	

<sup>\*</sup> Included in Research and development expenses are amounts incurred on FDA expenses of \$2,358,178 (2019: \$2,059,753).

The Condensed Consolidated Statement of Comprehensive Income is to be read in conjunction with the accompanying notes to the Half Year Report.

# **Condensed Consolidated Statement of Financial Position**



As at 30 June 2020

#### Consolidated

		Cons	Consolidated		
		30 June 2020	31 December 2019		
	Notes	\$	\$		
Assets					
Current Assets					
Cash and cash equivalents		8,063,535	12,660,323		
Trade and other receivables		2,990,048	3,979,595		
Inventories		3,790,476	2,495,443		
Current tax asset		280,108	225,585		
Other assets		462,265	249,674		
Total Current Assets		15,586,432	19,610,620		
Non-current Assets					
Property, plant and equipment		2,052,820	2,070,854		
Right-of-use assets	6	4,050,138	4,207,931		
Investments	7	-	-		
Intangible assets		5,226,637	5,145,349		
Deferred tax assets		1,384,229	1,493,663		
Total Non-current Assets		12,713,824	12,917,797		
Total Assets		28,300,256	32,528,417		
Liabilities					
Current Liabilities					
Trade and other payables		4,317,877	2,632,362		
Lease liabilities		210,372	172,582		
Provisions		1,011,896	652,254		
Tax liabilities		98,670	22,932		
Total Current Liabilities		5,638,815	3,480,130		
Non-current Liabilities					
Lease liabilities		4,625,484	4,749,883		
Provisions		20,602	23,023		
Deferred tax liabilities		227,251	277,568		
Deferred income liabilities	8	793,868	793,868		
Total Non-current Liabilities		5,667,205	5,844,342		
Total Liabilities		11,306,020	9,324,472		
Net Assets		16,994,236	23,203,945		
Equity					
Equity  Contributed equity	9	31,575,791	31,576,003		
Employee equity benefits reserve	9	1,178,048	1,041,373		
Foreign currency translation reserve  Accumulated losses		(872,969)	(552,244) (8,861,187)		
Accumulated 1055e5		(14,886,634) <b>16,994,236</b>	23,203,945		

The Condensed Consolidated Statement of Financial Position is to be read in conjunction with the accompanying notes to the Half Year Report.

# **Condensed Consolidated Statement of Cash Flows**



For the half year ended 30 June 2020

#### Consolidated

	••••••		
	30 June 2020	30 June 2019	
	\$	\$	
Operating activities			
Receipts from customers	8,687,840	7,208,657	
Payments to suppliers and employees	(11,744,081)	(7,552,856)	
Interest received	3,729	22,845	
Borrowing costs paid	(119,150)	(17,764)	
Income tax (paid) / received	(26,443)	1,565,291	
Net cash flows (used in) / from operating activities	(3,198,105)	1,226,173	
Investing activities			
Net payments for acquisition of subsidiary	(340,971)	(343,209)	
Purchase of property, plant and equipment	(300,829)	(169,702)	
Payments for deferred expenditure*	(216,650)	(168,059)	
Net cash flows used in investing activities	(858,450)	(680,970)	
Financing activities			
Dividends paid	(375,566)	(330,250)	
Repayment of bank borrowings	-	(89,732)	
Repayment of lease liabilities	(173,726)	(237,796)	
Net cash flows used in financing activities	(549,504)	(657,778)	
Net decrease in cash and cash equivalents	(4,606,059)	(112,575)	
Cash and cash equivalents			
at beginning of the period	12,660,323	5,854,959	
net foreign exchange differences from translation of cash and cash equivalents	9,271	23,337	
at end of the period	8,063,535	5,765,721	

The Condensed Consolidated Statement of Cash Flows is to be read in conjunction with the accompanying notes to the Half Year Report.

<sup>\*</sup> Included in payments for deferred expenditure are amounts incurred on Ultralute \$110,944 (2019: \$105,743) and the development of the next generation of the Technegas generator \$233 (2019: \$10,482).

## **Condensed Consolidated Statement of Changes in Equity**For the half year ended 30 June 2020



Tot the half year ended of earle 2020	Contributed Equity	Other Contributed Equity	Total Contributed Equity	Retained Profits / (Accumulated Losses)	Foreign Currency Translation Reserve	Employee Equity Benefits Reserve	Total
Consolidated	\$	\$	\$	\$	\$	\$	\$
Balance at	•••••••••••••••••••••••	***************************************			***************************************		***************************************
1 January 2019	27,238,193	(5,333,158)	21,905,035	(5,011,100)	(540,971)	663,005	17,015,969
Adjustment for change in accounting policy (note 2)	-	-	-	(71,818)	-	-	(71,818)
Restated balance at 1 January 2019	27,238,193	(5,333,158)	21,905,035	(5,082,918)	(540,971)	663,005	16,944,151
Loss for the half year	-	-	-	(3,024,510)	-	-	(3,024,510)
Other comprehensive income	-	-	-	-	106,741	-	106,741
Total comprehensive loss for the half year	-	-	-	(3,024,510)	106,741	-	(2,917,769)
Dividends paid	-	-	-	(330,250)	-	-	(330,250)
Cost of share based payments	-	-	-	-	-	26,987	26,987
Total transactions with owners and other transfers		_	_	(330,250)		26,987	(303,263)
Balance at							
30 June 2019	27,238,193	(5,333,158)	21,905,035	(8,437,678)	(434,230)	689,992	13,723,119
Balance at 1 January 2020	36,909,161	(5,333,158)	31,576,003	(8,861,187)	(552,244)	1,041,373	23,203,945
1 January 2020	30,909,101	(3,333,136)	31,370,003	(0,001,101)	(332,244)	1,041,373	23,203,943
Loss for the half year	-	-	-	(5,649,881)	-	-	(5,649,881)
Other comprehensive income	-	-	-	-	(320,725)	-	(320,725)
Total comprehensive loss for the half year	-	-	-	(5,649,881)	(320,725)	-	(5,970,606)
Cost of raising capital	(212)	-	(212)	-	-	-	(212)
Dividends paid	-	-	-	(375,566)	-	-	(375,566)
Cost of share based payments	_	_	_	-	_	136,675	136,675
Total transactions with owners and other transfers	(212)	_	(212)	(375,566)	-	136,675	(239,103)
Balance at							
30 June 2020	36,908,949	(5,333,158)	31,575,791	(14,886,634)	(872,969)	1,178,048	16,994,236

The Condensed Consolidated Statement of Changes in Equity is to be read in conjunction with the accompanying notes to the Half Year Report.



For the half year ended 30 June 2020

#### 1. CORPORATE INFORMATION

The half year financial report of Cyclopharm Limited for the half year ended 30 June 2020 was authorised for issue with a resolution of the directors as of the date of this half year report.

Cyclopharm is a Company limited by shares incorporated and domiciled in Australia. The shares are publicly traded on the Australian Securities Exchange.

The nature of the operations and principal activities of the Group are described in the Directors' Report.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### a) Basis of Preparation

These general purpose condensed consolidated interim financial statements for the half-year reporting period ended 30 June 2020 have been prepared in accordance with requirements of the Corporations Act 2001 and Australian Accounting Standard AASB 134 Interim Financial Reporting. The Group is a for-profit entity for financial reporting purposes under Australian Accounting Standards.

This interim financial report is intended to provide users with an update on the latest annual financial statements of Cyclopharm Limited and its controlled entities (referred to as the "Group"). As such, it does not contain information that represents relatively insignificant changes occurring during the half-year within the Group. It is therefore recommended that this financial report be read in conjunction with the annual financial statements of the Group for the year ended 31 December 2019, together with any public announcements made during the following half-year.

#### **Accounting Policies**

The same accounting policies and methods of computation have been followed in this interim financial report as were applied in the most recent annual financial statements. The half-yearly condensed consolidated financial statements have been prepared on a historical cost basis.

#### **Critical Accounting Estimates and Judgments**

The critical estimates and judgments are consistent with those applied and disclosed in the December 2019 annual report.

#### New and Amended Accounting Standards and Interpretations adopted by the Group

No Australian Accounting Standards (new and amended) with the mandatory application date of 1 January 2020 were applicable to the Group.

#### New Accounting Standards and Interpretations Not Yet Adopted

Accounting Standards and Interpretations issued by the AASB that are not yet mandatorily applicable to the Group, together with an assessment of the potential impact of such pronouncements on the Group when adopted in future periods, are discussed below:

Applicable to annual reporting periods beginning on or after 1 January 2022:

## AASB 2014-10: Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (Amendments to AASB 10 and AASB 128)

Amend AASB 10 and AASB 128 to remove the inconsistency in dealing with the sale or contribution of assets between an investor and its associate or joint venture. A full gain or loss is recognised when a transaction involves a business (whether it is housed in a subsidiary or not). A partial gain or loss is recognised when a transaction involves assets that do not constitute a business, even if these assets are housed in a subsidiary.



For the half year ended 30 June 2020 Continued

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Preparation**

New Accounting Standards and Interpretations Not Yet Adopted (continued)

The mandatory application date of AASB 2014-10 has been amended and deferred to annual reporting periods beginning on or after 1 January 2022 by AASB 2017-5.

These new and amended Standards are not expected to have a significant impact on the Group's financial statements.



For the half year ended 30 June 2020 Continued

#### 3. REVENUE FROM CONTRACTS WITH CUSTOMERS

Set out below is the disaggregation of the Group's revenue from contracts with customers:

For	the	period	ended	30	June	2020
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	Technegas	Molecular Imaging	Total
ments	\$	\$	\$
Type of goods or service			
Sales of equipment and consumables	5,099,310	-	5,099,310
Income from Cyclotek NSW Pty Ltd	-	153,717	153,717
After sales services	513,630	-	513,630
Total revenue from contracts with customers	5,612,940	153,717	5,766,657
Geographical markets			
Asia Pacific	988,407	153,717	1,142,124
Europe	3,623,444	-	3,623,444
Canada	901,645	-	901,645
Other	99,444	-	99,444
Total revenue from contracts with customers	5,612,940	153,717	5,766,657
Timing of revenue recognition			
Goods transferred at a point in time	5,482,220	153,717	5,635,937
Services transferred over time	130,720	-	130,720
Total revenue from contracts with customers	5,612,940	153,717	5,766,657

#### For the period ended 30 June 2019

	Technegas	Molecular Imaging	Total
ments	\$	\$	\$
Type of goods or service			
Sales of equipment and consumables	5,888,860	-	5,888,860
After sales services	614,034	-	614,034
Total revenue from contracts with customers	6,502,894	-	6,502,894
Geographical markets			
Asia Pacific	995,977	-	995,977
Europe	4,093,229	-	4,093,229
Canada	1,179,721	-	1,179,721
Other	233,967	-	233,967
Total revenue from contracts with customers	6,502,894	-	6,502,894
Timing of revenue recognition			
Goods transferred at a point in time	6,409,215	-	6,409,215
Services transferred over time	93,679	-	93,679
Total revenue from contracts with customers	6,502,894	=	6,502,894

There are no impairment losses on receivables and contract assets arising from contracts with customers.





For the half year ended 30 June 2020 Continued

#### 4. SEGMENT REPORTING

	Consolidated	
Technegas	Molecular Imaging	Total
\$	\$	\$
5,612,940	153,717	5,766,657
3,127	602	3,729
5,616,067	154,319	5,770,386
(5,271,122)	145,318	(5,125,804)
(386,544)	-	(386,544)
(5,657,666)	145,318	(5,512,348)
(117,818)	(1,332)	(119,150)
(5,775,484)	143,986	(5,631,498)
42,868	(61,251)	(18,383)
(5,732,616)	82,735	(5,649,881)
26,844,409	1,455,847	28,300,256
11,277,687	28,333	11,306,020
	\$ 5,612,940 3,127 5,616,067 (5,271,122) (386,544) (5,657,666) (117,818) (5,775,484) 42,868 (5,732,616)	\$ \$ 5,612,940 153,717 3,127 602 5,616,067 154,319  (5,271,122) 145,318 (386,544) - (5,657,666) 145,318 (117,818) (1,332) (5,775,484) 143,986 42,868 (61,251) (5,732,616) 82,735





For the half year ended 30 June 2020 Continued

#### 4. SEGMENT REPORTING

Consolidated				
Technegas	Molecular Imaging	Total		
\$	\$	\$		
6,502,894	-	6,502,894		
22,086	759	22,845		
6,524,980	759	6,525,739		
(2,237,607)	(41,670)	(2,279,277)		
(362,578)	(77,359)	(439,937)		
(2,600,185)	(119,029)	(2,719,214)		
(127,281)	(10,322)	(137,603)		
(2,727,466)	(129,351)	(2,856,817)		
(167,693)	-	(167,693)		
(2,895,159)	(129,351)	(3,024,510)		
21,680,931	3,116,978	24,797,909		
9,666,383	1,408,407	11,074,790		
	\$ 6,502,894 22,086 6,524,980  (2,237,607) (362,578) (2,600,185) (127,281) (2,727,466) (167,693) (2,895,159)  21,680,931	Technegas Molecular Imaging \$ \$  6,502,894 - 22,086 759  6,524,980 759  (2,237,607) (41,670) (362,578) (77,359) (2,600,185) (119,029) (127,281) (10,322) (2,727,466) (129,351) (167,693) - (2,895,159) (129,351)		



For the half year ended 30 June 2020 Continued

#### 5. NET TANGIBLE ASSETS AND EARNINGS PER SHARE

#### **Net Tangible Assets per share**

#### Consolidated

	30 June 2020	31 December 2019
	\$	\$
Net assets per share	0.21	0.30
Net tangible assets per share	0.15	0.23
	Number	Number
Number of ordinary shares for net assets per share	79,258,955	78,238,398
	30 June 2020	31 December 2019
	\$	\$
Net assets	16,994,236	23,203,945
Net tangible assets	11,767,599	18,058,596

The number of ordinary shares includes the effects of 1,045,000 Long Term Incentive Performance ('LTIP') shares issued on 4 May 2020, 539,525 LTIP shares issued on 11 December 2019, 200,000 LTIP shares issued on 30 May 2019 (2019: 200,000 Long Term Incentive Performance shares issued on 30 May 2019) and excludes 24,443 LTIP shares cancelled on 5 May 2020 as set out in Note 9.

#### Loss per share

Net loss attributable to equity holders of the parent

- basic loss per share for continuing operations

basic loss per sharediluted loss per share

Weighted average number of ordinary shares for basic loss per share Weighted average number of ordinary shares for diluted loss per share

30 June 2020	30 June 2019
\$	\$
(5,649,881)	(3,024,510)

cents	cents
(7.35)	(4.46)
(7.35)	(4.46)
(7.35)	(4.46)

Number	Number
76,818,765	67,809,232
76,818,765	67,809,232

The weighted average number of ordinary shares for basic loss per share excludes the effects of 1,045,000 Long Term Incentive Performance ('LTIP') shares issued on 4 May 2020, 269,911 LTIP shares issued on 11 December 2019, 200,000 LTIP shares issued on 30 May 2019 and 500,000 LTIP shares issued on 2 July 2018 (2019: 200,000 LTIP shares issued on 30 May 2019, 500,000 LTIP shares issued on 2 July 2018 and 225,000 LTIP shares issued on 19 April 2017) as they are contingently returnable.



Consolidated

For the half year ended 30 June 2020 Continued

#### 6. NON-CURRENT ASSETS - RIGHT-OF-USE ASSETS

	30 June 2020	31 December 2019	
	\$	\$	
Land and buildings - right-of-use	5,198,239	5,200,067	
Less: Accumulated depreciation	(1,169,746)	(1,030,860)	
	4,028,493	4,169,207	
Plant and equipment - right-of-use	260,899	260,097	
Less: Accumulated depreciation	(239,254)	(221,373)	
	21,645	38,724	
Total right-of-use assets	4,050,138	4,207,931	

The Group leases land and buildings for its offices, manufacturing facilities and warehouse under agreements of between two to ten years with, in some cases, options to extend. The leases have various escalation clauses. On renewal, the terms of the leases are negotiated. The Group also leases plant and equipment under agreements of four years.

#### 7. INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD

Associated companies			
Name	Principal Country of Shares Activities Incorporation		
Macquarie Medical Imaging Pty Ltd	Imaging centre	Australia	Preference
Macquarie Medical Imaging Pty Ltd			
At 1 January			
(Repayment made by) / Loan to associa	ate		
Reversal / (Share) of losses after income	e tax		
At 30 June / 31 December			

CycloPet Pty Ltd has a 20% (2019: 20%) interest in Macquarie Medical Imaging Pty Ltd (MMI). It is anticipated that MMI will be de-registered in late 2020 upon the finalisation of its accounts payable and receivables. The share of the associate's loss not recognised during the period was \$20,375 (30 June 2019: loss of \$232,135) and the cumulative share of the associate's loss not recognised as at 30 June 2020 was \$3,616,505 (31 December 2019: \$3,596,130).

The share of loss of associate not recognised as at 30 June 2020 is extracted from the unaudited financial report of the associate, and it may be revised when that financial report has been audited. The fair value of the Group's investment in Macquarie Medical Imaging Pty Ltd was \$nil (2019: \$nil).



For the half year ended 30 June 2020 Continued

#### 8. DEFERRED INCOME LIABILITIES

A portion of the Research & Development Grant refund received/receivable has been recognised as deferred income liabilities and will be amortised over the same period as the amortisation of the related intangible development asset.

#### 9. CONTRIBUTED EQUITY

		Consolidated			
		30 June 2020	30 June 2019	30 June 2020	30 June 2019
	Notes	Number	Number	\$	\$
Issued and paid up capital					
Ordinary shares		79,258,955	68,898,873	36,908,949	27,238,193
Other contributed equity		-	-	(5,333,158)	(5,333,158)
Total issued and paid up capital		79,258,955	68,898,873	31,575,791	21,905,035
Ordinary shares					
Issued and paid up capital					
Balance at the beginning of the period		78,238,398	68,698,873	36,909,161	27,238,193
Issue of Long Term Incentive Plan shares	(i)	1,045,000	200,000	-	-
Cancellation of Long Term Incentive Plan shares	(ii)	(24,443)	-	-	-
Share issue cost (net of tax)		-	-	(212)	-
Balance at the beginning and end of period		79,258,955	68,898,873	36,908,949	27,238,193

Ordinary shares have the right to receive dividends as declared and, in the event of winding up the Company, to participate in the proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held. Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company.

- (i) 1,045,000 Long Term Incentive Plan shares were issued on 4 May 2020 under the non-recourse loan payment plan at an exercise price of \$1.22 (2019: 200,000 Long Term Incentive Plan shares were issued on 30 May 2019 under the non-recourse loan payment plan at an exercise price of \$1.50) and
- (ii) 24,443 (2019: nil) Long Term Incentive Plan shares were cancelled on 5 May 2020.

#### **Dividends**

An unfranked final dividend of 0.5 cents per share in respect of the financial year ended 31 December 2019 (2019: unfranked final dividend of 0.5 cents per share in respect of the financial year ended 31 December 2018) was paid during the current financial period. Furthermore, the Directors declared an unfranked interim dividend of 0.5 cents per share which has not been recognised in these condensed consolidated financial statements as it was declared subsequent to 30 June 2020.

Fully paid ordinary shares
Final dividend for the financial year
- No franking credits attached

Consolidated						
30 June 2020	30 June 2019	30 June 2020	30 June 2019			
Cents per share	Cents per share	\$	\$			
0.5	0.5	(275 500)	(220.250)			
0.5	0.5	(375,566)	(330,250)			
0.5	0.5	(375,566)	(330,250)			



For the half year ended 30 June 2020 Continued

#### 10. COMMITMENTS AND CONTINGENCIES

#### (a) Capital commitments

Cyclopharm has entered into agreements to fund research projects with unrelated institutions. The commitments for these projects total \$423,473 and will be expensed when incurred. Payments will be made based on the achievement of certain milestones.

There were no other capital commitments as at the date of this report.

#### (b) Contingent liabilites

In December 2019, a business venture collaboration agreement combined CycloPet Pty Ltd and Pettech Solutions Limited's cyclotron facilities under a single operating enterprise known as Cyclotek NSW Pty Limited (Cyclotek NSW). Cyclopharm and Cyclotek NSW have entered into a sub-lease agreement as tenants in common whereby Cyclotek NSW is solely responsible for the tenant's obligations except for make good obligations until such time as it exercises the right to transfer its interest as tenant in common to Cyclopharm. Being a tenant in common, Cyclopharm's contingent liabilities as at 30 June 2020 amounts to \$3,366,657 if Cyclotek NSW is unable to fulfil its obligations as tenant. The amount comprises payments under a sub-lease agreement commencing 1 January 2020 until the expiry of two options to renew expiring on 31 December 2039.

There were no other contingent liabilities as at the date of this report (2019: \$3,158,049). In December 2019, Cyclopharm issued 300,000 ordinary shares in exchange for the termination of a put option to a 50% shareholder of Macquarie Medical Imaging Pty Limited (MMI). The cost had the put option been exercised at 30 June 2019 was estimated not to exceed \$3,158,049.



For the half year ended 30 June 2020 Continued

#### 11. SIGNIFICANT RELATED PARTY TRANSACTIONS

The condensed consolidated financial statements include the financial statements of Cyclopharm and its subsidiaries as stated below.

The following table provides the total amount of transactions that were entered into with related parties for the relevant financial period:

CONSOLIDATED		Purchases from related parties \$	Amounts owed by related parties \$	Provision for doubtful debts on Amounts owed by related parties
Cell Structures Pty Ltd	2020	26,660	-	-
	2019	25,925	-	-
Macquarie Medical Imaging Pty Ltd	2020	-		-
	2019	-	230,782	230,782

#### Ultimate parent entity

Cyclopharm Limited is the ultimate parent entity in the wholly owned group.

#### Terms and conditions of transactions with related parties

- During the half year, payments of \$26,660 (2019: \$25,925) were made to Cell Structures Pty Ltd (an entity controlled by Director, Mr. Tom McDonald). All payments are related to Mr. McDonald's role as a non-executive director, including consultancy services provided by him.
- CycloPet Pty Ltd, a wholly owned subsidiary of Cyclopharm has a 20% interest in Macquarie Medical Imaging. Prior to ceasing commercial operations at the end of April 2014, CycloPet manufactured products that were sold to Macquarie Medical Imaging Pty Ltd. As the trade debtor balance of \$230,782 as at 30 June 2019 was not expected to be repaid in the short term, it was included as an interest in the associate and a share of the associate's losses had been recognised under the equity method in the 2014 financial year. This amount has been written off as unrecoverable upon MQ Health taking over the business operations of Macquarie Medical Imaging Pty Ltd from 7 December 2019. Refer to Note 7 for details of the investment in the associate.

Transactions between related parties are at normal commercial prices and on normal commercial terms and conditions no more favourable than those available to other parties unless otherwise stated.

#### 12. DIVIDEND DECLARED DETAILS

The Company has declared an unfranked interim dividend of 0.5 cents per share which will be paid on 14 September 2020. The record date for the interim dividend is 7 September 2020.



For the half year ended 30 June 2019 Continued

#### 13. EVENTS AFTER THE BALANCE SHEET DATE

#### **Shares Issued**

1,015,500 Long Term Incentive Plan shares were issued on 24 July 2020.

No other matters or circumstances have arisen since the end of the financial period, not otherwise dealt with in the financial report, which significantly affected or may significantly affect the operations of the economic entity, the results of those operations, or the state of affairs of the economic entity in future financial periods.



## **Directors' Declaration**

In the opinion of the directors of Cyclopharm Limited:

- 1. (a) The financial statements and notes of the consolidated entity are in accordance with the Corporations Act 2001, including:
  - (i) giving a true and fair view of the consolidated entity's financial position as at 30 June 2020 and of its performance for the half-year ended on that date; and
  - (ii) complying with Accounting Standard *AASB 134 Interim Financial Reporting*, Corporations Regulations 2001 and other mandatory professional reporting requirements.
  - (b) There are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the directors made pursuant to section 303(5) of the Corporations Act 2001:

James McBrayer

Managing Director & CEO

Janes & MCBreyer

Sydney, 25 August 2020



## INDEPENDENT AUDITOR'S REVIEW REPORT TO THE MEMBERS OF CYCLOPHARM LIMITED

#### **Report on the Half-Year Financial Report**

#### Conclusion

We have reviewed the half-year financial report of Cyclopharm Limited (the Company and its subsidiaries ("the Group")), which comprises the condensed consolidated statement of financial position as at 30 June 2020, the condensed consolidated statement of comprehensive income, condensed consolidated statement of changes in equity and condensed consolidated statement of cash flows for the half-year ended on that date, a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of the Group does not comply with the Corporations Act 2001 including:

- a) giving a true and fair view of the Group's financial position as at 30 June 2020 and of its performance for the half-year ended on that date; and
- b) complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001.

#### **Basis for Conclusion**

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity.* Our responsibilities are further described in the Auditor's Responsibilities for the Review of the Financial Report section of our report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional & Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001* which has been given to the directors of the Company, would be in the same terms if given to the directors as at the time of this auditor's review report

#### Responsibility of the Directors for the Financial Report

The directors of the Group are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Nexia Sydney Audit Pty Ltd

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#### Auditor's Responsibility for the Review of the Financial Report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 30 June 2020 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

**Nexia Sydney Audit Pty Ltd** 

**Andrew Hoffmann** 

Director

Sydney, 25 August 2020



### **General Information**

#### **Directors**

#### **David Heaney**

Non-Executive Chairman

#### James McBraver

Managing Director & CEO

#### **Thomas McDonald**

Non-Executive Director

#### **Company Secretary**

James McBrayer

## Registered Office Cyclopharm Limited

Unit 4, 1 The Crescent Kingsgrove NSW 2208

T: 02 9541 0411 F: 02 9543 0960

#### Cyclomedica Australia Pty Limited

Unit 4, 1 The Crescent Kingsgrove NSW 2208 T: 02 9541 0411 F: 02 9543 0960

#### **CycloPET Pty Limited**

Unit 4, 1 The Crescent Kingsgrove NSW 2208

#### **Cyclomedica Canada Limited**

35 Main St N Suite 23, Waterdown, Ontario LOR 2H0 Canada

#### **Cyclomedica Germany GMBH**

Lützenkirchener Str. 410 51381 Leverkusen Germany

#### Cyclomedica Europe Ltd

Unit A5, Calmount Business Park Ballymount Dublin 12 Ireland

#### Inter Commerce Medical byba

Stoksebaan 14 Vosselaar, 2350 Belgium

## Cyclomedica Nordic AB (formerly known as Medicall Analys AB)

Gustavslundsvagen 145 plan 3 Bromma, 16751 Sweden

#### **Auditors**

Nexia Sydney Audit Pty Ltd Level 16 1 Market Street Sydney NSW 2000

#### **Share Registry**

NextRegistries Level 16, 1 Market Street Sydney NSW 2000 T: 02 9276 1700 F: 02 9251 7138

#### **Bankers**

National Australia Bank Level 21 255 George Street Sydney NSW 2000

#### Solicitors

HWL Ebsworth Level 19 480 Queen Street Brisbane QLD 4001

#### **Stock Exchange Listing**

The ordinary shares of Cyclopharm Limited are listed on the Australian Securities Exchange Ltd (code: CYC).