

То	COMPANY ANNOUNCEMENTS		
Company	Australian Securities Exchange	No of Pages	41 incl. cover
Date	22 August 2019		
From	James McBrayer		
Subject	Appendix 4D		

Please see attached 30 June 2019 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 2019

30 June 2018

The information contained in this report is to be read in conjunction with Cyclopharm Limited's 2018 Annual Report and any announcements to the market by Cyclopharm Limited during the half year ended 30 June 2019 and up until the date of this Appendix 4D.

### 2. Results for announcement to the market

2.1 Revenues from ordinary activities	Up 3%		to	6,502,894
2.2 Loss from ordinary activities after tax attributable to members	Down 342% (larger loss)		to	(3,024,510)
2.3 Loss for the period attributable to members	Down 342% (larger loss)		to	(3,024,510)
2.4 Dividends	Amount per security		Franked amount per security	
Final dividend proposed	Not applicable		Not applicable	
Interim dividend	0.5 cents per share		0 cer	nts per share
		I		
2.5 Record date for determining entitlements for the final dividend	9 September 2	2019		



#### 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 2019 included:

- Record Group revenue of \$6,502,894 (1H2018: \$6,341,766),
- Net loss after tax of \$3,024,510\* (1H2018: \$684,689),
- Technegas Division Underlying EBITDA<sup>1</sup> of \$0.329 million (1H2018: \$0.459 million), and
- Net cash balance of \$5.766 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)	2019	2018
CONSOLIDATED SALES	6,503	6,342
GROSS MARGIN	5,385	5,002
GROSS MARGIN % SALES	82.8%	78.9%
CONSOLIDATED EBITDA	(2,279)	(1,115)
ADD BACK:		
CPET DIVISION EBITDA	42	179
OTHER NON-OPERATING EXPENSES*	(130)	(96)
FDA EXPENSES	2,060	1,456
SYSTEM UPGRADES AND QUALITY IMPROVEMENTS EXPENSES	987	-
REDUCTION IN ADMINISTRATION EXPENSES ARISING FROM THE ADOPTION OF AASB16 LEASES	(173)	-
NET (RECOVERIES) / EXPENSES FOR ALMEDIS ALTMANN GMBH	(178)	35
TECHNEGAS UNDERLYING EBITDA	329	459

\* Realised and unrealised foreign exchange gains and losses and finance revenue

Technegas continued to grow its leading position in the markets in which it is sold. Technegas delivered a 3% increase in first half revenues to \$6.50 million compared to \$6.34 million in the pcp. This improved revenue performance was driven by:

- Increased sales of Individual Patient Administration Set (PAS) of \$5.10 million delivering a \$201,000 increase in revenues;
- an increase of \$168,000 in Technegas service revenues; and
- Decreased sales of Technegas generators contributing a \$208,000 decrease in revenues to \$784,000.

Gross margins in the first half increased from 78.9% to 82.8% reflecting a change in sales mix towards the higher margined PAS. In addition, our strategy in Europe of owning the distributors for our Technegas business contributed to improving margins in the business, which we expect to continue to grow.

Lower EBITDA for the half year was driven by increased costs associated with implementing quality improvements and systems upgrades across the business to ensure compliance with USFDA guidelines as well as the new International Medical Device Single Audit Program. The addition of three key management position hires during the quarter also boosted wages costs. Combined, these initiatives were imperative to position the business strongly for the next growth phase of the company, post the anticipated FDA Technegas approval in 2020.

Cyclopharm's net cash at the end of the period of \$5.766 million.

\* Income tax expense changed from a benefit of \$646,682 to an expense of \$167,693.

<sup>&</sup>lt;sup>1</sup> Underlying Results represent results from the Technegas 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 with Almedis Altmann GMBH.



### OUTLOOK

Given the strong clinical support for Technegas as the functional ventilation imaging agent of choice in determining PE, we believe demand for Technegas 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 indications, particularly for COPD, remains a key priority as they have the potential to significantly expand Technegas' revenue and profitability over the medium to longer term.

The Directors are excited by the 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 2019. We anticipate approval by the USFDA to commence sales in 2020 and are investing in the systems, infrastructure and personal required to introduce Technegas to the United States market.

Cyclopharm is progressing Ultralute<sup>™</sup>'s registration as a medical device in Europe. We look forward to making further announcements, later this year regarding Ultralute's<sup>™</sup> progress and potential for it to be a complementary driver in the next stage of Cyclopharm's growth.

In summary, I expect Cyclopharm to achieve modest underlying sales and earnings growth in 2019 and to maintain a healthy capital position. I look forward to continuing to report to our shareholders as we gain momentum in realising our profitable growth objectives and delivering rewards to our investors.



### 3. Net tangible assets

	30 June 2019	30 June 2018
Net Tangible Assets per security	\$0.13	\$0.17

### 4. Entities over which control has been gained or lost during the period

### **Control over entities**

Name of entity (or group of entities)

On 31 May 2019, Cyclomedica USA, LLC, a wholly owned subsidiary, was incorporated in the United States of America.

### Loss of control over entities

Name of entity (or group of entities)

None

### 5. Dividends

An unfranked dividend of 0.5 cents per share was paid to shareholders on 15 April 2019 for the year ended 31 December 2018. The Directors have declared an unfranked interim dividend of 0.5 cents per share to be paid on 16 September 2019.

### 6. Dividend reinvestment plans

### Not applicable



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

Material investment in associates and joint ventures are as follows :				
30 June 2019	30 June 2018			
20%	20%			

The share of the associate's loss for the period was \$nil (2018: \$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 2019

Cyclopharm Limited and its Controlled Entities ABN 74 116 931 250

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During the half year, Cyclopharm continued to implement its strategic priorities:

- 1. Expanding Technegas sales by attaining approval to distribute Technegas in the USA in 2020;
- 2. Expanding the use of Technegas beyond the traditional diagnosis of Pulmonary Embolism (PE) into significantly larger applications such as Chronic Obstructive Pulmonary Disease (COPD) and Asthma, Lung Cancer, Lung Volume Reduction and Pulmonary Hypertension for both diagnosis and patient management;
- 3. Identifying, developing and commercialising complementary innovative technology such as Ultralute™; and
- 4. Leveraging our core global regulatory strengths, fiscal discipline, strong balance sheet and welldeveloped expertise in nuclear medicine and pulmonary healthcare to seek out complementary technologies and businesses.

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

In the half year to 30 June 2019, Cyclopharm continued to successfully execute its growth strategy of leveraging its significant intellectual property, technology and technical expertise to broaden sales in to new countries and expand end-use device applications and complementary businesses.

During the period, Cyclopharm generated record revenues of \$6.50 million and expanded its gross margins to 82.8% of sales (vs 1H18: 78.9%) driven by higher proportion of consumable sales and higher gross margins from sales into Europe. Net loss after tax for the period was \$3.02 million, which includes \$2.06 million of pre-tax expenses associated with the Group's United States Food and Drug Administration (USFDA) clinical trial of Technegas.

Cyclopharm's core Technegas Division generated underlying EBITDA<sup>1</sup> of approximately \$329,000 compared to \$459,000 in the prior corresponding period, (pcp). The reduction in underlying earnings reflects an increase in short term costs associated with investments of \$987,000 in systems upgrades and quality improvements across the business ahead of the anticipated USFDA approval to market Technegas in the USA.

The approval to sell Technegas in the USA, which accounts for around half of the total nuclear medicine departments in the world, is expected in 2020 and represents a major business opportunity for Cyclopharm. The existing 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 the Group's Canadian experience, Cyclopharm believes that Technegas 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.

Technegas 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 particularly in patients with COPD and the potential for nuclear medicine imaging.

<sup>&</sup>lt;sup>1</sup> Underlying Results represent results from the Technegas 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 with Almedis Altmann GMBH.

<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

The USFDA New Drug Application remains on track to be submitted in the second half of 2019, with expected total associated costs in line with previous estimates of US\$7.5 million. The Company is closely monitoring the final costs required to complete the submission and anticipate the Company's cash reserves should be sufficient.

In preparation for operations in the United States of America, on 31 May 2019, Cyclomedica USA, LLC was incorporated as a wholly owned subsidiary of Cyclomedica Ireland Ltd. The subsidiary will be based in Atlanta, Georgia.

The 3% increase in 1H revenues was driven by higher sales of Individual Patient Administration Set (PAS) (up \$0.20 million or 4%) and service revenue increasing by \$0.17 million. TechnegasPlus generators revenue was lower by \$0.21 million at \$0.78 million, principally reflecting lower half year sales of generators attributed to timing difference supported by new sales of 10 generators thus far in Q3.

The increase in higher margin PAS sales combined with improving margins in our European operations, as a result of owning our European distribution network lead to a first half increase in gross margins from 78.9% to 82.8%

Cyclopharm's commitment to the field of nuclear medicine is demonstrated by the several clinical research projects underway to expand the use of Technegas in in a range of respiratory diseases we term 'Beyond PE'. For example, Cyclopharm estimates the diagnostic and patient monitoring market potential for the sufferers of COPD and Asthma combined is valued at \$900m per annum. To deliver on our Beyond PE objectives, Cyclopharm announced in 2017 a research partnership with the University of Newcastle and the Hunter Medical Research Institute to assess the potential of using Technegas to phenotype asthmatics and to evaluate their response to therapy. As at 9 August 2019, full recruitment of 100 eligible patients was achieved with an additional 39-patient subset undergoing follow-up scans to assess response to therapy. We expect that initial research findings will be published during H2 2019 with substantive additional publications to follow during 2020.

Further, in May 2018, Cyclopharm announced it was funding a \$387,000, three-year, 100-patient study by the Woolcock Institute for Medical Research in collaboration with The University of Sydney and the Northern Sydney Local Health District. This study seeks to develop better tools to diagnose and manage patients suffering from Asthma and COPD. The Sydney based trial is expected to commence during Q3 2019.

Ultralute<sup>™</sup> is a proprietary technology, developed and owned by Cyclopharm, that extends the useful life of Molybdenum-99 (Mo-99) generators by up to 50%. Cyclopharm is currently seeking to register Ultralute<sup>™</sup>, in Europe, as a medical device to support better acceptance of this new first in class technology. The Company does not expect Ultralute<sup>™</sup> to make a contribution to revenues in the current year.

Over the full year, Cyclopharm expects ongoing growth in its core business in 2019 as well as further progress in the development of the company's key growth opportunities.

Having regard to the ongoing solid 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 16 September 2019 to shareholders on the register on 9 September 2019.

### A strong, growing core business in existing markets and three significant "transformational" growth opportunities well underway



## First half highlights continued

Half Year ended 30 June		2019	2018	Inc / (Dec)	% Change
Sales Revenue	\$	6,502,894	6,341,766	161,128	3%
Loss before tax and finance costs	\$	(2,719,214)	(1,319,906)	(1,399,308)	(106%)
Net Loss after tax*	\$	(3,024,510)	(684,689)	(2,339,821)	(342%)
Loss Per Share	cents	(4.46)	(1.01)	(3.45)	(342%)



### Technegas

The Technegas business delivered record underlying revenues during the half year. Sales of Individual Patient Administration Set (PAS) were up \$0.20 million; service revenue increased by \$0.17 million and gross margins rose to 82.8%.



Technegas generator revenue was lower at \$0.78 million. Loss before tax and finance costs was \$2.719 million for the half year. The loss was primarily attributable to the USFDA trial expenses and an increase in short term costs associated with investments of \$987,000 in systems upgrades and quality improvements across the business ahead of the anticipated USFDA approval to market Technegas in the USA.



Funded three-year, 100-patient study by 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.



Process for United States Food and Drug Administration approval of Technegas in the United States market remains on-budget and on-track, with USFDA approval targeted for 2020.



Canadian Association of Nuclear Medicine and European Association of Nuclear Medicine names Technegas as the preferred ventilation imaging agent for diagnosing Pulmonary Embolism as well as citing the potential for application Beyond PE.



Incorporation of wholly owned subsidiary, Cyclomedica USA, LLC on 31 May 2019.



### Ultralute™

Registration of Cyclopharm's new patented Ultralute<sup>™</sup> technology in Europe as a medical device technology targeted in late 2019 is expected to optimise commercial value.

\* Income tax expense changed from a benefit of \$646,682 to an expense of \$167,693.



- Record revenues
- Increased gross margins
- Investment in systems, processes and people in preparation for US market entry

Cyclopharm recorded sales revenue of \$6,502,894 (1H2018: \$6,341,766) and a net loss after tax of \$3,024,510 (1H2018: NLAT \$684,689) for the half year ending 30 June 2019. Technegas revenue was 3% higher than the pcp. The increase in half year revenues was achieved by a 4% increase in sales of Individual Patient Administration Set (PAS) (up \$0.20 million) while service revenue increased by \$0.17 million. TechnegasPlus generators revenue was lower by \$0.21 million at \$0.78 million.

Sales margins for the period expanded to 82.8% of revenue driven by a higher proportion of sales from higher margin PAS and higher margins on sales into the European markets. The increased margins experienced in Europe reflect the capturing of distribution margins following the acquisition of our distributers in those markets in recent years.

The expansion of gross profit was reinvested in improving the company's quality processes, systems and management depth in anticipation of entry into the US market in 2020. Reflecting this, on an underlying basis (adjusting for USFDA expenses and foreign exchange gains and losses). Technegas division's EBITDA for the half EBITDA vear was \$329,000. This performance 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 Division incurred a loss before tax of \$2.64 million in the First Half compared to a loss before tax of \$1.15 million in the pcp.

## Cyclopharm's Underlying Results<sup>4</sup>:

HALF-YEAR ENDED 30 JUNE (amounts in \$000's)	2019	2018
Consolidated Sales	6,503	6,342
Gross margin	5,385	5,002
Gross margin % sales	82.8%	78.9%
Consolidated EBITDA	(2,279)	(1,115)
Add back:		
CPET division EBITDA	42	179
Other non-operating expenses*	(130)	(96)
FDA expenses	2,060	1,456
System upgrades and quality improvement expenses	987	-
Reduction in administration expenses arising from the adoption of AASB 16 Leases	(173)	-
Net (Recoveries) / Expenses for Almedis Altmann GMBH	(178)	35
Technegas Underlying EBITDA	329	459

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

\* Realised and unrealised foreign exchange gains and losses and finance revenue.

<sup>&</sup>lt;sup>4</sup> Underlying Results represent results from the Technegas 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 with Almedis Altmann GMBH.



Continued

Lower EBITDA for the half year was driven by increased costs associated with implementing quality improvements and systems upgrades across the business. The addition of three key management position hires during the quarter also boosted wages costs. Combined, these initiatives were imperative to position the business strongly for the next growth phase of the company, post the anticipated FDA Technegas approval in 2020.

Our strategy to expand the use of Technegas is showing good progress. We have initiated a clinical trial, in collaboration with the Hunter Medical Research Institute and the University of Newcastle, to evaluate the use of Technegas in identifying ventilation traits in patients with severe asthma as an indicator to therapeutic selection. A secondary endpoint in the Newcastle study will be to evaluate how well patients respond to therapy. To date, all patients of the 100 patient study have been enrolled with 39-patient subset а undergoing further tests to determine response to therapy. More information on this trial is available on the Hunter Medical Research Institute's website at: https://hmri.org.au/news-article/nuclearimaging-clear-airway-diagnosis.

Sales in Germany remain depressed despite a gain from litigation of \$178,233 net of expenses recorded during the period. Whilst progress is being made to resolve this matter, legal proceedings are expected to continue throughout 2H 2019.

Ultralute<sup>™</sup> is a first in class proprietary technology developed to bring significant cost savings and efficiencies in nuclear medicine by extending the useful life of Molybdenum-99 generators by up to 50%. Molybdenum-99 generators produce the isotope Technetium 99m, the isotope used in 85% of all nuclear medicine procedures. Following the initial introduction of Ultralute to the market as laboratory equipment, Cyclopharm believes marketing Ultralute<sup>™</sup> as a medical device technology, will enhance its sales and long term commercial benefit to the Company. To this end, Cyclopharm is pursuing regulatory approval to market Ultralute<sup>™</sup> as a medical device in Europe and expects sales in that market in 2020 and for Ultralute<sup>™</sup> to form part of the platform for Cyclopharm's next stage of growth.

The Group continues to focus its business on large transformational revenue opportunities. In this regard, the Company is undertaking a strategic review of its Molecular Imaging facility, located at Macquarie University Hospital, which may include its sale. While this review is underway, the company is utilising, the facility progress research and development activities. Reflecting this status and the facility's ongoing rental expense, the Molecular Imaging operation recorded a loss before tax of \$129,351 compared to a loss of \$180,470 in the pcp.

The Group's net cash at the end of the period was \$5.766 million.

Expectations for the second half of the financial year 2019, include:

- Continuing to advance the process for FDA approval of Technegas in the US market
- 2. Supporting clinical trial programs targeting applications for Technegas in both the diagnosis and management of specific chronic respiratory disease states;
- Ongoing positive cash flows from its underlying business to support investment in growth opportunities and the capacity to pay dividends to shareholders.

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## **OPERATING REVIEW**

Technegas continued to grow its leading position in the markets in which it is sold. Technegas delivered a 2.5% increase in first half revenues to \$6.50 million compared to \$6.34 million in the pcp. This improved revenue performance was driven by:

- Increased sales of Individual Patient Administration Set (PAS) of \$5.10 million delivering a \$201,000 increase in revenues;
- an increase of \$168,000 in Technegas service revenues; and
- Decreased sales of Technegas generators contributing a \$208,000 decrease in revenues to \$784,000.

Gross margins in the first half increased from 78.9% to 82.8% reflecting a change in sales mix towards the higher margined PAS. In addition, our strategy in Europe of expanding direct representation for our Technegas business contributed to improving margins in the business, which we expect to continue to grow. Furthermore, the Company is leveraging its direct representation in 8 European markets by progressing talks with third party radiopharmaceutical companies for distribution opportunities beyond our existing sales base. We expect some traction on this front, in terms of revenue and margin growth, by late 2019/early 2020.

## TECHNEGAS MARKET REVIEW

## Europe

During the first half of 2019, Europe accounted for 57% of Technegas revenues compared to 58% in the pcp, underscoring the region's continued importance. European sales revenue of \$3.68 million was consistent with the pcp. The reduction is revenue from generator sales was principally due to timing of sales. Generator sales have already rebounded with 10 units shipped for sale during the first six weeks of Q3.

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 \$1.25 million in revenue, representing 19% of Technegas revenues in the period.

Sales revenue in Canada was 6% higher than in the same period last year at \$1.17 million up from \$1.10 million. Cyclopharm views its success in Canada as a strong indicator of prospects for Technegas in the USA if, as anticipated, USFDA approval to market Technegas in the USA is obtained in 2020.

## Asia Pacific

Sales revenue in Asia Pacific during the period of \$1,433,000 was consistent with the pcp of \$1,425,000. We expect 2019 sales in Asia Pacific will be consistent with 2018.

## Approval of Technegas for sale in the US

Gaining approval to sell Technegas in the USA is a priority for Cyclopharm. The US market is set to be the largest market for Technegas globally, delivering a substantial increase in shareholder value. As at 16 August 2019, 161 patients have been fully enrolled in the study from a total of nine active locations.

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Cyclopharm received USFDA approval for its Technegas trial design in November 2016. through Special Protocol а process. Assessment Following the company's submission of its first 40-patient interim study in the first half of 2018, Cyclopharm met with USFDA in October 2018 to explore opportunities to improve the clinical trial program. As a result of that meeting, USFDA provided constructive guidance relating to an alternative 505(b)2 Application Pathway and New Drug approved a variation in February 2019 to the existing clinical trial program that is expediting patient enrolment.

The timing of our New Drug Application is on track to be submitted in H2 2019, with approval for sales expected in 2020.

In parallel with the clinical elements of our USFDA New Drug Application, in 2018 Cvclopharm initiated a comprehensive documentation review of our medical devices to ensure compliance to the most recent USFDA guidelines as well as the new International Medical Device Single Audit Program (MDSAP). MDSAP is a regulatory harmonisation initiative between Australia, Brazil, Japan, Canada and the United States. MDSAP compliance will minimise disruptions that currently occur from multiple regulatory audits, provide predictable audit schedules and incorporate the ISO 13485 compliance required for our CE mark in Europe. The Company achieved MDSAP certification during 1H 2019.

We remain confident that the application for market entry into the United States will be successful, due to positive trial results to date, Technegas' existing global footprint and long-standing safe and efficacious track record of use.

Expenditure on the USFDA trials will continue to be expensed until approval is achieved. The total cost of the USFDA trial and registration program remains on track with our previously announced expectation of approximately US\$7.5 million. For the half year, these expenses totalled



\$2,059,753 compared to \$1,455,733 in the pcp.

## 'Beyond PE'

Cyclopharm continues to make progress in developing new indications for Technegas. Other disease states beyond Pulmonary Embolism (PE), which include COPD, asthma, Chronic thromboembolic pulmonary hypertension (CTEPH). lung transplants and significant lung cancer. offer market opportunities for Technegas. At Cyclopharm, we call this 'Beyond PE'.

Reinforcing the opportunities from the Beyond PE initiatives, a 2017 Lancet Commission report identified the need for innovative ways to study asthma to develop new Asthma and COPD treatment regimens and to monitor the success and progress of treatment. This report identified that advancements in treatment regimens had effectively hit a 'road-block' with no material advancements in many years.

Beyond PE The strategy is beina progressed through participating in clinical studies, the findings from which will be presented to respiratory clinicians globally. By leveraging off new indications such as Asthma and COPD, Cyclopharm expects that the traditional PE market will benefit by introducing the improved and evolving technology to а new generation of clinicians.

For example, Cyclopharm is actively progressing opportunities to present findings from recently completed Chinese COPD trials, which showed Technegas was effective at diagnosing the extent of emphysema in trial patients and at an earlier stage of the disease than standard diagnostic methods. Technegas was also more accurate at measuring impairment in lung function and therefore better able to monitor the effectiveness of treatment.

Another initiative underway is the collaboration with the University of Newcastle, Hunter Regional Medical



Continued

Institute and John Hunter Hospital on a 100patient study to test two specific hypotheses:

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

The implication in advancing these hypotheses further could expand the use of Technegas by improving the diagnosis and management of patients with COPD and other small airways diseases.

100 eligible patients have been recruited to date. A 39-patient subset of these 100 are undergoing further tests to determine response to therapy. It is envisioned that the first articles referencing this trial will be published in the coming months. The cost of the trial is estimated to be approximately \$600,000. For more information go to: https://hmri.org.au/news-article/nuclearimaging-clear-airway-diagnosis.

Technegas is also the focus of a new Woolcock Institute for Medical Research clinical trial, seeking to develop better tools to diagnose and manage patients suffering from Asthma and COPD. The three-year, 100 patient trial is being conducted in collaboration with The University of Sydney and the Northern Sydney Local Health District. The trial is being funded by Cyclopharm and will cost \$387,000.

The trial will assess Technegas as the imaging agent that could fulfil the criteria of a novel and effective measurement tool to advance the study of asthma, and the development of personalised treatment of Asthma and COPD. The trial is expected to commence in the third quarter of 2019.

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 in diagnosis and patient management. These markets represent significant opportunities to expand sales of Technegas and drive shareholder value over the medium term with targeted revenues of up to \$900m per annum.

## ULTRALUTE<sup>™</sup>

Following initial commercial sales of Cyclopharm's patented nuclear medicine technology Ultralute<sup>TM</sup> the decision was taken to pursue registration of Ultralute<sup>TM</sup>, within Europe, as a medical device technology, which is expected to optimise the commercial value of this technology over the mid to longer term.

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.

In 2017 the International Atomic Energy Agency (IAEA) and Cyclopharm collaborated in a multi-country, multi-centre Ultralute<sup>™.</sup> evaluation of The IAEA Ultralute<sup>™</sup> described "new as а innovation...that has significant global potential in the nuclear medicine supply chain".

The Group expects meaningful commercial sales of Ultralute<sup>™</sup> within the medical device category in Europe in 2020 and believes the commercial prospects for Ultralute<sup>™</sup> mean it will provide the basis for enhanced shareholder returns over the longer term.

## MACQUARIE MEDICAL IMAGING

Macquarie Medical Imaging ("MMI"), Cyclopharm's joint venture diagnostic

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imaging service located at Macquarie University Hospital ("MUH") in Sydney, achieved a 1% increase in sales during the half year in comparison with the pcp.

MMI provides patients access to state-ofthe-art imaging facilities at MUH and a satellite practice located at the nearby Macquarie Shopping Centre. Growth in MMI is tied closely to the hospital's strategies for both inpatient and outpatient services, including a new breast cancer clinic and expanded specialties such as cardiothoracic services, cancer care services, expanded PET indications and research.

The joint venture is accounted for on an equity basis due to Cyclopharm's minority shareholding. As a result, MMI's full accounts are not consolidated into our accounts.

A Term Sheet has been signed with MUH regarding the potential acquisition of MMI by MUH. Due Diligence is currently underway.

## CYCLOPET

On 19 September 2017 Cyclopharm announced the signing of a term sheet between Cyclopharm, Cyclotek, ANSTO and Macquarie University. The intention of the collaboration will utilise the existing cyclotron facility located at MUH primarily for research and development.

It is expected that discussions will be concluded during 2H 2019.

### OUTLOOK

Given the strong clinical support for Technegas as the functional ventilation imaging agent of choice in determining PE<sup>5</sup>, we believe demand for Technegas 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.

It is expected that during 2H 2019 discussions regarding the future status of both MMI and the cyclotron facility located at MUH will be concluded.

Developing additional Technegas indications, particularly for COPD, remains a key priority as they have the potential to significantly expand Technegas' revenue and profitability over the medium to longer term in indications valued at \$900m 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 2019. We anticipated approval by the USFDA to commence sales in 2020 and are investing in the systems, infrastructure and personal required to introduce Technegas to the United States market.

Cyclopharm is progressing Ultralute<sup>™</sup>'s registration as a medical device in Europe. We look forward to making further announcements, later this year regarding Ultralute's<sup>™</sup> progress and potential for it to be a complementary driver in the next stage of Cyclopharm's growth.

In summary, I expect Cyclopharm to achieve modest underlying sales and earnings growth in 2019 and to maintain a healthy capital position. I look forward to continuing to report to our shareholders as we gain momentum into 2020 as we continue to execute our growth strategies and deliver rewards to our investors.

Janes & MCBreyer

James McBrayer Managing Director

Sydney, 22 August 2019

<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 2019.

#### 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 V R Gould	Non-Executive Director
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 \$2,856,817 (2018: loss before tax of \$1,331,371) impacted by higher FDA expenses incurred of \$2,059,753 (2018: \$1,455,733) and consultancy expenses of \$987,740 to improve the company's quality processes, systems and management depth in anticipation of entry into the US market in 2020. The Molecular Imaging division recorded a loss before tax of \$129,351 (2018: loss before tax of \$180,470).

The increase in half year revenues was achieved by higher sales of Individual Patient Administration Set (PAS) (up \$0.20 million or 4%) while service revenue increased by \$0.17 million. TechnegasPlus generators revenue was lower by \$0.21 million at \$0.78 million.

As a result of adopting AASB 16 Leases, the current period's loss before tax was higher by \$0.07 million which included an increased depreciation expense of \$0.23 million and increased finance costs of \$0.12 million offset by a reduction in administration expenses of \$0.28 million.

#### **Financial position**

Net assets have decreased from \$17,015,969 as at 31 December 2018 to \$13,723,119 as at 30 June 2019 predominantly due to the net loss after tax of \$3,024,510 for the half year and dividends paid of \$330,250.

#### SIGNIFICANT CHANGES IN STATE OF AFFAIRS

#### Shares issued during the half year

200,000 Long Term Incentive Plan shares were issued on 30 May 2019.

#### Options issued during the half year

200,000 Options were issued on 27 May 2019.





Continued

#### Incorporation of Cyclomedica USA, LLC

On 31 May 2019, Cyclomedica USA, LLC was incorporated in the United States of America as a wholly owned subsidiary of Cyclomedica Ireland Ltd.

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

#### SIGNIFICANT EVENTS AFTER BALANCE DATE

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 16 September 2019. The record date for the interim dividend is 9 September 2019.

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.

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 FY2019 final dividend will be an amount equal to or greater than the 2019 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:

Janes & MCBruger

James McBrayer Managing Director & CEO

Sydney, 22 August 2019



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 2019, 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

1/0C

Andrew Hoffmann Director

Sydney

Dated: 22 August 2019

#### Nexia Sydney Audit Pty Ltd

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## Condensed Consolidated Statement of Comprehensive Income

For the half year ended 30 June 2019

		Consolidated		
		30 June 2019	30 June 2018	
		\$	\$	
No	tes			
CONTINUING OPERATIONS				
Sales revenue	3	6,502,894	6,341,766	
Finance revenue		22,845	57,747	
Total Revenue		6,525,739	6,399,513	
Cost of materials and manufacturing		(1,247,606)	(1,461,681)	
Employee benefits expense		(2,385,060)	(1,880,008)	
Advertising and promotion expense		(112,140)	(190,841)	
Depreciation and amortisation expense		(439,937)	(204,712)	
Freight and duty expense		(176,720)	(244,887)	
Research and development expenses*		(2,212,885)	(1,536,058)	
Administration expense		(2,547,243)	(2,018,506)	
Other expenses		(123,362)	(182,726)	
Loss before tax and finance costs		(2,719,214)	(1,319,906)	
Finance costs		(137,603)	(11,465)	
Loss before income tax		(2,856,817)	(1,331,371)	
Income tax (expense) / benefit		(167,693)	646,682	
Net loss for the period		(3,024,510)	(684,689)	
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 ta	ax)	106,741	4,588	
Total comprehensive loss for the year		(2,917,769)	(680,101)	
	_			
	5	cents	cents	
-basic loss per share for continuing operations		(4.46)	(1.01)	
-basic loss per share		(4.46)	(1.01)	
-diluted loss per share		(4.43)	(1.01)	

\* Included in Research and development expenses are amounts incurred on FDA expenses of \$2,059,753 (2018: \$1,455,733).

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 2019

		Consolidated		
		30 June 2019		
	Notes	\$	\$	
Assets				
Current Assets				
Cash and cash equivalents		5,765,721	5,854,959	
Trade and other receivables		3,216,836	6,247,065	
Inventories		2,560,529	2,771,546	
Current tax asset		205,384	78,377	
Derivative - foreign exchange contract		-	274,904	
Other assets		506,805	227,599	
Total Current Assets		12,255,275	15,454,450	
Non-current Assets				
Property, plant and equipment		2,335,037	2,468,406	
Right-of-use assets	6	4,524,711	-	
Investments	7	-	-	
Intangible assets		4,639,491	4,570,344	
Deferred tax assets		1,043,395	1,043,521	
Total Non-current Assets		12,542,634	8,082,271	
Total Assets		24,797,909	23,536,721	
Liabilities				
Current Liabilities		0 000 505	0 500 405	
Trade and other payables		3,283,585	3,599,465	
Interest bearing loans and borrow ings		30,845	120,577	
Lease liabilities Provisions		1,354,312	-	
		839,990	855,517	
Tax liabilities Total Current Liabilities		179,560	643,644 5 210 202	
		5,688,292	5,219,203	
Non-current Liabilities			000.004	
Trade and other payables		-	336,864	
Lease liabilities Provisions		4,700,677	-	
Deferred tax liabilities		22,262	300,609	
Deferred income liabilities	o	-	517	
Total Non-current Liabilities	8	663,559 5 386 408	663,559	
		5,386,498	1,301,549	
Total Liabilities		11,074,790	6,520,752	
Net Assets		13,723,119	17,015,969	
Equity				
Contributed equity	9	21,905,035	21,905,035	
Employee equity benefits reserve		689,992	663,005	
Foreign currency translation reserve		(434,230)	(540,971)	
Accumulated losses		(8,437,678)	(5,011,100)	
Total Equity		13,723,119	17,015,969	

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 2019

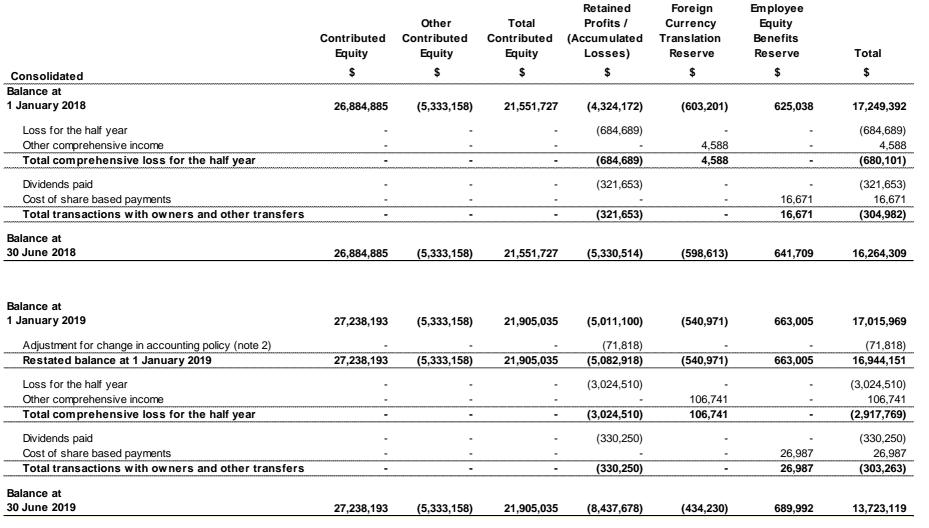
	Consolidated		
	30 June 2019	30 June 2018	
	\$	\$	
Operating activities			
Receipts from customers	7,208,657	6,422,905	
Payments to suppliers and employees	(7,552,856)	(7,626,522)	
Interest received	22,845	57,747	
Borrow ing costs paid	(17,764)	(11,465)	
Income tax received	1,565,291	1,419,190	
Net cash flows from operating activities	1,226,173	261,855	
Investing activities			
Net payments for acquisition of subsidiary	(343,209)	(594,137)	
Purchase of property, plant and equipment	(169,702)	(57,435)	
Payments for deferred expenditure*	(168,059)	(352,557)	
Net cash flows used in investing activities	(680,970)	(1,004,129)	
Financing activities			
Dividends paid	(330,250)	(321,653)	
Repayment of bank borrow ings	(89,732)	(26,608)	
Repayment of lease liabilities	(237,796)	-	
Net cash flows used in financing activities	(657,778)	(348,261)	
Net decrease in cash and cash equivalents	(112,575)	(1,090,535)	
Cash and cash equivalents			
at beginning of the period	5,854,959	8,689,676	
net foreign exchange differences from translation of cash and cash equivalents	23,337	12,189	
at end of the period	5,765,721	7,611,330	

\* Included in payments for deferred expenditure are amounts incurred on Ultralute \$105,743 (2018: \$189,134) and the development of the next generation of the Technegas generator \$10,482 (2018: \$154,400).

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

## Condensed Consolidated Statement of Changes in Equity





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 2019

### 1. CORPORATE INFORMATION

The half year financial report of Cyclopharm Limited for the half year ended 30 June 2019 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 2019 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 2018, 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 2018 annual report.

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

The Group has adopted the following Australian Accounting Standards (new and amended) from the mandatory application date of 1 January 2019.

#### AASB 16: Leases

The Group has adopted AASB 16 from 1 January 2019. The standard replaces AASB 117 Leases and for lessees eliminates the classifications of operating leases and finance leases. Except for short-term leases and leases of low-value assets, right-of-use assets and corresponding lease liabilities are recognised in the statement of financial position. Straight-line operating lease expense recognition is replaced with a depreciation charge for the right-of-use assets (included in operating costs) and an interest expense on the recognised lease liabilities (included in finance costs). In the earlier periods of the lease, the expenses associated with the lease under AASB 16 will be higher when compared to lease expenses under AASB 117. However Loss before tax, depreciation and finance results reduces as the operating expense is now replaced by interest expense and depreciation in profit or loss. For classification within the statement of cash flows, the interest portion is disclosed in operating activities and the principal portion of the lease payments are separately disclosed in financing activities.



For the half year ended 30 June 2019 Continued

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Preparation**

New and Amended Accounting Standards and Interpretations adopted by the Group (continued)

#### Impact of adoption

AASB 16 was adopted using the modified retrospective approach and as such the comparatives have not been restated. The impact of adoption on opening retained profits as at 1 January 2019 was as follows:

	1 January 2019 \$'000
Operating lease commitments as at 1 January 2019 (AASB 117) Finance lease commitments as at 1 January 2019 (AASB 117) Operating lease commitments discount based on the weighted average incremental borrowing rate of 4.5% (AASB 16)*	3,008 62 3,629
Short-term leases not recognised as a right-of-use assets (AASB 16) Accumulated depreciation as at 1 January 2019 (AASB 16)	(7) (2,065)
Right-of-use assets (AASB 16) Lease liabilities – current (AASB 16) Lease liabilities – non-current (AASB 16) Reclassification of outstanding lease payments Reversal of Make Good provision Reversal of Lease Incentive	4,627 (1,017) (4,939) 812 286 159
Reduction in opening retained profits as at 1 January 2019	(72)

### Right-of-use assets

A right-of-use asset is recognised at the commencement date of a lease. The right-of-use asset is measured at cost, which comprises the initial amount of the lease liability, adjusted for, as applicable, any lease payments made at or before the commencement date net of any lease incentives received, any initial direct costs incurred, and, except where included in the cost of inventories, an estimate of costs expected to be incurred for dismantling and removing the underlying asset, and restoring the site or asset.

Right-of-use assets are depreciated on a straight-line basis over the unexpired period of the lease or the estimated useful life of the asset, whichever is the shorter. Where the Group expects to obtain ownership of the leased asset at the end of the lease term, the depreciation is over its estimated useful life. Right-of-use assets are subject to impairment or adjusted for any remeasurement of lease liabilities.

The Group has elected not to recognise a right-of-use asset and corresponding lease liability for short-term leases with terms of 12 months or less and leases of low-value assets. Lease payments on these assets are expensed to profit or loss as incurred.

<sup>\*</sup> This includes the impact of assessing the lease term under AASB16 in determining the reduction in opening retained profits as at 1 January 2019.



For the half year ended 30 June 2019 Continued

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### **Basis of Preparation**

New and Amended Accounting Standards and Interpretations adopted by the Group (continued)

### Lease liabilities

A lease liability is recognised at the commencement date of a lease. The lease liability is initially recognised at the present value of the lease payments to be made over the term of the lease, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Lease payments comprise of fixed payments less any lease incentives receivable, variable lease payments that depend on an index or a rate, amounts expected to be paid under residual value guarantees, exercise price of a purchase option when the exercise of the option is reasonably certain to occur, and any anticipated termination penalties. The variable lease payments that do not depend on an index or a rate are expensed in the period in which they are incurred.

Lease liabilities are measured at amortised cost using the effective interest method. The carrying amounts are remeasured if there is a change in the following: future lease payments arising from a change in an index or a rate used; residual guarantee; lease term; certainty of a purchase option and termination penalties. When a lease liability is remeasured, an adjustment is made to the corresponding right-of-use asset, or to profit or loss if the carrying amount of the right-of-use asset is fully written down.

### Interpretation 23: Uncertainty over Income Tax Treatments

Interpretation 23 clarifies how to apply the recognition and measurement requirements in AASB 112 Income Taxes when there is uncertainty over income tax treatments.

Consequential amendments are made to AASB 1 First-time Adoption of Australian Accounting Standards as a result of Interpretation 23 by AASB 2017-4.

The adoption of this Interpretation does not have a material impact on the Group's financial statements.

# AASB 2017-6: Amendments to Australian Accounting Standards – Prepayment Features with Negative Compensation.

This Standard amends AASB 9 to permit entities to measure at amortised cost or fair value through other comprehensive income particular financial assets that would otherwise have contractual cash flows that are solely payments of principal and interest but do not meet that condition only as a result of a prepayment feature.

The adoption of AASB 2017-6 does not have a material impact on the Group's financial statements.

# AASB 2017-7: Amendments to Australian Accounting Standards – Long-term Interests in Associates and Joint Ventures

This Standard amends AASB 128 to clarify that an entity is required to account for long-term interests in an associate or joint venture, which in substance form part of the net investment in the associate or joint venture but to which the equity method is not applied, using AASB 9 Financial Instruments before applying the loss allocation and impairment requirements in AASB 128.

The adoption of this Standard does not have a material impact on the Group's financial statements.



For the half year ended 30 June 2019 Continued

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### **Basis of Preparation**

#### 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.

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 2019 Continued

### 3. REVENUE FROM CONTRACTS WITH CUSTOMERS

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

	For the	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	-	5,888,86		
After sales services	614,034	-	614,034		
Total revenue from contracts with customers	6,502,894	-	6,502,89		
- Geographical markets					
Asia Pacific	995,977	-	995,97		
Europe	4,093,229	-	4,093,22		
Canada	1,179,721	-	1,179,72		
Other	233,967	-	233,96		
Total revenue from contracts with customers	6,502,894	-	6,502,89		
Timing of revenue recognition					
Goods transferred at a point in time	6,409,215	-	6,409,21		
Services transferred over time	93,679	-	93,67		
Total revenue from contracts with customers	6,502,894	-	6,502,89		

	For the	the period ended 30 June 2018			
	Technegas	Molecular Imaging	Total		
ments	\$	\$	\$		
Type of goods or service					
Sales of equipment and consumables	5,897,005	-	5,897,00		
After sales services	444,761	-	444,76		
Total revenue from contracts with customers	6,341,766	-	6,341,76		
Geographical markets					
Asia Pacific	1,156,451	-	1,156,45		
Europe	3,963,037	-	3,963,03		
Canada	1,109,112	-	1,109,11		
Other	113,166	-	113,16		
Total revenue from contracts with customers	6,341,766	-	6,341,76		
Timing of revenue recognition					
Goods transferred at a point in time	6,167,166	-	6,167,16		
Services transferred over time	174,600	-	174,60		
Total revenue from contracts with customers	6,341,766	-	6,341,76		

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



For the half year ended 30 June 2019 Continued

### 4. SEGMENT REPORTING

		Consolidated			
the period ended	Technegas	Molecular Imaging	Total		
June 2019	\$	\$	\$		
Revenue					
Sales to external customers	6,502,894	-	6,502,894		
Finance revenue	22,086	759	22,84		
Total segment revenue	6,524,980	759	6,525,739		
Result					
Loss before tax, depreciation and finance costs	(2,237,607)	(41,670)	(2,279,277		
Depreciation and amortisation	(362,578)	(77,359)	(439,937		
Loss before tax and finance	(2,600,185)	(119,029)	(2,719,214		
Finance costs	(127,281)	(10,322)	(137,603		
Loss before tax	(2,727,466)	(129,351)	(2,856,817		
Income tax	(167,693)	-	(167,693		
Loss for the period	(2,895,159)	(129,351)	(3,024,510		
Assets and liabilities					
Segment assets	21,680,931	3,116,978	24,797,90		
Segment liabilities	9,666,383	1,408,407	11,074,790		

AASB 16 was adopted using the modified retrospective approach and as such the comparatives have not been restated. Therefore, the current and comparative Loss before tax, depreciation and finance costs are not directly comparable.



For the half year ended 30 June 2019 Continued

### 4. SEGMENT REPORTING

		Consolidated			
the period ended	Technegas	Molecular Imaging	Total		
June 2018	\$	\$	\$		
Revenue					
Sales to external customers	6,341,766	-	6,341,766		
Finance revenue	56,957	790	57,747		
Total segment revenue	6,398,723	790	6,399,513		
Result					
Loss before tax, depreciation and finance costs	(936,159)	(179,035)	(1,115,194		
Depreciation and amortisation	(204,681)	(31)	(204,712		
Loss before tax and finance	(1,140,840)	(179,066)	(1,319,906		
Finance costs	(10,061)	(1,404)	(11,465		
Loss before tax	(1,150,901)	(180,470)	(1,331,371		
Income tax	553,309	93,373	646,68		
Loss for the period	(597,592)	(87,097)	(684,689		
Assets and liabilities					
Segment assets	19,660,378	2,891,649	22,552,02		
Segment liabilities	5,372,874	914,844	6,287,718		



For the half year ended 30 June 2019 Continued

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

### Net Tangible Assets per share

	Consolidated		
	30 June 2019	31 December 2018	
	\$	\$	
Net assets per share	0.20	0.25	
Net tangible assets per share	0.13	0.18	
	Number	Number	
Number of ordinary shares for net assets per share	68,898,873	68,698,873	
	30 June 2019	31 December 2018	
	\$	\$	
Net assets	13,723,119	17,015,969	
Net tangible assets	9,083,628	12,445,625	

The number of ordinary shares includes the effects of 200,000 Long Term Incentive Performance ("LTIP") shares issued on 30 May 2019 as set out in Note 9.

#### Loss per share

	Consol	lidated
	30 June 2019	30 June 2018
	\$	\$
Net loss attributable to equity holders of the parent	(3,024,510)	(684,689)
	cents	cents
- basic loss per share for continuing operations	(4.46)	(1.01)
- basic loss per share	(4.46)	(1.01)
- diluted loss per share	(4.43)	(1.01)
	Number	Number
Weighted average number of ordinary shares for basic loss per share	67,809,232	67,891,316
Weighted average number of ordinary shares for diluted loss per share	68,198,873	67,891,316

The weighted average number of ordinary shares for basic loss per share excludes the effects of 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 (2018: 225,000 LTIP shares issued on 19 April 2017 and 138,000 LTIP shares issued on 25 July 2016) as they are contingently returnable.



For the half year ended 30 June 2019 Continued

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

	Consolidated		
	30 June 2019	31 December 2018	
	\$	\$	
Land and buildings - right-of-use	6,752,998	-	
Less: Accumulated depreciation	(2,283,889)		
	4,469,109		
Plant and equipment - right-of-use	260,528	-	
Less: Accumulated depreciation	(204,926)	-	
	55,602		
Total right-of-use assets	4,524,711		

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						Conso
Associated companies   Name Principal Activities Country of Incorporation Shares Ownershill   30 June 2019   Macquarie Medical Imaging Pty Ltd Imaging centre Australia Preference 20%   Consort   acquarie Medical Imaging Pty Ltd Imaging centre Australia Preference 30 June 2019   acquarie Medical Imaging Pty Ltd Imaging centre Australia Preference 30 June 2019   acquarie Medical Imaging Pty Ltd Imaging centre S 30 June 2019   acquarie Medical Imaging Pty Ltd Imaging centre Imaging centre S   1 January Imaging Pty Ltd Imaging centre Imaging centre Imaging centre   (Repayment made by) / Loan to associate Imaging centre Imaging centre Imaging centre   Reversal / (Share) of losses after income tax Imaging centre Imaging centre Imaging centre					30 Ju	ne 2019
Name       Principal Activities       Country of Incorporation       Shares       Ownershit         Macquarie Medical Imaging Pty Ltd       Imaging centre       Australia       Preference       20%         Macquarie Medical Imaging Pty Ltd       Imaging centre       Australia       Preference       20%         I January       I January       Imaging Pty Ltd         Reversal / (Share) of losses after income tax       Imaging Pty Ltd       Imaging Pty Ltd       Imaging Pty Ltd       Imaging Pty Ltd						+
Name     Activities     Incorporation     Shares     Ownership       Macquarie Medical Imaging Pty Ltd     Imaging centre     Australia     Preference     20%       Activities     Australia     Preference     20%       Activities     Australia     Preference     20%       Activities     Australia     Preference     20%       Australia     Preference     30 June 2019     30 June 2019       Australia     Australia     Preference     30 June 2019       Australia     Australia     Preference     30 June 2019       Australia     Australia     Preference     30 June 2019       Australia     Australia     Australia     Australia       Australia     Austra	Associated companies					-
Macquarie Medical Imaging Pty Ltd Imaging centre Australia Preference 20% Conso acquarie Medical Imaging Pty Ltd \$ 1 January (Repayment made by) / Loan to associate Reversal / (Share) of losses after income tax	Name		-	Shares		Ownersh
Consort       acquarie Medical Imaging Pty Ltd     30 June 2019       1 January     \$       (Repayment made by) / Loan to associate     -       Reversal / (Share) of losses after income tax     -					30 Ju	ne 2019
30 June 2019       acquarie Medical Imaging Pty Ltd     \$       1 January     -       (Repayment made by) / Loan to associate     -       Reversal / (Share) of losses after income tax     -	Macquarie Medical Imaging Pty Ltd	Imaging centre	Australia	Preference		20%
acquarie Medical Imaging Pty Ltd     \$       1 January     -       (Repayment made by) / Loan to associate     -       Reversal / (Share) of losses after income tax     -						Consc
1 January     -       (Repayment made by) / Loan to associate     -       Reversal / (Share) of losses after income tax     -					30 Ju	ne 2019
(Repayment made by) / Loan to associate     -       Reversal / (Share) of losses after income tax     -	Macquarie Medical Imaging Pty Ltd					\$
Reversal / (Share) of losses after income tax	t 1 January					-
	(Repayment made by) / Loan to assoc	ciate				-
30 June / 31 December -	Reversal / (Share) of losses after inc	ome tax				-
	t 30 June / 31 December					-

Cyclopet Pty Ltd has a 20% (2018: 20%) interest in Macquarie Medical Imaging Pty Ltd. The share of the associate's loss not recognised during the period was \$232,135 (30 June 2018: loss of \$182,755) and the cumulative share of the associate's loss not recognised as at 30 June 2019 was \$2,482,088 (31 December 2018: \$2,249,954).

The share of loss of associate not recognised as at 30 June 2019 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 (2018: \$nil).



For the half year ended 30 June 2019 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 2019	30 June 2018	30 June 2019	30 June 2018
	Notes	Number	Number	\$	\$
Issued and paid up capital					
Ordinary shares		68,898,873	68,254,316	27,238,193	26,884,885
Other contributed equity		-	-	(5,333,158)	(5,333,158)
Total issued and paid up capital		68,898,873	68,254,316	21,905,035	21,551,727
Ordinary shares					
Issued and paid up capital					
Balance at the beginning of the period		68,698,873	68,254,316	27,238,193	26,884,885
Issue of Long Term Incentive Plan shares	(i)	200,000	-	-	-
Balance at the beginning and end of period		68,898,873	68,254,316	27,238,193	26,884,885

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) 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.

### Dividends

An unfranked final dividend of 0.5 cents per share in respect of the financial year ended 31 December 2018 (2018: unfranked final dividend of 0.5 cents per share in respect of the financial year ended 31 December 2017) 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 2019.

	Consolidated			
	30 June 2019	30 June 2018	30 June 2019	30 June 2018
	Cents per share	Cents per share	\$	\$
Fully paid ordinary shares				
Final dividend for the financial year				
- No franking credits attached	0.5	0.5	(330,250)	(321,653)
	0.5	0.5	(330,250)	(321,653)



For the half year ended 30 June 2019 Continued

## **10. COMMITMENTS AND CONTINGENCIES**

### (a) Capital commitments

There are no capital commitments as at the reporting date.

### (b) Contingent liabilites

Pursuant to a Shareholders' Agreement, Cyclopet Pty Limited (a wholly owned subsidiary of Cyclopharm Limited) has undertaken to provide a put option to a 50% shareholder of Macquarie Medical Imaging Pty Limited ("MMI") such that if this option was exercised, Cyclopet would be required to purchase all Redeemable Preference Shares and Ordinary Shares held by the 50% joint venturer for the value of the Redeemable Preference Shares plus any accumulated interest plus \$1 for the Ordinary Shares. The cost to Cyclopet had the put option been issued and exercised at balance date is estimated not to exceed \$3,158,049 (31 December 2018: \$2,838,442). If the put option was issued and exercised, control of MMI would be transferred to the Group and MMI's financial statements would be consolidated from that date.



For the half year ended 30 June 2019 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		Sales to related parties \$	Purchases from related parties \$	Amounts owed by related parties \$	Provision for doubtful debts on Amounts owed by related parties \$
Cell Structures Pty Ltd	2019		25,925		
	2018	-	25,500	-	-
Macquarie Medical Imaging	2019	-	-	230,782	230,782
	2018	-	-	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 \$25,925 (2018: \$25,500) 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. As the trade debtor balance of \$230,782 (2018: \$230,782) is not expected to be repaid in the short term, it is included as an interest in the associate and a share of the associate's losses has been recognised under the equity method as disclosed in Note 7.

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 16 September 2019. The record date for the interim dividend is 9 September 2019.



For the half year ended 30 June 2019 Continued

### 13. EVENTS AFTER THE BALANCE SHEET DATE

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 2019 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:

Janes SMCBruger

James McBrayer Managing Director & CEO

Sydney, 22 August 2019



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

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

We have reviewed the accompanying half-year financial report of Cyclopharm Limited, which comprises the condensed consolidated statement of financial position as at 30 June 2019, the condensed statement of comprehensive income, condensed statement of changes in equity and condensed statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration of the consolidated entity comprising Cyclopharm Limited and the entities it controlled at the half-year's end or from time to time during the half-year.

#### **Directors' Responsibility for the Half-Year Financial Report**

The directors of the company are responsible for the preparation and fair presentation of the half-year financial report in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001*. This responsibility includes establishing and maintaining internal control relevant to the preparation and fair presentation of the half-year financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

#### Auditor's Responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE *2410 Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 30 June 2019 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*. As the auditor of Cyclopharm Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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. As 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

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#### Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*. We confirm that the independence declaration required by the *Corporations Act 2001*, has been given to the directors of Cyclopharm Limited.

#### Conclusion

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

- (a) giving a true and fair view of the consolidated entity's financial position as at 30 June 2019 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and *Corporations Regulations 2001.*

Nexia Sydney Audit Pty Ltd

Allo C

**Andrew Hoffmann** Director Sydney, 22 August 2019





## **General Information**

#### Directors

David Heaney Non-Executive Chairman

James McBrayer Managing Director & CEO

Vanda Gould Non-Executive Director

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

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

### CycloPet

Basement 2 Macquarie University Hospital 3 Technology Place Macquarie University NSW 2109

## Cyclomedica Canada

615 Old York Road, Burlington, Ontario L7P 4Y6 Canada

## **Cyclomedica Germany**

Lützenkirchener Str. 410 51381 Leverkusen Germany

### Cyclomedica Europe

Unit A5, Calmount Business Park Ballymount Dublin 12 Ireland

### 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).