CLINUVEL

Appendix 4D
Half yearly report

Half year ended 31 December 2022

Name of entity: **CLINUVEL Pharmaceuticals Limited**	
ABN: 88 089 644 119	**Previous corresponding period:** Half year ended 31 December 2021

RESULTS FOR ANNOUNCEMENT TO THE MARKET

				($A'000)
Revenues from ordinary activities	Increased	19%	to	29,355
Profit from operating activities before tax attributable to members	Increased	67%	to	14,600
Profit from ordinary activities after tax attributable to members	Increased	94%	to	11,388
Net Profit for the period attributable to members	Increased	94%	to	11,388

Dividends (distribution)

	Amount per security	Franked amount per security
Final dividend (prior year)*	4.0 ¢	Fully franked
Interim dividend	*Nil ¢	*Nil ¢
*CLINUVEL PHARMACEUTICALS LIMITED paid the dividend on 21 September 2022		
Previous corresponding period (31 December 2021)	2.5 ¢	Unfranked
Record date for determining entitlements to the dividend	N/A	N/A

Brief explanation of any of the figures reported above and short details of any bonus or cash issue or other item(s) of importance not previously released to the market:
* Not applicable

Net Tangible Asset Backing

	Current period	Previous corresponding period
Net tangible asset backing per ordinary security	$2.78	$2.14

Control gained or lost over entities having material effect – n/a
Details of Aggregate Share of Profits (losses) of Associates and Joint Venture Entities – n/a

Commentary on results

In accordance with Listing Rule 4.2A, for commentary on the results of CLINUVEL PHARMACEUTICALS LIMITED please refer to the Executive Summary & Key Highlights and the Review of Operations in the attached Directors' Report. The information in the Half Year Report should be read in conjunction with the details and explanations provided herewith, along with the most recent Annual Report. All figures are reported in Australian dollars ($).

DIRECTORS' REPORT

Your Directors present today in compliance with the Corporations Act 2001, and Accounting Standard AASB134 Interim Financial Reporting and the Corporations Regulations 2001, the Company's and its controlled entities' report for the half year ended 31st December 2022), the financial results reflecting the financial evolution and growth of the company.

Directors

The names of Directors in office at any time during or since the end of the half year are:

- Dr. K. E. Agersborg
- Mr. W. Blijdorp
- Sir. J. A. Likierman
- Prof. J. V. Rosenfeld
- Mrs. B. M. Shanahan
- Mrs. S. E. Smith
- Dr. P. J. Wolgen

Directors have been in office since the start of the financial year to the date of this report unless otherwise stated.

Executive Summary

Message from the Chief Financial Officer

In my capacity as Chief Financial Officer, I take the opportunity to provide commentary on the headline results of the CLINUVEL Group of companies for the half year to 31 December 2022. A more detailed explanation to these financial results can be found within this report on pages 4 – 10.

Headline Results

Half Year Financial Report Ended 31 December 2022

(compared to the six months to 31 December 2021, or 'pcp')

1. Growth in commercial distribution programs, a 19% increase to Revenues;
2. Controlled Expenses, supporting expansion of the development pipeline and business growth, 1% increase; and
3. A 94% increase to NPAT, 67% increase to EBIT;
4. 16% growth in Cash and Cash Equivalents since the start of reporting period to $140.7 million, net assets increased 11%.
5. Growth in earnings per share of 93%.

1. REVENUES: increase of 19% (pcp)[1] to $29.36 m

This excellent result was due to a continued focus on maximising EPP patient outreach in Europe and the USA. Total prescriptions of SCENESSE® implants rose, overall patient numbers grew, more treatment centers were onboarded, and price stability was maintained across those regulatory jurisdictions where revenues are generated. Revenues have grown incrementally since commencement of commercial distribution. Over the five years to December 2022, we have recorded a total revenues compounded growth rate of 33%. This is a solid result over a sustained period of time.

2. EXPENSES: increase by 1% (pcp) to $16.38m

Expenses were contained to a negligible 1% increase. A number of categories require brief mentioning. Our largest expense category is our people, and head count expansion pushed our personnel expenses to exceed $6.1m, a 19% increase to the pcp. Materials and related expenses increased 14%, but this needs to be considered with bringing to account over $2.6m of purchases onto the balance sheet as inventory, ensuring capacity to service our commercial distribution programs in the near term and beyond.

Increased activities across most business segments saw rises of 46% in finance, corporate and general expenses, 5% rise in clinical and non-clinical, and 128% in marketing and branding costs. At the same time, we saw a decline of 12% in legal and insurance charges.

Finally, a non-cash accounting charge of $3.8 million, reflecting a 19% increase to the value of performance rights granted to eligible staff across the Group, including the Managing Director. Within this context, the Company issues periodically (usually every 4 years) performance rights to staff and executive managers, which carry up to a 4-year vesting period, during which time predetermined performance conditions need to be met.

We had previously projected overall expenditures, excluding investments of a capital nature, to reach $175 million for the five financial years ending June 2025. We are comfortably on track to remain within this projection. We are half-way along the timeline and to date our result of total expenditures has reached approximately 41% of this target.

3. NET PROFITS AFTER TAX: increase of 94% (pcp)

Prominent is the surge in net profit after tax, owing to an increase in commercial sales of SCENESSE® against curbing overall costs during the reporting period, combined with the favourable movement in temporary differences to our deferred tax position.

4. NET ASSETS: an increase of 11% (pcp)

We finished the half year in an even stronger cash in bank position, with cash held increasing 16% to exceed $140.7 million. These reserves enable the Group to sustain further investments as part of its life cycle management of afamelanotide, and to the regulatory dossier of NEURACTHEL®, its proprietary portfolio of small molecules, and the development of its specialised consumer product lines (4). The position affords the company with an enviable financial independence to self-finance its planned operations without the burden of servicing increasingly expensive bank debt, nor rely on volatile capital markets.

5. EPS: an increase of 93% (pcp)

With a 93% increase in NPAT, the measure of earnings per share similarly trended upward, moving from 11.9 cents per share to 23.0 cents per share. The profitability of the company allocated to its owners continues to rise and is supported by the long-term strategy to capital markets.

Financial Updates

At the end of each quarter the Company has issued a cash flow report and in doing so, has voluntarily complied with ASX Listing Rules to release this information for nearly five years beyond

its obligation to do so. As we mature into the future, we intend to dispense with this form of financial update. Nevertheless, we will continue to report on the financial performance and state of the Company each half year, and full year as part of our mandatory reporting requirements. In addition, the Company will aim to issue up to two Strategic Updates and up to six regular newsletters annually and we will provide further financial updates throughout the year as part of these communications.

Summary

Overall, I am very pleased with the set of results for the six months ending 31 December 2022. We have remained on track in seeing through our business plan, boosted by increases in both revenues and profits, whilst controlling the growth in our expense base. Against a backdrop of easing global economic growth, and global inflationary pressures, we feel these results have exceeded expectations. We are dedicated to serving patients and shareholders and continue to work tirelessly with the aim to deliver strong full year results for FY2023.

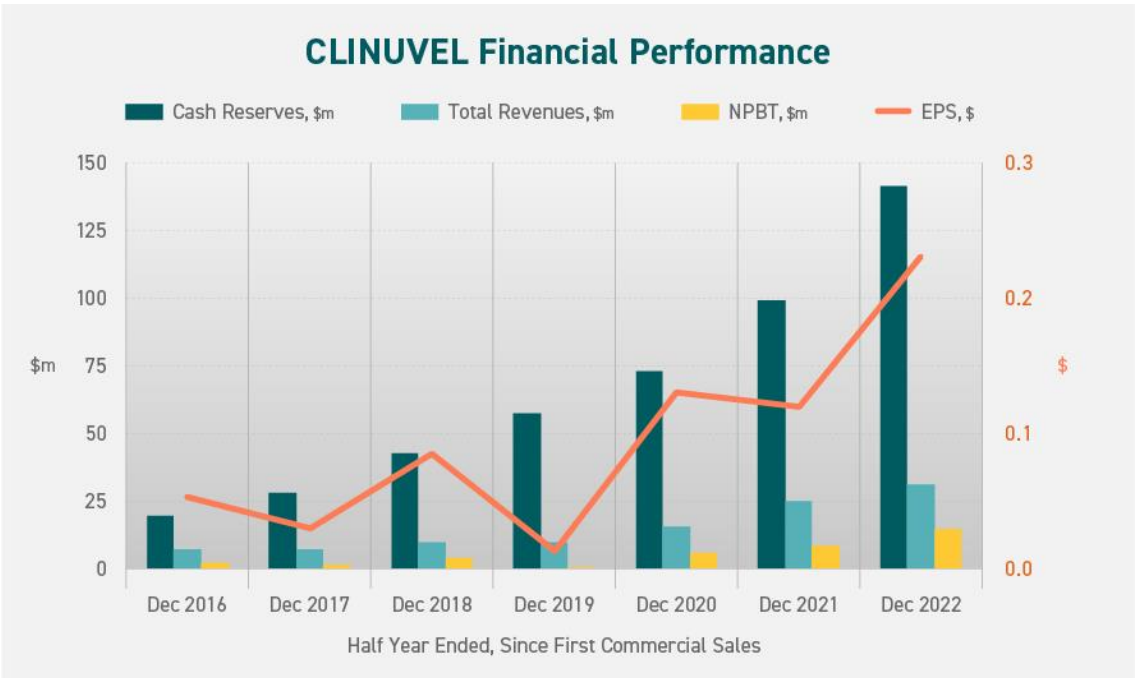
Darren Keamy
Chief Financial Officer

Key Financial Highlights

Positive Results in the Half Year to 31 December 2022

	31 December 2022	31 December 2021	Change
Revenues, $	29,355,042	24,631,266	**+19.2%**
Expenses, $	16,376,227	16,203,455	**+1.1%**
Profit after tax, $	11,387,675	5,870,380	**+94.0%**
Total net assets, $	139,171,112		**+10.8%***
Cash, $	140,703,376		**15.8%***
Basic Earnings per Share, $	0.230	0.119	**93.3%**
Net Tangible Assets Backing per share, $	2.777	2.144	**29.5%**

*Increase from 30 June 2022.

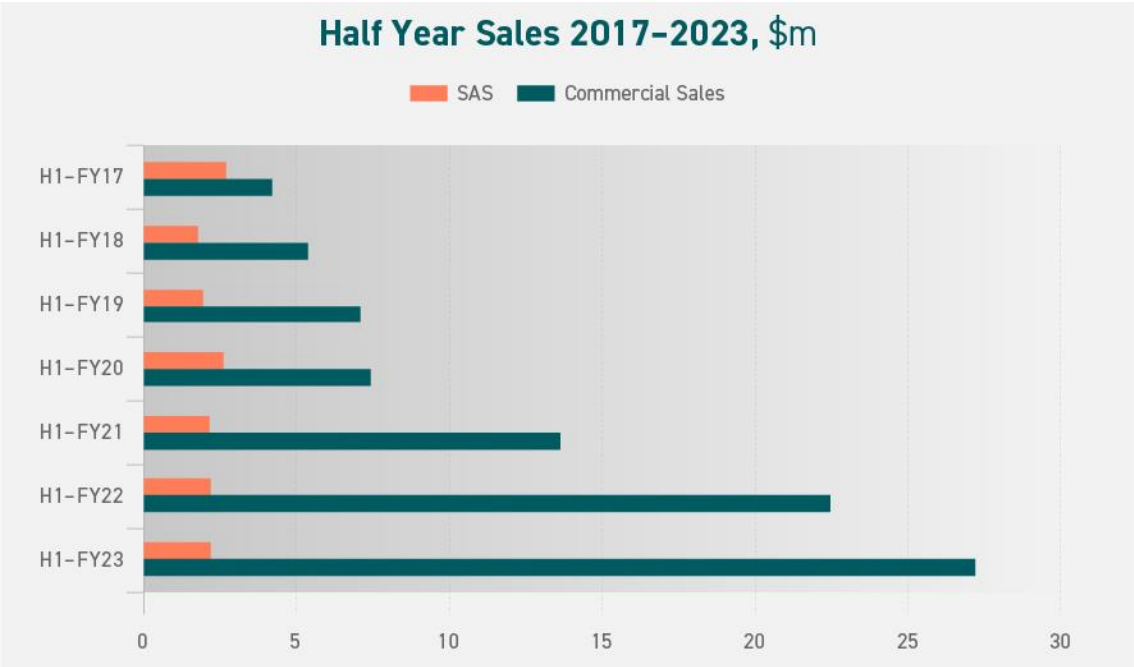


Details of the Financial Results

Revenues

H1-FY2023	H1-FY2022	Difference	%
$29.355m	$24.631m	$4.724m	19% increase

Total revenues from the distribution programs yielded a 19% increase to the pcp. This has followed the consistent trend of revenue growth since 2016, when commercial sales first commenced. The extent of the revenue growth for the July to December half years is illustrated below – this period is the highest recorded for a July to December half year, driven by patient demand, increased treatments, and greater access to patients from maturing distribution.



Commercial Sales

H1-FY2023	H1-FY2022	Difference	% reported
$27.194m	$22.467m	$4.727m	21% increase *18.55% increase on constant currency basis

*H1-FY2023 revenues converted to A$ at the average conversion rate used for sales in the same month for H1-FY2022

Revenues from commercial sales of distribution of SCENESSE® increased 21% in the six months to 31 December 2022, compared to the pcp. This result was driven by a combination of:

- Greater patient numbers receiving the drug upon the US commercial distribution program entering its third year from initial launch. The number of new Specialty Centers participating in the program willing to administer SCENESSE® also grew, rising 10% by December 2022. The number of national and local private insurers has also grown by more than 10%. The payment coverage for SCENESSE® in the US continues to be funded by private health providers and Medicare agencies under the Prior Authorization cost-control process. With relevant healthcare procedure codes in place, swifter access is now available for new patients. Characteristic of the SCENESSE® treatment, a cyclical pattern is seen, whereby more demand is expected from February to November, and less during the winter months on both continents.
- Meeting long-term patient demand serviced through European EPP Expert Centres, which have become experienced in administering SCENESSE®, and collecting data under the European post-authorisation safety study (EMA). Patient numbers have increased in selected

EPP Expert Centres, particularly in those centres which have built more capacity for outpatient care. CLINUVEL continues to maintain a policy to charge a uniform net price for SCENESSE® across all European countries, while discussions are ongoing with other payors either directly or with authorized agencies.

Reimbursements – Special Access Schemes

H1-FY2023	H1-FY2022	Difference	% reported
$2.161m	$2.164m	-$0.003m	-0.1% decrease *-4.4% decrease on constant currency basis

Reimbursement under Special Access Schemes in Switzerland remained constant. Treatment access in Switzerland has enabled EPP patients to assume a normal symptom-free life for over 10 years.

Other Income

H1-FY2023	H1-FY2022	Difference	%
$0.284m	$0.159m	$0.125m	79% increase

The presentation currency of the Group is Australian dollars. The Group invoices its commercial sales and special access reimbursement invoices in non-Australian dollar currencies. Trade debtors are recognised in non-Australian currencies and cash receipts are received in non-Australian dollar currencies. Non-Australian dollar currencies are held to meet ongoing working capital requirements, which become payable in those currencies. Unrealised adjustments are brought to account to restate trade debtors, trade creditors and foreign currencies held into Australian dollar currency as at each reporting date. Unrealised adjustments from restating debtors, creditors and cash held in a currency different to the entity's functional currency was a $0.195m gain in the period. Government grants for the period was limited to Jobs Support Scheme payments in Singapore of $0.011m. Other income also includes realised gains of $0.077m from exchange rate movements on transactions paid in a currency different to the entity's functional currency.

Interest Income

H1-FY2023	H1-FY2022	Difference	%
$1.337m	$0.139m	$1.198m	862% increase

The Group's strong financial performance saw positive cash flows throughout the reporting period, whereby cash and cash equivalents grew by 16%. The period saw a significant rise in the official interest rates, enabling banks to increase the yield on interest-bearing accounts on offer. The combination of these two factors enabled the Group to:

(a) Increase average cash at hand, held in term deposits and in interest-bearing working capital bank accounts over the 6 months to 31 December by 73%, and

(b) earn a higher average yield on interest on its term deposits, and in interest-bearing working capital bank accounts over the 6 months to 31 December of 200 basis points.

Expenditures

H1-FY2023	H1-FY2022	Difference	%
$16.376m	$16.203m	$0.173m	1% increase

The modest increase is outlined in the Executive Summary and Key Highlights section.

Personnel

H1-FY2023	H1-FY2022	Difference	%
$6.097m	$5.105m	$0.992m	19% increase

The expansion strategy of the business requires the necessary structure to be in place to drive forward innovation and commercialisation, and to facilitate entry into a specialized consumer market. As a result, staff numbers increased to fill newly created roles considered integral to execute these plans. The total headcount between the two reporting periods increased by over 16%. The largest staffing increases were in the areas of Clinical Affairs and Quality Assurance, Communications, Branding and Marketing. In an environment of demand for skilled personnel, cost increases to base salary levels were also recognised to ensure the workforce remained globally competitive and incentivised. To support personnel retention, promote market competitiveness, and to encourage work productivity, in the second half of FY2022 the Group implemented a new structured benefits program for its global workforce.

People and Environment are one of the Group's five principal values, which are central to all of the Group's working practices. The Group aspires to create an environment, where our people can develop, excel in their careers, and become the next generation of industry-leading managers.

Materials and Related Expenses

H1-FY2023	H1-FY2022	Difference	%
$4.588m	$4.037m	$0.551m	14% increase

Materials and related expenses primarily reflect purchases to support the acquisition and movement of materials used in the production of finished product by the Group's contract manufacturers. Expenses also cover other purchases of materials related to the development programs.

The Group engaged its contract manufacturer of SCENESSE® during the reporting period to proceed with a number of batch manufacturing campaigns to answer longer-term commercial demand, as well as to meet forecasted clinical supply needs of the expanded R&D program. Further campaigns to manufacture finished product are intended in the course of FY2023. To facilitate further manufacturing campaigns, ordering occurred on both raw material peptide and excipients during the reporting period.

Materials, supplies and related conversion expenses were incurred for the diversified formulation development programs. Part of the costs were attributed to method and process development work completed on the ACTH drug substance aimed at advancing NEURACTHEL® formulations. Another contributor to the expenses was the first purchase and transfer of materials to the contract manufacturer, which is engaged in manufacturing the first OTC topical formulation, planned for launch in FY2023.

Share Based Payments

HY-2023	HY-2022	Difference	%
$3.827m	$3.223m	$0.604m	19% increase

This is a non-cash accounting charge for share-based payments in the form of performance rights granted to select staff across the Group, including the Managing Director.

Performance Rights, being an option to acquire ordinary shares of CLINUVEL PHARMACEUTICALS LTD for nil exercise price, are offered from time to time to:

(a) retain and motivate staff to drive the long-term growth and success of the Company; and

(b) to align their interests with increased shareholder wealth over the longer term.

During H1-FY2022, the Group issued 743,174 unlisted performance rights to staff of the CLINUVEL group of companies and their value at grant date of 26 August 2021 was between $18.73 and $26.22 per performance right. The increase in the non-cash accounting charge for share-based payments reflects the expensing of the 743,174 performance rights over a four-month period in H1-FY2022 compared to a full six months in H1-FY2023.

The probability of achievement of 'non-market' performance conditions attached to each performance right are re-assessed at each reporting period. As at 31 December 2022, the assessment of the remaining 696,111 performance rights issued to staff in H1-FY2022 was for only 34% of the total issued rights, which will likely vest at their expiry date. For the Managing Director's 2019 performance rights, the assessment is 18% of his issued performance rights.

With an expiry date of 20 November 2023, each staff member who has been granted performance rights must be employed by CLINUVEL on that day, for him or her to exercise those performance rights, whose underlying performance conditions may have otherwise been met.

50,814 performance rights lapsed during H1-FY2023. No new performance rights were issued in H1-FY2023.

Commercial Distribution

H1-FY2023	H1-FY2022	Difference	%
$1.307m	$1.176m	$0.131m	11% increase

Commercial distribution expenditures ensure our product is provided to end users under Good Distribution Practice and to satisfy our risk management commitments with regulatory agencies. These activities include pharmacovigilance, quality systems, safety reporting, PASS Registry data capture and dossier updates.

The expense result was impacted by increased volumes in product movement to service the growth in our European and US commercial distribution programs. Key factors driving this result include:

- manufacturing royalty expenses from increased commercial sales volumes;
- increased interaction with regulatory authorities related to maintenance of dossier and regulatory inspections of systems supporting commercial distribution;
- streamlined activities resulting in reduced expenditures towards data collection, handling and processing of information generated from the post-authorisation safety study in Europe. Data analysis and storage play a critical role in maintaining a risk management plan as agreed with the European Medicines Agency (EMA); and
- post-marketing regulatory activities and reliance on third party providers.

Finance, Corporate and General

H1-FY2023	H1-FY2022	Difference	%
$1.268m	$0.868m	$0.400m	46% increase

Finance, corporate and general expenses drive the overall internal support functions necessary to ensure the execution of the multi-pronged growth strategy. The Group operates in seven different locations, with a workforce across four different continents which require the infrastructure and support to fulfil their assigned functions. Examples of expenditures include IT, corporate support, audit and tax, listing and registry fees, travel, and short-term rents.

In H1-FY2023 the Group saw a significant return of staff travel when compared to the pcp accounting for almost 80% of the increase in costs. Travel restrictions were largely lifted in relevant jurisdictions and activities across all Group functions supported the need for staff and officers to travel.

Other factors contributing to the increase in finance, corporate and general expenses include:

(a) a rise in professional services in response to the increasing complexity and expansion of the Company across multiple jurisdictions; and

(b) higher IT support-related fees to assist the expansion of the workforce and its systems.

Legal, Insurance and IP

H1-FY2023	H1-FY2022	Difference	%
$0.543m	$0.619m	$0.076m	12% decrease

Expenditures towards external legal support, patent & trademark expenses and various insurances play an important role in the Group's risk management framework. It contributes towards protecting the Group's most important assets from many forms of loss, ensuring compliance and affording a competitive advantage in the market.

The Group takes out various business-related insurances as part of its overall risk management strategy. In H1-FY2023 increased market competition in underwriting certain business risks, including Directors and Officers insurance, led to decreases to insurance premiums. Fees for third party legal assistance were received for a range of matters in the ordinary course of business, including general asset protection and the Group's responses to various pricing negotiations in Europe. There was also a 10% decrease to IP fees compared to the prior period, reflecting the rationalisation of patents and trademarks.

Clinical & Non-Clinical Development

H1-FY2023	H1-FY2022	Difference	%
$0.590m	$0.564m	$0.026m	5% increase

Clinical & non-clinical development expenses reflect the direct investment of the Group in its clinical trial programs of SCENESSE® beyond EPP, along with the activities related to product development, paediatric formulations and new products, including PRÉNUMBRA® and NEURACTHEL®. This category includes analytical testing, pre-clinical and non-clinical activities.

The increase of controlled expenses is in line with the strategic plan outlined in October 2020 to advance its research and development initiatives of new products and new markets with $175 million expenditure planned for the 5 years commencing FY2021.

These expenses for H1-FY2023 were driven by the advances in the clinical programs including:

(a) evaluating SCENESSE® in three clinical studies in Xeroderma Pigmentosum (XP) and a control of healthy volunteers with fair skin types prone to DNA photodamage and increased risk of skin cancers;

(b) a new clinical study (CUV104), evaluating the safety and efficacy of afamelanotide as a monotherapy in vitiligo, focussing on patients with darker skin complexions;

(c) data management services for the CUV801 clinical study evaluating the safety and efficacy of afamelanotide in arterial ischaemic stroke (AIS); and

(d) preparatory work towards the follow-on study CUV803, evaluating the new drug candidate PRÉNUMBRA® Instant (afamelanotide) as a treatment for patients diagnosed with AIS.

An overview of the clinical program is provided in the Review of Operations section below.

Offsetting the expense result toward these programs was a reduction in regulatory-related fees and pre-clinical assessments of SCENESSE® in alternative formulations.

Depreciation and Amortisation

H1-FY2023	H1-FY2022	Difference	%
$0.376m	$0.393m	$0.017m	4% decrease

The decrease in depreciation and amortisation charges is attributable to fixed assets deployed within the RDI Centre in Singapore whose value is consumed over time at a diminishing rate. The Company is committed to ensuring its state-of-the-art Singapore laboratories is equipped to support its product development and formulation programs. The commitment is reflected in expenditures towards property, plant and equipment, totalling $0.395m for the period.

Communication, Branding and Marketing

H1-FY2023	H1-FY2022	Difference	%
$0.410m	$0.180m	$0.230m	128% increase

The Group has invested in resources to expand its visibility among existing but predominantly new audiences. It is building a team of professionals with an expertise in diverse media channels and product marketing to prepare for new product launches.

In H1-FY2023 the Company intensified its communications outflow, conducting targeted presentation roadshows, or 'Soirées', in major cities bringing together analysts, banks and their clients, brokers and family offices, and shareholders to develop further understanding of the Company's mission. Additionally, social media channels were further developed to reach targeted audiences.

Changes in Inventories of Raw Materials, Work in Progress and Finished Goods

H1-FY2023	H1-FY2022	Difference	%
($2.631m)	$0.040m	$2.671m	6678% decrease

Changes in inventories of raw materials, work in progress and finished goods represents the adjustment to inventory building expenditures in excess of the current rate of commercial sales. For H1-FY2023, an adjustment of $2.631 million was recorded to account for an increase in the value of inventory held since 30 June 2022. For H1-FY2022, the result was a $0.040 million loss in the expense result, reflecting a decrease to the value of inventory held.

Income Tax Expense

H1-FY2023	H1-FY2022	Difference	%
$3.212m	$2.855m	$0.357m	12% increase

In H1-FY2023, the Group was exposed to income tax on taxable profit derived from its operations, resulting in a debit to income tax expense of $3.212 million. The result included:

- benefits received from utilising unused tax losses in certain subsidiaries;
- decreases in temporary differences primarily related to exchange rate movements that result in decreases to a deferred tax liability for the business

Earnings per Share

The weighted number of issued ordinary shares remained unchanged at 49,410,388 for the current period and for the pcp. Basic earnings per share for the period ended 31 December 2022 was $0.230 compared to $0.119 per share for the same period to 31 December 2021. The change represents a 93% improvement to earnings per share.

Review of Operations

Company Overview

CLINUVEL is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for specialised populations. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, assisted DNA repair, repigmentation, and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel, and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP).

Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA.

Commercial Operations

CLINUVEL distributes SCENESSE® for EPP patients in Europe, the USA, and Israel. Throughout the period, commercial operations have focused on:

- increasing access to treatment for EPP patients, actively liaising with porphyria treatment centres and organisations responsible for the ongoing reimbursement treatment costs; and
- ensuring continuing compliance with global and local regulatory requirements, including the collection of key data through ongoing post-authorisation safety studies.

European and Swiss Distribution

Demand for SCENESSE® treatment continued in the European Union and Switzerland, with patients treated through a network of EPP Expert Centres.

During the period CLINUVEL submitted a formal application to the European Medicines Agency (EMA) to expand the approved indication for SCENESSE® in the European Union to include the treatment of adolescent EPP patients (aged 12-17).

US Distribution

Patient treatment uptake, and ongoing use in the US continues to increase as CLINUVEL approaches the third anniversary of commercial distribution. A network of more than 40 Specialty Centers has been built to provide treatment to EPP patients across the US. Over 100 national and local insurers are reimbursing the cost of treatment according to individual insurance plans under Prior Authorization arrangements.

Distribution in Other Jurisdictions

Patients in Israel are being treated and we are committed to treat patients in Australia and gain regulatory approvals to distribute SCENESSE® in other jurisdictions.

New Pharmaceutical Product Development

Drawing on its expertise in photoprotection and knowledge of the melanocortin family of hormones, CLINUVEL is developing a range of pharmaceutical products for patient groups and dermatocosmetic products for targeted audiences at Highest Risk of exposure to light in the general population.

The pharmaceutical product portfolio encompasses:

- Expanding the clinical indications for SCENESSE® (refer below).
- PRÉNUMBRA®, liquid formulations of afamelanotide, developed in Instant and Modified-release forms to provide flexible treatment options in a range of indications for adults and paediatric patients. PRÉNUMBRA® Instant is intended for first use in the clinic in the next study on AIS (refer below).
- A novel formulation of the melanocortin adrenocorticotropic hormone (ACTH), NEURACTHEL®. NEURACTHEL® Instant and NEURACTHEL® Modified-release are intended for patients with neurological, endocrinological and degenerative disorders. During the first half of FY2023, work on the manufacturing process and analytical method development was completed. CLINUVEL intends to develop NEURACTHEL® to treat children with infantile spasms and patients with multiple sclerosis, with other indications to be disclosed.
- Topical formulations of melanocortins for a range of indications being developed by the Singapore RDI Centre. These include alpha-Melanocyte Stimulating Hormone analogues, CUV9900, Parvysmelanotide (VLRX001), and Phimelanotide (VLRX002).

The development of the dermatocosmetic product range is discussed in the Healthcare Solutions section below.

Expanded Clinical Program

CLINUVEL is executing an innovative clinical program to evaluate the safety and efficacy of afamelanotide for a range of patients with genetic, metabolic, systemic, and life-threatening, acute disorders. The expanded clinical program is summarised below:

DNA Repair Program

The DNA Repair Program aims to assess the ability of afamelanotide to assist the repair of DNA of skin damaged by UV radiation and visible light. Deficient DNA repair mechanisms (nucleotide excision repair and basic excision repair) place over two billion individuals globally at increased risk of skin cancer. CLINUVEL's initial clinical focus is on patients with the rare genetic disorder XP, a life-threatening disorder caused by an inability to repair UV-provoked DNA skin damage.

CLINUVEL's initial clinical program involves three studies and up to 22 individuals:

- CUV156 – commenced October 2021, six patients with the XPC complementation, first results released;
- CUV151 – commenced February 2022, up to ten healthy volunteers with fair skin types (Fitzpatrick I-III), serving as control group for XP, study completed and first results released; and
- CUV152 – commenced March 2022, six patients with either the XPC or XPV complementation.

Preliminary results of CUV156 and CUV151 were announced in January 2023. CUV156 showed afamelanotide was well tolerated and assists XPC patients by reducing UV-provoked skin damage. First results from CUV151 showed that afamelanotide reduced the UV-erythema dose-response in nine volunteers, indicative of reducing the first signs of UV-induced DNA damage.

Readouts from all three studies are expected during 2023. Subject to the results of these studies, two additional studies – CUV153 and CUV154 – are planned, taking the number of XP patients involved in the studies to 38 with a total study population of up to 48.

Arterial Ischaemic Stroke (AIS)

AIS accounts for around 85% of the estimated 15 million strokes suffered worldwide each year. Stroke is a leading cause of serious, long-term disability and is a significant burden on health systems. Afamelanotide is known to offer neuroprotection and act as a potent anti-oxidative hormone. As a drug therapy, afamelanotide is assessed on its ability to improve blood flow and increase the delivery of oxygen and nutrients to the brain.

The world's first clinical study (CUV801) assessing afamelanotide as a treatment for stroke commenced in June 2021. The positive results of the study, involving six patients and multiple doses of afamelanotide, were announced in May 2022. Afamelanotide was evaluated as safe in mild to moderate AIS with five patients achieving improved scores on the National Institutes of Health Stroke Scale. One patient with a complex cardiovascular history passed away following a second stroke. Brain scans of the five patients showed reduction of affected tissue and all demonstrated strong functional recovery up to 42 days after treatment.

This study has provided confidence to advance the AIS program, with the next study (CUV803). Pending regulatory and ethics approvals, CUV803 is expected to commence during 2023.

Vitiligo

Vitiligo is a common skin disorder affecting between 0.1-2% of the world's population, in which the pigment producing cells of the skin (melanocytes) are absent or demonstrate lack of activity. The resulting lighter, depigmented patches of skin impacts appearance and causes psychological and emotional distress. The Virtual Public Meeting on Patient-Focused Drug Development for Vitiligo held by the US Food & Drug Administration (FDA) in 2021 highlighted the disorder forces those with vitiligo to avoid sun exposure, adversely impacting their lifestyle. In addition, the psychosocial impact and profound loss of identity translates to loss of not only quality of life, but also an inhibited way of life.

CLINUVEL's initial studies, (CUV102 and CUV103), showed afamelanotide is able to repigment vitiliginous lesions (depigmented patches of skins) in combination with narrowband UVB phototherapy (NB-UVB). The vitiligo program is now being advanced with a focus on patients of darker skin complexion (Fitzpatrick IV-VI), for whom the need for repigmentation treatment is

regarded as the greatest. Afamelanotide is being assessed as a monotherapy in the ongoing clinical study CUV104. A larger study, evaluating the effects of the drug in combination with NB-UVB (CUV105), is expected to commence in 2023.

Healthcare Solutions

The Healthcare Solutions Division is translating the accumulated technological know-how and expertise in melanocortins built over two decades of research and development to the general population in need of protection and regeneration from exposure to UV and high energy visible (HEV) light. The focus in the half year to December 2022 was to complete product development work through the Singapore RDI Centre and advance the digital marketing strategy. The first phase of this strategy has been to inform targeted audiences of the impact on the skin of solar exposure by engaging CLINUVEL Ambassadors (CUVAs) and CLINUVEL Intriguing Professionals (CUVIPs). Over 500,000 people in the targeted immunocompromised, skin cancer susceptible, and extreme outdoor audiences have been reached.

The first products shall be released in 2023, commencing with a polychromatic solar screen, CYACÊLLE® which will provide protection to a wider range of UV light than the broadband sunscreens currently available. This will be followed by the second product with reflective and refractive properties to manage solar exposure. Subsequent products in development containing melanocortins will assist DNA skin repair, and the stabilisation of melanogenesis.

Other Activities

The Company held the 2022 Annual General Meeting (AGM) of Shareholders on 26 October, returning to an 'in-person' meeting. It was also streamed live for the first time. A panel discussion involving CLINUVEL Directors and executives was hosted by independent analyst Dr David Stanton of Jefferies Australia. Shareholder's questions were answered in an innovative and informative session. All the resolutions presented to the meeting were passed, supporting the ongoing strategy and operations of the business.

In September, Strategic Update V was presented at the Monaco Soirée and the Company also presented to the H.C. Wainwright Global Investment Conference. In October, a Soirée was held with stakeholders in Sydney, followed by an investor presentation in Melbourne, ahead of the AGM. In November, CLINUVEL presented to the Jefferies London Healthcare Conference, the Wilsons Rapid Insights Conference, and the Morgans Value in the Vines Conference.

All the Company's announcements and key media interviews during this period are available on the CLINUVEL website, with other updates available on the CLINUVEL News website.

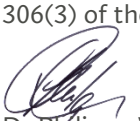
Included in this document is the Half Year Report Appendix 4D, together with the Financial Report, this Directors' Report and Declaration and Audit Independent Review Report relating to the half year ended 31 December 2022.

This Half Year Report forms part of this announcement to the Australian Securities Exchange Limited and should be read in conjunction with CLINUVEL's Annual Report for the year ended 30 June 2022.

Auditor Independence Declaration

The independence declaration of our auditor as per section 307C of the Corporations Act is attached and forms part of the Directors' Report.

Signed in accordance with a resolution of the Board of Directors made pursuant to section 306(3) of the Corporations Act 2001.



Dr Philippe Wolgen
Managing Director
Dated this 24th day of February 2023

Grant Thornton Audit Pty Ltd
Level 22 Tower 5
Collins Square
727 Collins Street
Melbourne VIC 3008
GPO Box 4736
Melbourne VIC 3001
T +61 3 8320 2222

Auditor's Independence Declaration

To the Directors of Clinuvel Pharmaceuticals Limited

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Clinuvel Pharmaceuticals Limited for the half-year ended 31 December 2022, I declare that, to the best of my knowledge and belief, there have been:

a no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and

b no contraventions of any applicable code of professional conduct in relation to the audit.

Grant Thornton Audit Pty Ltd
Chartered Accountants

M A Cunningham
Partner – Audit & Assurance

Melbourne, 24 February 2023

Statement of profit or loss and other comprehensive income
For the half year ended 31 December 2022

	CONSOLIDATED	
	31 December 2022	31 December 2021
	$	$
Revenues		
Commercial sales of goods	27,193,717	22,467,332
Sales reimbursements	2,161,325	2,163,934
Total revenues	**29,355,042**	**24,631,266**
Interest income	1,337,297	139,339
Total interest income	**1,337,297**	**139,339**
Other Income (loss)		
Unrealised gain (loss) on restating foreign currency balances and currencies held	195,440	(16,010)
Realised net currency gain (loss) on transactions	77,032	(34,982)
Government grants	11,367	209,670
Total other income	**283,839**	**158,678**
Expenses		
Personnel-related	6,097,368	5,104,904
Materials and related expenses	4,587,757	4,036,712
Share-based payments	3,827,168	3,223,269
Commercial distribution	1,307,064	1,175,653
Finance, corporate and general	1,268,072	868,121
Clinical and non-clinical development	590,253	563,977
Legal, insurances and IP	543,014	618,574
Communication, branding and marketing	410,119	179,825
Depreciation and amortisation	376,086	392,695
Changes in inventories of raw materials, work in progress and finished goods	(2,630,674)	39,725
Total expenses	**16,376,227**	**16,203,455**
Profit before related income tax expenses	**14,599,951**	**8,725,828**
Income tax expense	3,212,276	2,855,448
Operating profit after income tax	11,387,675	5,870,380
Net profit for the year	**11,387,675**	**5,870,380**
Other comprehensive income		
Items that may be re-classified subsequently to profit or loss		
Exchange differences of foreign exchange translation of foreign operations	373,640	695,518
Other comprehensive income for the period, net of income tax	373,640	695,518
Total comprehensive income for the period	**11,761,315**	**6,565,898**
Basic earnings per share – cents per share	23.0	11.9
Diluted earnings per share – cents per share	22.0	11.4

This statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes to the financial statements.

Statement of financial position as at 31 December 2022

	CONSOLIDATED	
	31 December 2022	30 June 2022
	$	$
Current assets		
Cash and cash equivalents	140,703,376	121,509,282
Trade and other receivables	10,664,578	16,201,937
Inventories	4,462,565	1,831,891
Other assets	981,526	1,039,453
Total current assets	**156,812,045**	**140,582,563**
Non-current assets		
Property, plant and equipment	1,531,628	1,540,702
Right-Of-Use assets	996,203	1,159,642
Intangible assets	185,030	185,030
Deferred tax assets	767,892	481,600
Total non-current assets	**3,480,753**	**3,366,974**
Total assets	**160,292,798**	**143,949,537**
Current liabilities		
Trade and other payables	4,267,945	3,277,857
Income tax payable	11,992,369	7,279,449
Lease liabilities	322,542	315,068
Provisions	1,239,951	2,859,828
Total current liabilities	**17,822,807**	**13,732,202**
Non-current liabilities		
Lease liabilities	813,125	941,463
Provisions	113,730	101,548
Deferred tax liabilities	2,372,024	3,615,281
Total non-current liabilities	3,298,879	4,658,292
Total liabilities	**21,121,686**	**18,390,494**
Net assets	**139,171,112**	**125,559,043**
Equity		
Contributed equity	151,849,375	151,849,375
Reserves	16,312,904	12,112,096
Accumulated losses	(28,991,167)	(38,402,428)
Total equity	**139,171,112**	**125,559,043**

This statement of financial position should be read in conjunction with the accompanying notes to the financial statements.

Statement of changes in equity
for the half year ended 31 December 2022

	Share Capital	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
	$	$	$	$	$
Balance at 1 July 2021	**151,849,375**	**4,343,422**	**674,405**	**(58,129,768)**	**98,737,434**
Employee share-based payment options	-	3,209,531	-	13,738	**3,223,269**
Dividends paid	-	-	-	(1,235,266)	**(1,235,266)**
Transactions with owners	**151,849,375**	**7,552,953**	**674,405**	**(59,351,296)**	**100,725,437**
Profit for the year	-	-	-	5,870,380	**5,870,380**
Other comprehensive income: Exchange differences of foreign exchange translation of foreign operations	-	-	695,518	-	**695,518**
Total other comprehensive income	-	-	**695,518**	-	**695,518**
Balance at 31 December 2021	**151,849,375**	**7,552,953**	**1,369,923**	**(53,480,916)**	**107,291,335**
Balance at 1 July 2022	**151,849,375**	**10,380,258**	**1,731,838**	**(38,402,428)**	**125,559,043**
Employee share-based payment options	-	3,827,168	-	-	**3,827,168**
Dividends paid	-	-	-	(1,976,414)	**(1,976,414)**
Transactions with owners	**151,849,375**	**14,207,426**	**1,731,838**	**(40,378,842)**	**127,409,797**
Profit for the year				11,387,675	11,387,675
Other comprehensive income: Exchange differences of foreign exchange translation of foreign operations	-	-	373,640	-	**373,640**
Total other comprehensive income	-	-	**373,640**	-	**373,640**
Balance at 31 December 2022	**151,849,375**	**14,207,426**	**2,105,478**	**(28,991,167)**	**139,171,112**

This statement of changes in equity should be read in conjunction with the accompanying notes to the financial statements.

Statement of cash flows
for the half year ended 31 December 2022

	CONSOLIDATED	
	31 December 2022	31 December 2021
	$	$
Cash flows from operating activities		
Receipts from customers	36,134,507	30,905,099
Payments to suppliers and employees	(15,462,848)	(14,129,762)
Interest received	340,110	113,196
GST and VAT refunds	11,279	225,689
Government grants	-	210,078
Net cash provided by operating activities	**21,023,048**	**17,324,300**
Cash flows from investing activities		
Payments for property, plant and equipment	(395,085)	(56,444)
Net cash used in investing activities	**(395,085)**	**(56,444)**
Cash flows from financing activities		
Dividends paid	(1,976,414)	(1,235,266)
Repayment of lease liabilities	(169,657)	(130,641)
Repayment of interest	-	(17,451)
Net cash provided by financing activities	**(2,146,071)**	**(1,383,358)**
Net increase in cash held	**18,481,892**	**15,884,498**
Cash and cash equivalents at beginning of the year	**121,509,282**	**82,690,982**
Effects of exchange rate changes on foreign currency held	712,202	416,869
Cash and cash equivalents at end of the year	**140,703,376**	**98,992,349**

This statement of cash flows should be read in conjunction with the accompanying notes to the financial statements.

Notes to the condensed financial statements
For the Half Year Ended 31 December 2022

Statement of Accounting Policies, General Information and Basis of Preparation of The Half Year Financial Report

The half year financial report is a general-purpose financial report prepared in accordance with the Corporations Act 2001 and AASB 134 Interim Financial Reporting. The half year financial report does not include notes of the type normally included in an Annual Report and shall be read in conjunction with the most recent annual financial report. The accounting policies adopted in the preparation of the half year financial report are consistent with those adopted and disclosed in the Group's 2022 annual financial report for the financial year ended 30 June 2022.

Contingent liabilities and assets

There are no known significant contingent liabilities or contingent assets as at the date of this report.

Dividends paid or recommended

A final fully franked dividend for 2022 of 4.0 cents per share was paid on 21 September 2022 and a final fully unfranked dividend for 2021 of 2.5 cents per share was paid on 17 September 2021.

Earnings per Share

Basic Earnings per Share

Basic earnings per share is determined by dividing net profit after income tax attributable to members of the Company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year.

Diluted Earnings per Share

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares.

Basic earnings per share were $0.230 on a weighted average number of 49,410,338 issued ordinary shares as at 31 December 2022. This compares with restated basic earnings per share of $0.119 as at 31 December 2021 on a weighted average number of 49,410,338 issued ordinary shares.

Events subsequent to balance date

There has not been any matter that has affected, or could significantly affect, the operations of the Consolidated Entity subsequent to balance date.

Revenue

The Group's revenue disaggregated by primary geographical markets is as follows:

	Six months to 31 December 2022			Six months to 31 December 2021		
	Commercial sales of goods	Sales reimbursements	Total	Commercial sales of goods	Sales reimbursements	Total
	$'000	$'000	$'000	$'000	$'000	$'000
Europe & USA	27,194	-	27,194	22,467	93	22,560
Switzerland, Others	-	2,161	2,161	-	2,071	2,071
Total	**27,194**	**2,161**	**29,355**	**22,467**	**2,164**	**24,631**

The Group's revenue disaggregated by pattern of revenue recognition is as follows: the Group recognises all revenue based on a point in time.

Segment reporting

A segment is a component of the Consolidated Entity that earns revenues or incurs expenses whose results are regularly reviewed by the chief operating decision makers and for which discrete financial information is prepared.

The Group has identified its operating segments based on the internal reports that are reviewed and used by the Chief Executive Officer (the Chief Operating Decision Maker) in assessing performance and in determining the allocation of resources. The Group operates in a single operating segment, being the biopharmaceutical sector, and the majority of its activities are concentrated on researching, developing and commercialising a sole asset, being its leading drug candidate. Accordingly, the Group's consolidated total assets are the total reportable assets of the operating segment.

The Group has established entities in more than one geographical area. The non-current assets that are not held within Australia are immaterial to the Group. The revenues earned from external customers by geographical location is detailed above. The consolidated entity has one operating segment within the definition of AASB 8 Operating Segments.

Share-Based Payments

Performance Rights are priced using either a Monte Carlo simulation pricing model for market conditions, or a Binomial Options Valuation pricing model for non-market conditions, taking into account factors specific to the Performance Rights Plan, such as the vesting period. For non-market conditions, the value of each performance right is multiplied by the number of performance rights expected to vest to arrive at a valuation. The performance rights expire the earlier of 7 years from date of grant of rights or 20 November 2023 or 20 December 2024. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. The exercise conditions are non-marketable. An illiquidity discount was applied to the pricing model. The fair value per right at grant date varies between $8.98 and $26.22.

Directors' Declaration

In the opinion of the Directors:

1. The financial statements and notes, of the company and of the Consolidated Entity, are in accordance with the Corporations Act 2001, including:
   (a) giving a true and fair view of the Consolidated Entity's financial position as at 31 December 2022 and its performance for the half year ended on that date;
   (b) with Accounting Standard AASB134 Interim Financial Reporting and the Corporations Regulations 2001; and
2. There are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors pursuant to section 303(5) of the Corporations Act 2001.

DR PHILIPPE WOLGEN
Director
Dated this 24th day of February 2023

Grant Thornton Audit Pty Ltd
Level 22 Tower 5
Collins Square
727 Collins Street
Melbourne VIC 3008
GPO Box 4736
Melbourne VIC 3001

T +61 3 8320 2222

Independent Auditor's Review Report

To the Members of Clinuvel Pharmaceuticals Limited

Report on the half-year financial report

Conclusion

We have reviewed the accompanying half-year financial report of Clinuvel Pharmaceuticals Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated condensed statement of financial position as at 31 December 2022, and the consolidated condensed statement of profit or loss and other comprehensive income, consolidated condensed statement of changes in equity and consolidated condensed statement of cash flows for the half-year ended on that date, a description of accounting policies, other selected explanatory notes, 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 Clinuvel Pharmaceuticals Limited's does not comply with the *Corporations Act 2001* including:

a giving a true and fair view of the Clinuvel Pharmaceuticals Limited's financial position as at 31 December 2022 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 Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and 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.

Directors' responsibility for the half-year financial report

The Directors of the Company 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.

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 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 31 December 2022 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.

Grant Thornton Audit Pty Ltd
Chartered Accountants

M A Cunningham
Partner – Audit & Assurance

Melbourne, 24 February 2023