Company Announcement

CLINUVEL

ASX: CUV
Nasdaq International Designation: CLVLY
XETRA-DAX: UR9

CLINUVEL RECORDS ANOTHER POSITIVE FINANCIAL RESULT

Revenues up, financial performance facilitates re-investment for further growth

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EXECUTIVE SUMMARY

- Net Profit of $1.059m, eighth consecutive half year profit
- Revenue up 11%, Expenses up 54%, compared to same period of 2018
- Balance Sheet strong with increase in cash balance to $57.432m
- European business driving revenue outcome as investment increases to support future growth

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Melbourne, Australia, 26 February 2020

CLINUVEL PHARMACEUTICALS LTD**,** a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders, today announced its financial result for the six months ended 31 December 2019. All figures are rounded and reported in Australian dollars.

FINANCIAL RESULT

CLINUVEL achieved positive results in the half year to 31 December 2019:

- Net Profit result of $1.059m, the eighth consecutive half year net profit result;
- Total Revenues of $9.971m, up 11% compared to the same period 2018;
- Expenses up 54%, compared to the same period 2018, with investment in key areas of the business to allow the Company's growing activities;
- As a result, net profit was 74% lower than in the half year ended December 2018;
- Balance Sheet remains strong, featuring nil Debt, Cash of $57.432m and Net Equity of $58m; and
- Positive Earnings Per Share of $0.022.

Full details of the financial results are in the following Appendix 4D Half Year Financial Report.

EUROPEAN GROWTH

The Company's European business continues to demonstrate revenue growth from distributing SCENESSE® (afamelanotide 16mg) for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).[1] More patients are receiving treatment for the first time and product supply has been expanded in those countries receiving SCENESSE® for up to the past four years where high patient retention rates approximate 95%. The Company has implemented a uniform pricing policy in the European Economic Area whereby the price of SCENESSE® remained consistent between the two reporting periods.

INVESTING IN STRATEGIC EXPANSION

CLINUVEL has focussed heavily on maintaining a deliberately prudent approach to containing expenses in the prior reporting periods, leading up to the decision by the US Food and Drug Administration (FDA) to approve SCENESSE®. With this essential regulatory highlight in October 2019, the Group is now in the position to increase its cost base to allow for expansion into new markets, in both existing and new R&D activities. This has been witnessed in part by the Group investing in additional personnel across its research and development, regulatory affairs and business support functions, as well as in activities across its manufacturing supply and distribution chain. These investments were a core consideration in the six months as it provides a platform for the Group to pursue its near- and longer-term objectives to expand into the USA and to further progress its product development pipeline. This includes

SCENESSE® as a treatment for the skin depigmentation disorder, vitiligo,[2] along with the new product development program underway at CLINUVEL's research and development facilities in Singapore, currently being expanded.[3] Ultimately, the expenses incurred to support these strategic initiatives are expected to result in new sources of revenue for the Group in future periods.

COMMENTARY
"The eighth consecutive half year profit is a timed and well-managed outcome as it has been sustained in a period where the Group further re-invested in the business which, as expected, had an effect on the net profit result," CLINUVEL's Chief Financial Officer, Darren Keamy said. "We had long planned to establish cash reserves to accommodate for any economic downturns, allowing CLINUVEL to execute its plans without significant concerns about building a promising business.

"As part of our long-term plans, growth in the existing revenue base from distribution of SCENESSE® in the Eurozone has enabled the Group to self-finance its growth which include expansion into the US. In balancing the entry into new territories, diffusion in new medical indications and control over our costs, we continue to progress the strategic initiatives set by the Board for long term performance of the Group."

– End –

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. SCENESSE® is approved in the USA to increase pain free light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

[2] Refer Company Announcement, 10 February 2020. CLINUVEL PHARMACEUTICALS LTD announced it has requested a Type C Guidance meeting with the FDA to seek agreement on the design of a multicentre Phase IIb vitiligo clinical study (CUV104) and the data package necessary to support a supplemental New Drug Application (sNDA) filing for CLINUVEL's drug SCENESSE® in vitiligo.

[3] Refer Company Announcement, 24 February 2020. CLINUVEL PHARMACEUTICALS LTD announced it is expanding its Singapore laboratories with the support of a grant from the Singapore Economic Development Board.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 and the US Food and Drug Administration in 2019 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at http://www.epp.care. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information please go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

Head of Investor Relations
Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

Investor enquiries
https://www.clinuvel.com/investors/contact-us

Forward-Looking Statements
This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors

that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2019 Annual Report. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

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APPENDIX 4D ASX Listing Rule 4.2A.3

HALF YEARLY REPORT

HALF YEAR ENDED 31 DECEMBER 2019

CLINUVEL PHARMACEUTICALS LIMITED

ABN 88 089 644 119

PREVIOUS CORRESPONDING PERIOD: HALF YEAR ENDED 31 DECEMBER 2018

RESULTS FOR ANNOUNCEMENT TO THE MARKET

				($A'000)
Revenues from continuing activities	Increased	11%	to	9,971
Profit from continuing activities after tax attributed to members	Decreased	74%	to	1,059
Net Profit for the period attributed to members	Decreased	74%	to	1,059

DIVIDENDS (DISTRIBUTION)

	Amount per security	Franked amount per security
Final dividend (prior year)*	2.5 ¢	Unfranked
Interim dividend	*Nil ¢	*Nil ¢
***CLINUVEL PHARMACEUTICALS LIMITED paid the dividend on 19 September 2019**		
Previous corresponding period (31 December 2018)	2.0 ¢	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

COMMENTARY ON RESULTS

For commentary on the results of CLINUVEL PHARMACEUTICALS LIMITED please refer to the Result of the Consolidated Entity 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.

NTA BACKING

	Current period	Previous corresponding period
Net tangible asset backing per ordinary security	$1.18*	$0.90

** has been adjusted to reflect the requirement of Australian Securities and Investments Commission to exclude right of use assets arising from the application of AASB 16 'Leases' from the calculations of net tangible assets.*

CONTROL GAINED OR LOST OVER ENTITIES HAVING MATERIAL EFFECT

Name of entity (or group of entities)	N/A
Consolidated profit (loss) from continuing items after tax of the controlled entity (or groups of entities) since the date in the current period on which control was acquired or lost	N/A
Date from which such profit has been calculated	N/A
Profit (loss) from continuing items after tax of the controlled entity or group of entities) while controlled the whole of the previous corresponding period	N/A

DIVIDENDS (IN THE CASE OF A TRUST, DISTRIBUTIONS)

Date the dividend (distribution) is payable	N/A
Record date determine entitlements to the dividend (distribution) (i.e. on the basis of proper instruments of transfer received by 5.00pm if securities are not CHESS approved, or security holding balances established by 5.00pm or such later time permitted by SCH business Rules if securities are CHESS approved)	N/A
If it is a final dividend, has it been declared or proposed?	N/A

DETAILS OF AGGREGATE SHARE OF PROFITS (LOSSES) OF ASSOCIATES AND JOINT VENTURE ENTITIES

Group's share of associates' and joint ventures entities:	Current period - $A'000	Previous corresponding period - $A'000
Profit (loss) from continuing activities before tax	N/A	N/A
Income tax on continuing activities	N/A	N/A
Profit (loss) from continuing activities after tax	N/A	N/A
Extraordinary items net of tax	N/A	N/A
Net profit (loss)	N/A	N/A
Adjustments	N/A	N/A
Share of net profit (loss) of associates and joint venture entities	N/A	N/A

DETAILS OF AGGREGATE SHARE OF PROFITS (LOSSES) OF ASSOCIATES AND JOINT VENTURE ENTITIES

Group's share of associates' and joint ventures entities:	Current period - $A'000	Previous corresponding period - $A'000
Profit (loss) from continuing activities before tax	N/A	N/A
Income tax on continuing activities	N/A	N/A
Profit (loss) from continuing activities after tax	N/A	N/A
Extraordinary items net of tax	N/A	N/A
Net profit (loss)	N/A	N/A
Adjustments	N/A	N/A
Share of net profit (loss) of associates and joint venture entities	N/A	N/A

CLINUVEL PHARMACEUTICALS LIMITED A.B.N. 88 089 644 119 AND CONTROLLED ENTITIES HALF YEAR FINANCIAL REPORT ENDED 31 DECEMBER 2019

DIRECTORS' REPORT

Your Directors present their report on the Company and its controlled entities for the half year ended 31 December 2019.

DIRECTORS

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

- Dr P.J. Wolgen
- Mr S. R. McLiesh (resigned 30 November 2019)
- Mrs B.M. Shanahan
- Mr W. Blijdorp
- Dr K.E. Agersborg
- Mrs S.E. Smith (commenced 23 September 2019)
- Prof J.V. Rosenfeld (commenced 26 November 2019)

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

EXECUTIVE SUMMARY

The Company continued to achieve positive results in the half year to 31 December 2019:

- Improved revenues to $9.971 million, up 11% compared to the same period of 2018;
- A 6% increase in cash held when compared to 30 June 2019 to $57.432 million, providing a robust foundation to finance further growth;
- An eight consecutive half year profit result;
- Net profit of $1.059 million, which was down by 74% compared to the half year ending 31 December 2018 primarily due to increased expenses in the business;
- An expense result of $8.741 million, up 54% on the equivalent period last year, reflecting the Company's increased investment in its R&D and in the business to prepare and support future growth;
- Balance sheet comprising nil debt and net equity of $58.027 million;
- A 20% reduction to current liabilities to $3.952 million; and
- Positive earnings per share of $0.022, a decrease of 74% on the same period last year, reflecting the change in profit result period-on-period.

Consolidated Entity	6 Months Ended 31 Dec 2019	6 Months Ended 31 Dec 2018	Change
	$	$	%
Revenues	9,971,065	8,981,388	11%
Net Profit before income tax	1,059,248	4,075,519	(74%)
Profit after income tax expense	1,059,248	4,075,519	(74%)
Basic earnings per share	0.022	0.085	(74%)
Net tangible assets backing per share	1.177*	0.900	31%

** has been adjusted to reflect the requirement of Australian Securities and Investments Commission to exclude right of use assets arising from the application of AASB 16 'Leases' from the calculations of net tangible assets.*

RESULT OF THE CONSOLIDATED ENTITY ('GROUP') AND BALANCE SHEET

The Group result for the half year ended 31 December 2019 was a $1.059 million net profit. This is the Group's eight consecutive half year profit result and when compared to the prior corresponding period, reflects double digit revenue growth offset by higher expenses incurred to progress the growth of the business. The net profit for the half year ended 31 December 2018 was $4.076 million, 74% higher.

The preceding seven half year results have demonstrated the European market of SCENESSE® (afamelanotide implant 16mg) in erythropoietic protoporphyria (EPP), as a standalone market, can generate a consistent profit result for the Group, and for the half year ended 31 December 2018, a 45% profit margin. The December 2018 half year was characterised by the Group focussing on responding to the US Food and Drug Administration (FDA)'s review of its New Drug Application (NDA), submitted in June 2018. In addition, it focussed on the goals to grow its EPP market in Europe and to carefully progress its early-stage in-house product development programs. During this time, the Group maintained a deliberate approach to contain expenditures, such as ensuring its expenditures in manufacturing were concentrated on validation work to support the recently submitted NDA, to reduce reliance on external third-party support, and to keep R&D spend to a minimum.

In October 2019, the Group achieved one of its most critical objectives, rarely achieved in the Australian biotechnology industry, being an NDA approval by the US FDA for SCENESSE® for adult EPP patients in the USA. Attaining an approval was a trigger for the Group to take further initiatives to pursue its long term strategy to grow the business. Supporting these initiatives requires a deliberate and managed increase to the underlying existing cost base across the entire group of companies. To progress the growth of the business, to implement important R&D programs and to pursue and prepare for future revenue growth, the Group has made, and will make further decisions that will incur higher expenditures. Examples of this in the current reporting period include increases to the Group's personnel resources, promotional and marketing expenditures and internal development programs aimed at meeting expected future demand for SCENESSE® and its follow-on products that have commenced after the positive FDA outcome.

Consequently, the expense result for the December 2019 half year should therefore be assessed in the context of the effective containment of expenses in prior reporting periods, combined with increased activities and resources in the current period to support future growth following the milestone achievement of FDA approval. These expenses are expected to facilitate new sources of revenue for the Group in future reporting periods. The various initiatives of the Group are outlined in the Review of Operations below.

Beyond the Group increasing its activities to support and pursue long term growth, the December 2019 half year was also punctuated by the Group generating further positive cash flows, with a 6% increase in cash held. The Group also saw an 11% overall increase to revenues when compared to the prior corresponding period, whereby it maintained its markets in those countries receiving SCENESSE® for up to the past four years. We have seen expert centres start to approach their critical mass, whilst others have seen new patients receive treatment for the first time. Steps have been made with select countries with small but known patient populations who have yet to agree to the net uniform price of SCENESSE®, potentially expanding the revenue base from European distribution. The supply of SCENESSE® in Switzerland under special access reimbursement, when compared to the prior corresponding period, has seen a more consistent trend of orders placed across the reporting period, with less tapering of orders as the cooler months approach. This signals that for many EPP patients, benefit is derived from receiving the drug all year round and when time of exposure to light sources may be less than during the warmer months of the year.

Key highlights of the financial activities of the consolidated entity for the six months to 31 December 2019 follows:

FINANCIAL HIGHLIGHTS

Balance Sheet

Cash and Cash Equivalents

Cash and cash equivalents increased 6% to $57.432 million compared to the 30 June 2019 balance of $54.269 million. The driver of the increase to overall cash and cash equivalents continues to be the increasing receipts received from the commercial sale of SCENESSE® in the EU and its supply to other countries including Switzerland under special access reimbursement schemes.

The rate of increase in cash and cash equivalents for the 6 months to December 2019 declined from 18% to 6% when compared to the prior corresponding period (6 months to December 2018). The decline is attributed to a 48% increase in total cash expenditures. Total cash expenditures increased from $6.196 million for the 6 months to December 2018 to $9.113 million for the 6 months to December 2019.

The cash and cash equivalent result was reduced by the Board of Directors declaring an unfranked dividend of $0.025 per share, resulting in a net distribution of $1.224 million to shareholders in September 2019. The dividend distribution was a 25% increase ($0.005) per share compared to the first-time dividend declared in September 2018 (2018 dividend distribution: $0.957 million).

Net Assets

A strong balance sheet was maintained, with net assets increasing from $57.180 million at 1 July 2019 to $58.027 million at the end of the reporting period. During this time, current liabilities decreased 20% to $3.952 million and trade and other receivables decreased 85% to $0.643 million. These decreases continue to reflect the seasonal nature of the business, whereby sales decrease on the onset of the cooler months in the northern hemisphere, resulting in a lower trade debtor balance. There was no debt or equity capital raised in the current or previous reporting period. Net tangible assets were $1.18 per share.

Revenues and Other Income

Commercial sales

Commercial sales of SCENESSE® implants in Europe totalled $7.394 million a 5% increase to the $7.066 million result for the prior corresponding period. The Company has maintained its commitment to implement a uniform pricing policy whereby the price of SCENESSE® remained consistent between the two reporting periods. Volume increases accounted for 49% of the overall increase in commercial sales period-on-period, with the remainder a result of a weaker Australian dollar providing price gains.

Special Access Reimbursements

The distribution of SCENESSE® under special access reimbursement schemes generated $2.577 million in sales reimbursement for the six months to 31 December

2019, a 35% increase on the six months to 31 December 2018 ($1.916 million); 72% of this increase was due to increased volumes and the remaining amount was due to favourable exchange rate movements between the Swiss Franc and the Euro against the Australian dollar.

Interest Income

Interest received from funds held in bank accounts and term deposits for the half year ended 31 December 2019 generated $0.309 million in interest income compared to $0.252 million for the same period last year, a 23% increase.

The positive financial performance of the Group saw an increase to its cash reserves and this resulted in an average 64% more cash held in higher-yielding Australian dollar fixed rate term deposits compared to the prior year. The increase to average cash balances earning a fixed term deposit rate was balanced out by a lower average interest rate of 67 basis points earned on these funds when compared to the prior period. The decline in average term deposit rates reflects the impact of Australian government monetary policy on term deposit rates on offer throughout the year.

Expenditures

Clinical Development

Congruent to CLINUVEL's objectives to increase its research and development activities following FDA approval (of 8 October 2019), clinical development costs increased 313% to $0.094 million compared to the same period last year ($0.023 million). The increase is due to heightened investments connected to the product development programs underway at the Company's Singaporean innovation hub, VALLAURIX PTE LTD, along with clinical costs related to development of protocols and furthering research in EPP. Although the increase in clinical development expenses represents an increase above 300% when compared to the prior corresponding period, it amounts to only 1% of total expenses for the period. This reflects the Group's continuing primary focus on executing its commercialisation in the EU and on obtaining regulatory approval in the USA ahead of advancing its clinical trial program.

Drug formulation R&D, manufacture & distribution

Expenses on the drug formulation R&D, manufacture and distribution program increased by 80%, from $0.617 million in the prior period to $1.110 million in the six months ended 31 December 2019. Whilst increased volumes from commercial sales in the EU and from special access reimbursement schemes have seen an increase to expensing of costs to inventory, cost increases from commercial manufacturing of SCENESSE® implants have been passed on to the Group by its implant contract manufacturer. Other factors impacting this result include development fees in synthesizing new raw material peptide in preparing for expected forecast demand in years to come, as well as additional costs in managing stock handling, movement and release, partly in response to Brexit requiring changes to the Group's distribution systems.

Regulatory (Pre- & Post-Marketing) & Non-clinical

Regulatory affairs for both pre- and post-marketing activities and non-clinical development costs increased 27% to $0.876 million for the six months ended 31 December 2019 compared to the same period last year ($0.689 million). The increase in spending reflects the general increase in regulatory compliance required as part of expanding further into the European market and after multiple years from the first phase of product launch. Audits of third parties involved in the supply chain, audits of internal compliance systems, inspection fees and preparing, submitting and paying for variations to the dossier were some of the additional activities impacting the expense result for the current reporting period. Certain pharmacovigilance functions previously brought in-house were outsourced again to third parties. The Group places particular emphasis to meeting and maintaining ongoing pharmacovigilance and risk management commitments to ensure the safety profile for SCENESSE® is clearly demonstrated.

Clinical, Regulatory & Commercial overheads

Clinical, Regulatory & Commercial ('C,R&C') overhead costs increased 22% to $1.617 million in the six months ended 31 December 2019 (31 December 2018: $1.328 million). The Group increased its C,R&C headcount, the majority of the new positions were in its Singaporean operations as part of the product development programs underway at VALLAURIX PTE LTD. The increase in personnel fits the Group's longer-term objectives to expand its product offerings through internal development projects and additional hiring of qualified and skilled staff is fundamental to accelerating these programs.

Business marketing & listing

Business marketing and listing fees increased from $0.623 million for the six months ended 31 December 2018 to $0.882 million for the current period. The main driver behind the 42% increase was the commitment made by the Group to engage in new marketing initiatives in globally presenting the company and its product development offerings at high profile industry exhibitions, including booth space, sponsorship, attendance and product promotion fees. The aim of these activities is to increase the Group's engagement with expert audiences, such as researchers and clinicians interested in CLINUVEL's R&D pipeline. Another major factor to the increase in business marketing and listing fees was further fee increases to listing and regulatory compliance costs linked to the Group's market value.

Patents and trademarks

Patents and trademark charges saw a 10% reduction, from $0.166 million in the same period last year to $0.150 million in the current period. First-time trademark fees in connection to complementary products being developed by the VALLAURIX PTE LTD innovation centre were incurred in the prior period. The Group continues to maintain and validate its existing portfolio of patents across key jurisdictions.

General administration

Expenses from general administration were $3.333 million for the six months ended 31 December 2019 compared to $1.854 million in the same period last year, an 80% increase. The increase is across a range of expense items, in recruitment fees, expensing of non-cash share-based payments, in increased head count and in changes to the remuneration arrangements of key management personnel, impacting salary and employee benefit expenses.

The increase in general administration expenses is to ensure the appropriate resources are in place to support the execution of the Company's demanding near-term and long-term expansion strategy.

Other

Other expenses increased 77% to $0.679 million in the six months ended 31 December 2019 (31 December 2018: $0.382 million). The Group increased its travel-related expenses, reflecting the transatlantic and transpacific mobility of staff to manage the worldwide activities.

Unrealised Foreign Currency Translation loss (Other Income (loss))

The movement of the Australian dollar relative to foreign currencies to which the Group has an exposure to has a resulted in an unrealised foreign currency movement loss of $0.509 million for the six months to 31 December 2019. This primarily relates to the restatement of the Euro currency held by the company to the Group's Australian dollar presentation currency at reporting date. This compares to a $0.495 million gain for the six months ended 31 December 2018 when the movements in the Australian dollar exchange rates at the reporting date trended down when compared to the exchange rates of foreign currencies held at the time.

Earnings per share

The Group was able to maintain a positive measure during a period of increased expansion, without achieving growth on its earnings per share. Basic earnings per share for the period ended 31 December 2019 was $0.022 on a weighted average number of 48,339,167 issued ordinary shares. This compares with basic earnings per share of $0.085 as at 31 December 2018 on a weighted average number of 47,845,584 issued ordinary shares.

REVIEW OF OPERATIONS

Company Overview

CLINUVEL PHARMACEUTICALS LTD is a global biopharmaceutical company focussed on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in understanding the interaction of light and human biology, CLINUVEL's research and development is focussed on innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide.

CLINUVEL's headquarters is in Melbourne, Australia with operations in Europe, Singapore and the USA.

Objectives

The key focus of the Group is on research and development of products addressing the interaction of skin with its environment, aiming to deliver innovative medical solutions for complex problems. Most of all, we work to translate scientific breakthroughs into novel commercial products to deliver lifelong care to patients and consumers.

The long-term financial objective of the Group is to maximise company value through the distribution of treatments to patients in need. The key to long term profitability is:

- continuing the successful research and development of a portfolio of assets centred around its key drug candidate SCENESSE®;
- successful commercialisation, manufacture and distribution; and
- maintenance of financial discipline and stability.

A key facilitator of these objectives is the ability to attract funding to support CLINUVEL's activities, should the need arise.

Performance Indicators

Management and the Board monitor the overall performance of the Group in relation to its strategic plan and annual operating and financial budgets.
The Board, with Management, have identified a range of key performance indicators (KPIs) that are used to monitor ongoing performance. Key managers monitor performance against these KPIs and provide regular reports to the Board for review, feedback and guidance, as necessary. This enables the Board to actively monitor and guide the Group's performance.

Dynamics of the Business

Key dynamics of the business are:

- The commercial operations of the Group are currently conducted in the European Union (EU) and Switzerland. Our European subsidiaries are concentrated on working with prescribing trained and accredited EPP Expert Centres to provide SCENESSE® to patients with EPP, working within the commitments agreed with the European Medicines Agency (EMA) as a condition for continuous marketing authorisation;
- In October 2019, the FDA granted marketing approval to distribute SCENESSE® (afamelanotide implant 16mg), to increase pain-free light exposure in adult patients with a history of phototoxic reactions from EPP in the USA. This significant milestone of regulatory approval means the Group is now positioned to increase its revenue base, pending establishment of commercial operations on the ground in the US and agreement on reimbursement of the cost of treatment with US insurers;

- There is a degree of seasonality to CLINUVEL's cash receipts which are markedly higher in the northern hemisphere during spring and summer when ambient light is more intense and demand for treatment from EPP patients is higher than in autumn and winter;
- CLINUVEL has agreed with EU payors a uniform net price per unit of SCENESSE®, reflecting the Group's values of fairness and equitable treatment of all prescribers, and intends to apply this policy in the USA;
- SCENESSE® is manufactured in the USA by a sole contract manufacturer and is distributed by the Group directly to accredited EPP Expert Centres;
- The Group has an ongoing clinical interest to further develop SCENESSE®, focussing on vitiligo, a skin repigmentation disorder, in North America, as well as variegate porphyria (VP), a disease indication belonging to the same family of disorders as EPP (porphyrias);
- The Group's product development program is conducted through its fully owned Singaporean subsidiary, VALLAURIX PTE LTD and is summarised in the Product Pipeline section below;
- The Melbourne headquarters of the Group covers the regulatory affairs, scientific programme, finance and investor relations functions.

Operational Overview

European Distribution of SCENESSE®

Our efforts to supply SCENESSE® to EPP Expert Centres across key European countries, including supply under special access to Switzerland, continued in the half-year ended 31 December 2019.

Brexit

We changed the structure of our European business during 2019 to accommodate our marketing authorisation to supply SCENESSE® in the EU.

We also appointed an alternate manufacturing partner to fulfil EU regulations on imported implants from our primary manufacturer located outside the EU.

Steps were also put in place to meet new guidelines on pharmaceuticals entering the European supply chain.

Progress of SCENESSE® for EPP in the USA

Since the FDA's approval on 8 October 2019, we have been focussed on the implementation of our US expansion plan. This involves:

- reaching agreement with the FDA on the pharmacovigilance protocol to apply for the next 8 years to monitor the safety of SCENESSE® in patients with EPP;
- activation of a network of porphyria centres to administer SCENESSE®;
- restructuring internal resources to implement quality management and pharmacovigilance systems;
- recruitment of a local team to support operational activities in the USA; and
- negotiation of agreements on reimbursement of the cost of treatment with US insurers.

Product Pipeline

The Group's strategy is to focus on developing and commercialising SCENESSE® as a preventative therapy to photo-protect patients with EPP. These patients are severely affected by exposure to visible light, UV light and other light sources. Further, the Group's strategy is to develop and commercialise SCENESSE® as a combination therapy with narrowband ultraviolet B (NB-UVB) phototherapy for patients with vitiligo in order to promote repigmentation of areas of the skin affected by vitiligo, and to pursue innovation in developing new and follow-on products by leveraging the Group's knowledge in photoprotection and repigmentation.

The Group has an active product development pipeline covering existing and new treatments for a range of skin related indications.

The pipeline includes research and development into:

- a paediatric formulation of SCENESSE®;
- SCENESSE® for adult vitiligo patients;
- SCENESSE® for adult patients with VP;
- next generation products based on melanocortin analogues CUV9900, parvysmelanotide, phimelanotide, currently being evaluated as an adjuvant maintenance therapy in vitiligo, with the intention of developing these analogues for medicinal purposes and to be administered topically; and
- a range of over the counter products for general photoprotective application.

Underpinned by the regulatory approvals in Europe and the USA, along with the information generated from its post-marketing commitments in Europe, the Group continues to work towards gaining regulatory approval for SCENESSE® for EPP patients in other markets worldwide. In this regard, CLINUVEL applied to the Australian Therapeutic Goods Administration (TGA) in December 2019 to register SCENESSE® on the Australian Therapeutic Goods Register (ATGR) as a treatment for patients with EPP. The TGA accepted the application on 31 January 2020 for evaluation under its Priority Registration Process with a target timeframe of 150 working days.

The Group continues to pursue a clinical program to evaluate the effectiveness of SCENESSE® to activate and repopulate melanocytes within vitiliginous lesions (depigmented skin areas) and achieve repigmentation in combination with NB-UVB in patients with vitiligo. Data from the clinical and pre-clinical studies evaluating efficacy and/or safety of SCENESSE® in combination with NB-UVB should result in the Group moving towards later stage clinical trials. Now that the FDA has approved the use of SCENESSE® in EPP, we are actively seeking to progress the development of SCENESSE® in vitiligo. In February 2020, we requested a Type C Guidance meeting with the FDA to discuss the design of a multicentre Phase IIb clinical study in the US and the data package necessary to support a supplemental New Drug Application (sNDA) filing for SCENESSE® in vitiligo.

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 2019.

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 2019.

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 26th day of February, 2020

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Independent Auditor's Report

To the Members of Clinuvel Pharmaceuticals Limited

Report on the review of 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 2019, and the consolidated condensed statement of profit or loss and other comprehensive income, consolidated condensed statement of changes in equity and consolidated 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, nothing has come to our attention that causes us to believe that the half year financial report of Clinuvel Pharmaceuticals Limited does not give a true and fair view of the financial position of the Company as at 31 December 2019, and of its financial performance and its cash flows for the half year ended on that date, in accordance with the *Corporations Act 2001*, including complying with Accounting Standard AASB 134 *Interim Financial Reporting*.

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 Company's financial position as at 31 December 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 Clinuvel Pharmaceutical 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. 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.

Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

Grant Thornton Audit Pty Ltd
Chartered Accountants

B A Mackenzie
Partner – Audit & Assurance

Melbourne, 26 February 2020

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE HALF YEAR ENDED 31 DECEMBER 2019

	CONSOLIDATED	
	31 December 2019	31 December 2018
	$	$
Revenues		
Sales reimbursements	2,576,774	1,915,814
Commercial sales of goods	7,394,291	7,065,574
Total revenues	9,971,065	8,981,388
Total interest income	309,016	252,055
Total other income (loss)	(479,714)	525,053
Expenses		
Clinical development	94,270	22,804
Drug formulation R&D, manufacture & distribution	1,110,469	617,302
Regulatory (Pre & Post Marketing) & Non-clinical	875,552	689,296
Clinical, Regulatory & Commercial overheads	1,617,278	1,328,356
Business marketing & listing	882,198	623,058
Licenses, patents and trademarks	149,965	165,885
General administrative (incl Board)	3,332,864	1,854,002
Other	678,523	382,274
Total expenses	8,741,119	5,682,977
Profit before related income tax expenses	**1,059,248**	**4,075,519**
Income tax (expense)/benefit	-	-
Profit after income tax expense	1,059,248	4,075,519
Net profit for the period	**1,059,248**	**4,075,519**
Other comprehensive income		
Items that may be re-classified subsequently to profit or loss		
Exchange differences of foreign exchange translation of foreign operations	547,687	123,105
Income tax (expense)/benefit on items of other comprehensive income	-	-
Other comprehensive income/(loss) for the period, net of income tax	547,687	123,105
Total comprehensive income/(loss) for the period	**1,606,935**	**4,198,624**
Basic earnings per share - cents per share	2.2	8.5
Diluted earnings per share - cents per share	2.1	8.2

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 2019

	CONSOLIDATED	
	31 December 2019	30 June 2019
	$	$
Current assets		
Cash and cash equivalents	57,431,850	54,268,758
Trade and other receivables	643,051	4,156,216
Inventory	1,910,122	2,136,084
Other assets	805,535	591,516
Total current assets	**60,790,558**	**61,152,574**
Non-current assets		
Property, plant and equipment	504,130	337,851
Right-of-use assets	296,450	368,805
Intangible assets	185,030	185,030
Deferred tax assets	301,112	301,112
Total non-current assets	**1,286,722**	**1,192,798**
Total assets	**62,077,280**	**62,345,372**
Current liabilities		
Trade and other payables	2,242,150	3,633,281
Lease liabilities	244,116	261,251
Provisions	1,465,307	1,065,510
Total current liabilities	**3,951,573**	**4,960,042**
Non-current liabilities		
Lease liabilities	63,943	171,267
Provisions	34,831	34,210
Total non-current liabilities	**98,774**	**205,477**
Total liabilities	**4,050,347**	**5,165,519**
Net assets	**58,026,933**	**57,179,853**
Equity		
Contributed equity	151,849,388	151,314,175
Reserves	1,802,351	1,352,416
Accumulated losses	(95,624,806)	(95,486,738)
Total equity	**58,026,933**	**57,179,853**

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 2019

	Share Capital	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
	$	$	$	$	$
Balance at 1 July 2018	**148,614,908**	**2,863,901**	**618,015**	**(112,680,836)**	**39,415,988**
Employee share-based payment options	-	103,183	-	-	**103,183**
Dividends paid	-	-	-	(957,161)	**(957,161)**
Recognise Purchase Minority interest in non-controlling interest	367,205	-	-	-	**367,205**
Transactions with owners	**148,982,113**	**2,967,084**	**618,015**	**(113,637,997)**	**38,929,215**
Profit for the period				4,075,519	**4,075,519**
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	123,105	-	**123,105**
Total other comprehensive income	**-**	**-**	**123,105**	**-**	**123,105**
Balance at 31 December 2018	**148,982,113**	**2,967,084**	**741,120**	**(109,562,478)**	**43,127,839**
Balance at 1 July 2019	**151,314,175**	**654,324**	**698,092**	**(95,486,738)**	**57,179,853**
Issue of Share Capital under share-based payment	535,213	(535,213)	-	-	-
Employee share-based payment options	-	437,461	-	26,704	**464,165**
Dividends paid	-	-	-	(1,224,020)	**(1,224,020)**
Transactions with owners	**151,849,388**	**556,572**	**698,092**	**(96,684,054)**	**56,419,998**
Profit for the period				1,059,248	**1,059,248**
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	547,687	-	**547,687**
Total other comprehensive income	**-**	**-**	**547,687**	**-**	**547,687**
Balance at 31 December 2019	**151,849,388**	**556,572**	**1,245,779**	**(95,624,806)**	**58,026,933**

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 2019

	CONSOLIDATED	
	31 December 2019	31 December 2018
	$	$
Cash flows from operating activities		
GST and VAT refunds	280,293	(41,242)
Receipts from customers	13,515,607	13,313,060
Interest received	344,901	130,561
Payments to suppliers and employees	(9,394,232)	(6,154,928)
Net cash provided by operating activities	**4,746,569**	**7,247,451**
Cash flows from investing activities		
Payments for property, plant and equipment	(206,178)	(188,114)
Net cash used in investing activities	**(206,178)**	**(188,114)**
Cash flows from financing activities		
Repayment of borrowing and leasing liabilities	(130,114)	-
Dividends paid	(1,224,021)	(957,160)
Net cash used in financing activities	**(1,354,135)**	**(957,160)**
Net increase in cash held	**3,186,256**	**6,102,177**
Cash and cash equivalents at beginning of the period	**54,268,758**	**36,198,451**
Effects of exchange rate changes on foreign currency held	(23,164)	525,669
Cash and cash equivalents at end of the period	**57,431,850**	**42,826,297**

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 2019

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.

NEW AUSTRALIAN ACCOUNTING STANDARDS ISSUED THIS YEAR

AASB Interpretation 23 Uncertainty Over Income Tax Treatments

Interpretation 23 requires the assessment of whether the effect of uncertainty over income tax treatments should be included in the determination of taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates. The Interpretation outlines the requirements to determine whether an the Group considers uncertain tax treatments separately, the assumptions an entity makes about the examination of tax treatments by taxation authorities, how an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates and how an entity considers changes in facts and circumstances.

The Group has adopted Interpretation 23 from 1 July 2019, based on an assessment of whether it is 'probable' that a taxation authority will accept an uncertain tax treatment. This assessment takes into account that for certain jurisdictions in which the Group operates, a local tax authority may seek to open the Group's books as far back as inception of the Group. Where it is probable, the Group has determined tax balances consistently with the tax treatment used or planned to be used in its income tax filings. Where the Group has determined that it is not probable that the taxation authority will accept an uncertain tax treatment, the most likely amount or the expected value has been used in determining taxable balances (depending on which method is expected to better predict the resolution of the uncertainty). There has been no impact from the adoption of Interpretation 23 in this reporting period. Other accounting pronouncements which have become effect from 1 July 2019 and have therefore been adopted do not have a significant impact on the Group's financial results or position.

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 unfranked dividend for 2019 of 2.5 cents per share was paid on 19 September 2019 and a final unfranked dividend for 2018 of 2.0 cents per share was paid on 8 October 2018.

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 $0.022 on a weighted average number of 48,339,167 issued ordinary shares. This compares with basic earnings per share of $0.085 as at 31 December 2018 on a weighted average number of 47,845,584 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.

GOING CONCERN

The financial report has been prepared on the going concern basis, which contemplates continuity of normal business activities and realisation of assets and settlement of liabilities in the ordinary course of business. The going concern of the Consolidated Entity is dependent upon it maintaining sufficient funds for its operations and commitments. The Directors continue to monitor the ongoing funding requirements of the Consolidated Entity. The Directors are confident that sufficient funds can be secured if required by a combination of capital raising, debt financing, licensing partnerships, sale of assets or joint ventures to enable the Consolidated Entity to continue as a going concern and as such are of the opinion that the financial report has been appropriately prepared on a going concern basis.

REVENUE

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

Six months to 31 December 2019			
	Commercial sales of goods	**Sales reimburse-ments**	**Total**
	$'000	$'000	$'000
Europe	7,394	23	7,417
Switzerland	-	2,554	2,554
Total	**7,394**	**2,577**	**9,971**

Six months to 31 December 2018			
	Commercial sales of goods	**Sales reimburse-ments**	**Total**
	$'000	$'000	$'000
Europe	7,065	-	7,065
Switzerland	-	1,916	1,916
Total	**7,065**	**1,916**	**8,981**

The Group's revenue disaggregated by pattern of revenue recognition is as follows: the Group recognises all revenue based on at 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 Consolidated Entity has one business 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.

It has established entities in more than one geographical area. Revenues from commercial sales and supply from special access reimbursement schemes are 100% earned from entities within Europe, which is consistent with the comparative period. The non-current assets that are not held within Australia are immaterial to the Group. For the six months to 31 December 2019, 100% of the commercial sales and supply from special access reimbursement schemes is generated from supply to European countries including Switzerland (31 December 2018: 100%).

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 2019 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 26th day of February, 2020

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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 year ended 31 December 2019, 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 review; and

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

Grant Thornton Audit Pty Ltd
Chartered Accountants

B A Mackenzie
Partner – Audit & Assurance

Melbourne, 26 February 2020