Company Announcement

ASX: **CUV**
XETRA-DAX: **UR9**
NASDAQ INTERNATIONAL DESIGNATION: CLVLY

APPENDIX 4D
HALF-YEAR FINANCIAL STATEMENT ENDING 31 DECEMBER 2018

Melbourne, Australia, 26 February 2019

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 Appendix 4D – Half Yearly Report for the period 01 July to 31 December 2018. All figures are rounded and reported in Australian dollars.

Executive Summary

CLINUVEL achieved positive results in the half year to 31 December 2018:

- Net profit of $4.076m, up 189% compared to the half year ending 31 December 2017;
- Improved revenues to $8.981m, up 27% compared to the same period of 2017
- Responsible expense management ($5.683m) in the growth phase of the business;
- Balance sheet comprising nil debt and with net equity of $43.128m; and an
- Earnings per share of $0.085 representing growth of 188%

This reflects the positive progression of the Group's business strategy and objectives.

CLINUVEL are in the third year of commercial distribution of SCENESSE® (afamelanotide 16mg)[1] and take pride in the meaningfully positive contribution the innovative treatment is having on patients with erythropoietic protoporphyria (EPP). The strategic decisions taken over the years to self-distribute SCENESSE®, to oversee and manage the supply chain and to build a network of accredited centres of porphyria expertise underpin the foundation of our current performance. CLINUVEL is converging towards an integrated biopharmaceutical business with various business functions executed inhouse to achieve further growth.

Full details of the financial results are in the accompanying Appendix 4D.

- End -

[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

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 treatment(s) 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 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, Switzerland, the US and Singapore. For more information go to http://www.clinuvel.com.
SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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InvestorRelations@clinuvel.com

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 2018 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.
www.clinuvel.com

APPENDIX 4D ASX Listing Rule 4.2A.3

HALF YEARLY REPORT

HALF YEAR ENDED 31 DECEMBER 2018

CLINUVEL PHARMACEUTICALS LIMITED

ABN 88 089 644 119

PREVIOUS CORRESPONDING PERIOD: HALF YEAR ENDED 31 DECEMBER 2017

RESULTS FOR ANNOUNCEMENT TO THE MARKET

				($A'000)
Revenues from continuing activities	Increased	27%	to	8,981
Profit from continuing activities after tax attributed to members	Increased	189%	to	4,076
Net Profit for the period attributed to members	Increased	189%	to	4,076

DIVIDENDS (DISTRIBUTION)

	Amount per security	Franked amount per security
Final dividend (prior year)	2.0 ¢	Unfranked
Interim dividend	Nil ¢	Nil ¢

***CLINUVEL PHARMACEUTICALS LIMITED has not paid any dividends during the 2017/18 financial year**

Previous corresponding period (31 December 2017)	Nil ¢	Nil ¢
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:

COMMENTARY ON RESULTS

For commentary on the results of CLINUVEL PHARMACEUTICALS LIMITED please refer to the Review and Results 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	$0.90	$0.57

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

CLINUVEL PHARMACEUTICALS LIMITED A.B.N. 88 089 644 119 AND CONTROLLED ENTITIES HALF YEAR FINANCIAL REPORT ENDED 31 DECEMBER 2018

DIRECTORS' REPORT

Your Directors present their report on the Company and its controlled entities for the half year ended 31 December 2018.

DIRECTORS

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

- Mr S.R. McLiesh
- Dr P.J. Wolgen
- Mrs. B.M. Shanahan
- Mr. W. Blijdorp
- Dr K.E. Agersborg

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 achieved positive results in the half year to 31 December 2018:

- Net profit of $4.076m, up 189% compared to the half year ending 31 December 2017;
- Improved revenues to $8.981m, up 27% compared to the same period of 2017;
- Responsible expense management ($5.683m) in the growth phase of the business;
- Cash held totalling $42.826m, underlying the basis for future growth, an increase of 53% compared to cash held at 31 December 2017;
- Balance sheet comprising nil debt and with net equity of $43.128m; and
- Earnings per share of $0.085 representing a growth of 188%.

This reflects the positive progression of the Group's business strategy and objectives.

We are in the third year of commercial distribution of SCENESSE® (afamelanotide 16mg) and take pride in the meaningfully positive contribution the innovative treatment is having on patients with erythropoietic protoporphyria (EPP). The strategic decisions taken over the years to self-distribute SCENESSE®, to oversee and manage the supply chain and to build a network of accredited centres of porphyria expertise underpin the foundation of our current performance. CLINUVEL is converging towards an integrated biopharmaceutical entity with various business functions executed inhouse and an aim to achieve further growth.

The Board of Directors have laid out their key objectives to effectively manage European expansion, establish a distribution team in the US in anticipation of an approval to the Company's New Drug Application (NDA) pending the US Food and Drug Administration's (FDA's) review process, as well as ongoing research and development into new indications and new products.

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

The Group result for the half year ended 31 December 2018 was a $4.076 million net profit, representing a 189% increase compared to the same period last year (a net profit of $1.411 million). This is the fifth consecutive half year profit result and the highest July-December period profit result historically for the Group, driven by a combination of an increase in overall revenues and a reduction in expenses.

Key highlights of the financial activities of the consolidated entity for the six months to 31 December 2018 include:

FINANCIAL HIGHLIGHTS

Cash and Cash Equivalents

Cash and cash equivalents increased 18% to $42.826 million compared to 30 June 2018 ($36.198 million). The driver of the increase in cash and cash equivalents was a 35% increase in receipts from customers from the commercial sale of SCENESSE® and its supply under special access reimbursement schemes.

The cash and cash equivalent result was impacted by the Board of Directors declaring a first-time unfranked dividend of $0.02 per share, resulting in a distribution to shareholders in October 2018 of $0.957 million.

In addition, the net increase in cash generated during the half year ended 31 December 2018 (excluding effects of exchange rate changes on foreign currency held) increased 52% when compared to the prior corresponding period, from $4.008 million to $6.102 million.

Total net assets were $43.128 million and net tangible assets were $0.897 per share, as at the 31 December 2018 balance date.

Revenues and Other Income

Commercial sales of SCENESSE® implants in Europe totalled $7.066 million, compared to $5.333 million for the half year ended 31 December 2017, an increase of 32%. The Company implemented its global uniform pricing policy whereby the price of SCENESSE® remained consistent between the two reporting periods.

Favourable movements in foreign exchange rates from a weaker Australian dollar in the current reporting period

saw a further 9% increase in commercial sales period-on-period.

The distribution of SCENESSE® under special access reimbursement schemes generated $1.916 million in sales reimbursement for the six months to 31 December 2018, a 10% increase on the six months to 31 December 2017 ($1.737 million); nearly 76% of this increase was due to favourable exchange rate movements between the Swiss Franc and the Euro against the Australian dollar, with the remaining increase a result of increased distribution under the schemes.

Included in other income is interest received from excess funds held in bank accounts and term deposits, generating $0.252 million interest income, up from $0.124 million for the same period last year, a 104% increase. The stronger interest income result is due to the Group's strengthened cash position, holding on average 95% more cash in higher-yielding Australian dollar fixed rate term deposits. These returned an average yield 0.12% higher than the interest yields earned in the same period last year.

The weakening of the Australian dollar relative to the foreign currencies to which the Company has an exposure resulted in a gain of $0.495 million for the six months to 31 December 2018. This relates to the restatement of foreign currencies held and trade debtor and creditor balances to the Group's Australian dollar presentation currency. This compares to a $0.043 million gain for the six months ended 31 December 2017 when the movements in the Australian dollar exchange rates were less volatile than those prevailing during the current reporting period.

Expenditures

Clinical development costs increased 63% to $0.023 million, compared to the same period last year ($0.014 million). Clinical development expenditures in recent years has been focussed on the completion of the CUV103 study in vitiligo and the gradual ramping up of activities connected to the product development programs underway at the Company's Singaporean innovation hub, VALLAURIX PTE LTD. In addition to the new product development work within its innovation centre, the Group is preparing to commence a Phase II study in variegate porphyria and initiate further development of SCENESSE® in a new indication.

Expenses on the drug formulation R&D, manufacture and distribution program increased by 43%, from $0.431 million in the prior period to $0.617 million in the six months ended 31 December 2018. Work that commenced in early 2018 at the Group's contract implant manufacturer to maintain and to optimise the existing manufacturing processes has continued in the current reporting period. This is a key reason for the 43% increase when compared to the previous corresponding period. Another key contributor to this result was an increase to the expensing of inventoriable costs from higher unit sales under the commercial sales program and special access reimbursement schemes.

Regulatory affairs for both pre- and post-marketing activities and non-clinical development costs decreased 24% to $0.689 million for the six months ended 31 December 2018 compared to the same period last year ($0.909 million). The reduced spend largely reflects the Group's progress with the NDA submission to the FDA. The prior reporting period consisted of a number of intensive activities performed by external experts together with our contract manufacturer to support the Company to prepare key modules of its NDA for submission under a rolling review. Additionally, certain pharmacovigilance functions were brought in-house and less reliance on external regulatory support also contributed to the reduction in pre and post marketing regulatory activities. These costs were partially offset by increased activities incurred to meet the commitments set by the European Medicines Agency (EMA) as part of the post-authorisation safety study (PASS).

Clinical, Regulatory & Commercial ('C,R&C') overhead costs increased 21% to $1.328 million in the six months ended 31 December 2018 (31 December 2017: $1.098 million). The increase reflects a 26% increase in C,R&C headcount, essential to drive the product development programs in VALLAURIX PTE LTD, to support the continued growth in the commercial distribution program in Europe and to prepare the Group for further business expansion.

Business marketing and listing fees increased 27% from $0.492 million for the six months ended 31 December 2017 to $0.623 million for the current period. The key drivers behind the increase are higher marketing personnel costs to support the Company's expanding focus on its digital and online marketing profile, along with increased media relations and public relations costs to promote the reach of the Company's news flow in the USA and elsewhere.

Patents and trademark charges saw a 23% reduction, from $0.214 million in the same period last year to $0.166 million in the current period. In the prior period, the Group's advancement of its product development program within the VALLAURIX PTE LTD innovation centre required additional investment to fortify its intellectual property position.

Expenses from general operations were $2.236 million for the six months ended 31 December 2018 compared to $2.734 million in the same period last year, a 18% decrease. If long-term incentive payments achieved in the prior period were excluded, expenses from general operations increased 16%. The increase is largely due to other personnel costs to support the overall business expansion, legal fees in connection to matters related to the European marketing authorisation and in responding to negotiations with various payors in Europe. Also affecting expenses from general operations was a significant increase in Director & Officer insurance premiums whereby insurers have been re-assessing their exposure to ASX-listed entities within the current business environment.

The Group's objective to grow earnings per share was achieved again in the period ended 31 December 2018. Basic earnings per share were $0.085 on a weighted average number of 47,845,584 issued ordinary shares. This compares with basic earnings per share of $0.03 as at 31 December 2017 on a weighted average number of 47,735,227 issued ordinary shares, a 188% increase.

The Company released a number of ASX market announcements throughout the six months ended 31

December 2018 describing the progress of, and developments within, the business.

REVIEW OF OPERATIONS

SCENESSE® is commercially approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

The final module of the NDA was submitted to the US FDA under a 'rolling review', on 22 June 2018. In the September quarter of 2018, further documentation to support the filing was requested. This included product manufacturing information and details on the European post-authorisation use of SCENESSE®. On 9 January 2019 the FDA advised the Company that it has set a Prescription Drug User Fee Act (PDUFA) date of 8 July 2019, evaluating the SCENESSE® NDA as a Priority Review. The FDA further advised that it does not intend to hold an advisory committee meeting during the final review of the SCENESSE® NDA, with proposed labelling and post-marketing requirements - if needed - to be communicated to CLINUVEL by 8 April 2019.

The commercial distribution of SCENESSE® in Europe has continued, with the number of patients seeking treatment year on year increasing. The Company continues to adhere to its commitments to the EMA and submitted its annual report on data collected in the European Disease Registry under the PASS. Dialogue has progressed with payors in several European countries to facilitate access to SCENESSE® for adult EPP patients. Negotiations to accept SCENESSE® for reimbursement in England continue, whereby an Appeal Hearing was held in front of an independent Appeal Panel appointed by the UK National Institute of Health and Care Excellence (NICE), the body responsible for advising the English National Health Service (NHS) on reimbursement of health technologies, including medications. The Appeal Panel concluded that NICE had failed to act fairly, exceeded its powers, and its decision not to recommend SCENESSE® for reimbursement for EPP patients was unreasonable in light of the evidence presented.

The implications of Brexit have influenced the Company's European operations. The Company has been working to transfer the marketing authorisation of SCENESSE® to a European legal entity and re-organise parts of the operation to ensure the Company complies with European regulations should the United Kingdom leave the European Union on or after 29 March 2019.

Product development initiatives in the Company's Singaporean innovation centre, VALLAURIX PTE LTD, have progressed. During the reporting period the laboratory facilities were expanded to incorporate a variety of critical analytical functions, with further analytical functions expected to be integrated into the facility in the near future. Head count has increased to support the pursuit of developing the CUV9900 and VLRX001 new chemical entities into clinical products in various formulations, along with topical formulations for non-prescription over-the-counter markets. Research and development activities have also progressed on furthering the development of a paediatric dosage form of SCENESSE® for EPP patients.

Research and development in the use of SCENESSE® in the pigmentary disorder vitiligo is expected to accelerate pending marketing authorisation for SCENESSE® for adult EPP patients by the FDA. The analyses of the pilot study CUV103 (Singapore) of 18 patients diagnosed with vitiligo was completed and final results were announced. The results of the pooled analysis of all patients in the CUV103 study who received SCENESSE® plus narrowband ultraviolet B therapy (NB-UVB) showed that the combination therapy was clinically effective in achieving repigmentation in patients with vitiligo.

Also announced during the reporting period was an agreement reached between the Company and two European porphyria expert centres on a clinical trial protocol to conduct a Phase IIa proof of concept study evaluating the safety and effectiveness of SCENESSE® in variegate porphyria (VP). VP is one of a group of porphyrias, including EPP, which is characterised by specific enzyme deficiencies along the biochemical pathway of haem synthesis. Work is currently underway to commence the study in the northern hemisphere spring of 2019. Furthermore, the Company is exploring the potential to expand the use of SCENESSE® in further indications of unmet clinical need under a clinical trial setting to determine if the drug can provide therapeutic benefit.

The Company issued a dividend to its shareholders for the first time in its history for the 12-month financial reporting period ended 30 June 2018. The dividend was unfranked and was set at A$0.02 per ordinary share. In September 2018 the Company was included in the S&P/ASX 300 Index, a broad benchmark of the capitalisation of Australian stocks used by investors to inform their assessments and decisions.

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 2018.

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 2018.

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, 2019

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Independent Auditor's Review 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 statement of financial position as at 31 December 2018, and the consolidated statement of profit or loss and other comprehensive income, consolidated 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 Clinuvel Pharmaceuticals Limited as at 31 December 2018, 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 2018 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 Pharmaceuticals 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 2019

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE HALF YEAR ENDED 31 DECEMBER 2018

	CONSOLIDATED	
	31 December 2018 $	31 December 2017 $
Revenues		
Sales reimbursements	1,915,814	1,736,720
Commercial sales of goods	7,065,574	5,332,828
Total revenues	**8,981,388**	**7,069,548**
Other income		
Interest revenue	252,055	123,635
Government R&D tax incentive	-	147
Unrealised foreign currency translation gain/(loss)	494,502	42,830
Realised net currency gain/(loss) on transactions	30,551	66,733
Total other income	**777,108**	**233,345**
Expenses		
Clinical development	(22,804)	(13,977)
Drug formulation R&D, manufacture & distribution	(617,302)	(431,215)
Regulatory (Pre & Post Marketing) & Non-clinical	(689,296)	(908,842)
Clinical, Regulatory & Commercial overheads	(1,328,356)	(1,097,618)
Business marketing & listing	(623,058)	(492,130)
Licenses, patents and trademarks	(165,885)	(214,489)
General operations (incl Board)	(2,236,276)	(2,733,675)
Total expenses	(**5,682,977**)	**(5,891,946)**
Profit/(loss) before related income tax expenses	**4,075,519**	**1,410,947**
Income tax (expense)/benefit	-	-
Profit/(loss) after related income tax expense	4,075,519	1,410,947
Profit/(loss) for the period	**4,075,519**	**1,410,947**
Other comprehensive income:		
Items that may be re-classified subsequently to profit and loss:		
Gains/(losses) arising from the conversion of foreign operations	123,105	278,028
Other comprehensive gain/(loss) for the period after income tax	123,105	278,028
Total comprehensive income/(loss) for the period	**4,198,624**	**1,688,975**
Profit/(loss) for the year attributable to:		
Non-controlling interest	-	(30,988)
Owners of the parent	4,075,519	1,441,935
	4,075,519	**1,410,947**
Total comprehensive income/(loss) attributable to:		
Non-controlling interest	-	(30,988)
Owners of the parent	4,198,624	1,719,963
	4,198,624	**1,688,975**
Basic earnings per share – cents per share	**8.5**	**3.0**
Diluted earnings per share – cents per share	**8.2**	**2.8**

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 2018

	CONSOLIDATED	
	31 December 2018 $	30 June 2018 $
Current assets		
Cash and cash equivalents	42,826,297	36,198,451
Trade and other receivables	1,036,643	5,090,271
Inventory	446,496	641,285
Other assets	606,527	339,062
Total current assets	**44,915,963**	**42,269,069**
Non-current assets		
Property, plant and equipment	325,712	168,739
Intangible assets	185,030	185,030
Deferred tax assets	281,779	281,779
Total non-current assets	**792,521**	**635,548**
Total assets	**45,708,484**	**42,904,617**
Current liabilities		
Trade and other payables	1,564,580	2,499,915
Provisions	996,213	970,906
Total current liabilities	**2,560,793**	**3,470,821**
Non-current liabilities		
Provisions	19,812	17,808
Total non-current liabilities	**19,812**	**17,808**
Total liabilities	**2,580,605**	**3,488,629**
Net assets	**43,127,879**	**39,415,988**
Equity		
Equity attributable to the owners of the parent:		
Contributed equity	148,982,113	148,614,908
Reserves	3,708,204	3,481,916
Accumulated losses	(109,562,478)	(112,680,836)
Equity attributable to the owners of the parent	**43,127,839**	**39,415,988**
Equity attributable to non-controlling (minority equity) interest	**-**	**-**
Total equity	**43,127,839**	**39,415,988**

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 2018

CONSOLIDATED	Share capital	Performance rights reserve	Foreign currency translation reserve	Retained earnings	Total attributable to Owners of parent	Non-controlling interest	Total equity
	$	$	$	$	$	$	$
Balance at 1 July 2017	**148,413,095**	**2,695,484**	**124,728**	**(125,847,024)**	**25,386,283**	**57,742**	**25,444,025**
Equity contribution by subsidiary non-controlling interest	-	-	-	-	-	-	**-**
Issue of Share Capital under share-based payment	-	-	-	-	-	-	**-**
Employee share-based payment options	-	183,431	-	57,465	240,896	**-**	**240,896**
Transactions with owners	**148,413,095**	**2,878,915**	**124,728**	**(125,789,559)**	**25,627,179**	**57,742**	**25,684,921**
Profit/(loss) for the period	-	-	-	1,441,935	1,441,935	(30,988)	**1,410,947**
Other comprehensive income:							
Exchange differences of foreign exchange translation of foreign operations	-	-	278,028	-	278,028	-	**278,028**
Balance at 31 December 2017	**148,413,095**	**2,878,915**	**402,756**	**(124,347,624)**	**27,347,142**	**26,754**	**27,373,896**
Balance at 1 July 2018	**148,614,908**	**2,863,901**	**618,015**	**(112,680,836)**	**39,415,988**	**-**	**39,415,988**
Equity contribution by subsidiary non-controlling interest	-	-	-	-	-	-	**-**
Issue of Share Capital under share-based payment	-	-	-	-	-	-	**-**
Employee share-based payment options	-	103,183	-	-	103,183	-	**103,183**
Dividends Paid				(957,161)	(957,161)		**(957,161)**
Recognise Purchase Minority interest in non-controlling interest	367,205				367,205		**367,205**
Transactions with owners	**148,982,113**	**2,967,084**	**618,015**	**(113,637,997)**	**38,929,215**	**-**	**38,929,215**
Profit/(loss) for the period				4,075,519	4,075,519	**-**	**4,075,519**
Other comprehensive income:							
Exchange differences of foreign exchange translation of foreign operations	-	-	123,105	-	123,105	**-**	**123,105**
Balance at 31 December 2018	**148,982,113**	**2,967,084**	**741,120**	**(109,562,478)**	**43,127,839**	**-**	**43,127,839**

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 2018

	CONSOLIDATED	
	31 December 2018 $	31 December 2017 $
Cash flows from operating activities		
GST and VAT refunds	(41,242)	123,715
Receipts from customers	13,313,060	9,837,412
Interest received	130,561	139,054
Payments to suppliers and employees	(6,154,928)	(6,075,779)
Net cash provided by (used in) operating activities	**7,247,451**	**4,024,402**
Cash flows from investing activities		
Payments for property, plant and equipment	(188,114)	(16,208)
Net cash provided by (used in) investing activities	**(188,114)**	**(16,208)**
Cash flows from financing activities		
Dividends paid	(957,160)	-
Net cash provided by (used in) financing activities	**(957,160)**	**-**
Net increase/(decrease) in cash held	**6,102,177**	**4,008,194**
Cash and cash equivalents at beginning of the period	**36,198,451**	**23,752,312**
Effect of exchange rate changes on foreign currency held	525,669	178,383
Cash and cash equivalents at end of the period	**42,826,297**	**27,938,889**

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 2018

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 applied in preparing the financial statements for the half year ended 31 December 2018 are consistent with those applied in preparing the comparative information presented in these financial statements and are the same as those applied by the Consolidated Entity in its consolidated financial report as at and for the year ended 30 June 2018, except as described below.

New standards adopted as at 1 July 2018

AASB 9 Financial Instruments

AASB 9 introduces new requirements for the classification and measurement of financial assets and liabilities and includes a forward-looking 'expected loss' impairment model and a substantially-changed approach to hedge accounting.
These requirements improve and simplify the approach for classification and measurement of financial assets compared with the requirements of AASB 139. The main changes are:

- Financial assets that are debt instruments will be classified based on: (i) the objective of the entity's business model for managing the financial assets; and (ii) the characteristics of the contractual cash flows.
- Allows an irrevocable election on initial recognition to present gains and losses on investments in equity instruments that are not held for trading in other comprehensive income (instead of in profit or loss). Dividends in respect of these investments that are a return on investment can be recognised in profit or loss and there is no impairment or recycling on disposal of the instrument.
- Introduces a 'fair value through other comprehensive income' measurement category for particular simple debt instruments.
- Financial assets can be designated and measured at fair value through profit or loss at initial recognition if doing so eliminates or significantly reduces a measurement or recognition inconsistency that would arise from measuring assets or liabilities, or recognising the gains and losses on them, on different bases.
- Where the fair value option is used for financial liabilities the change in fair value is to be accounted for as follows:
    - the change attributable to changes in credit risk are presented in Other Comprehensive Income ('OCI'); and
    - the remaining change is presented in profit or loss.

  If this approach creates or enlarges an accounting mismatch in the profit or loss, the effect of the changes in credit risk are also presented in profit or loss. Otherwise, the following requirements have generally been carried forward unchanged from AASB 139 into AASB 9:
    - classification and measurement of financial liabilities; and
    - derecognition requirements for financial assets and liabilities.

AASB 9 requirements regarding hedge accounting represent a substantial overhaul of hedge accounting that enable entities to better reflect their risk management activities in the financial statements.

Furthermore, AASB 9 introduces a new impairment model based on expected credit losses. This model makes use of more forward-looking information and applies to all financial instruments that are subject to impairment accounting.

AASB 15 Revenue from Contracts with Customers

AASB 15:

- replaces AASB 118 Revenue, AASB 111 Construction Contracts and some revenue-related Interpretations:
    - establishes a new control-based revenue recognition model;
    - changes the basis for deciding whether revenue is to be recognised over time or at a point in time;
    - provides new and more detailed guidance on specific topics (e.g., multiple element arrangements, variable pricing, rights of return, warranties and licensing); and
    - expands and improves disclosures about revenue.

CHANGES IN SIGNIFICANT ACCOUNTING POLICIES

AASB 15 *Revenue from Contracts with Customers* and AASB 9 *Financial Instruments* (2014) became mandatorily effective for periods beginning on or after 1 January 2018. Accordingly, the Group has applied AASB 15 and AASB 9 for the first time to the interim period ended 31 December 2018.

AASB 9 Financial Instruments

Recognition and derecognition

Financial assets and financial liabilities are recognised when the Group becomes a party to the contractual provisions of the financial instrument and are measured initially at fair value adjusted by transactions costs, except for those carried at fair value through profit or loss, which are measured initially at fair value. Subsequent measurement of financial assets and financial liabilities are described below.

Financial assets are derecognised when the contractual rights to the cash flows from the financial asset expire, or when the financial asset and substantially all the risks and rewards are transferred. A financial liability is derecognised when it is extinguished, discharged, cancelled or expires.

Classification and initial measurement of financial assets

Except for those trade receivables that do not contain a significant financing component and are measured at the transaction price in accordance with AASB 15, all financial assets are initially measured at fair value adjusted for transaction costs (where applicable).

Subsequent measurement of financial assets

For the purpose of subsequent measurement, financial assets, other than those designated and effective as hedging instruments, are classified into the following categories upon initial recognition:

- financial assets at amortised cost
- financial assets at fair value through profit or loss (FVPL)
- debt instruments at fair value through other comprehensive income (FVOCI)
- equity instruments at fair value through other comprehensive income (FVOCI)

Classifications are determined by both:

- The entity's business model for managing the financial asset
- The contractual cash flow characteristics of the financial assets

All income and expenses relating to financial assets that are recognised in profit or loss are presented within finance costs, finance income or other financial items, except for impairment of trade receivables which is presented within other expenses.

Financial assets at amortised cost

Financial assets are measured at amortised cost if the assets meet the following conditions (and are not designated as FVPL):

- they are held within a business model whose objective is to hold the financial assets and collect its contractual cash flows
- the contractual terms of the financial assets give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding

After initial recognition, these are measured at amortised cost using the effective interest method. Discounting is omitted where the effect of discounting is immaterial. The Group's cash and cash equivalents, trade and most other receivables fall into this category of financial instruments

Impairment of financial assets

Trade and other receivables

The Group makes use of a simplified approach in accounting for trade and other receivables and records the loss allowance at the amount equal to the expected lifetime credit losses. In using this practical expedient, the Group uses its historical experience, external indicators and forward-looking information to calculate the expected credit losses using a provision matrix.

The Group assess impairment of trade receivables on a collective basis as they possess credit risk characteristics based on the days past due.

Classification and measurement of financial liabilities

As the accounting for financial liabilities remains largely unchanged from AASB 139, the Group's financial liabilities were not impacted by the adoption of AASB 9. However, for completeness, the accounting policy is disclosed below.

The Group's financial liabilities include trade and other payables.

Financial liabilities are initially measured at fair value, and, where applicable, adjusted for transaction costs unless the Group designated a financial liability at fair value through profit or loss.

Subsequently, financial liabilities are measured at amortised cost using the effective interest method except for derivatives and financial liabilities designated at FVPL, which are carried subsequently at fair value with gains or losses recognised in profit or loss (other than derivative financial instruments that are designated and effective as hedging instruments).

All interest-related charges and, if applicable, changes in an instrument's fair value that are reported in profit or loss are included within finance costs or finance income.

The new Standard has been applied as at 1 July 2018 using the modified retrospective approach. The Group has assessed of the impact of AASB 9's changes and there is no impact on the financial instruments transactions and balances recognised in the financial statements.

<u>AASB 15 Revenue from Contracts with Customers</u>

Revenue arises from the sale of SCENESSE® implants.

The Group's revenue from contracts with customers arise from the commercial sales of goods and sales reimbursements. Commercial sales of goods are the commercial sales of SCENESSE® implants in Europe. Sales reimbursements are the distribution of SCENESSE® under special access reimbursement schemes.

To determine whether to recognise revenue, the Group follows a 5-step process:

1. Identifying the contract with a customer
2. Identifying the performance obligations
3. Determining the transaction price
4. Allocating the transaction price to the performance obligations

5. Recognising revenue when/as performance obligation(s) are satisfied

Based on the above revenue recognition process and the nature of all revenue streams from contracts with customers, the Group recognises revenue based on at a point in time rather than over time.

The below table summarises the application of AASB 15 to the Group's revenue streams:

Type of Revenue	Description and Performance Obligations	Revenue recognition policy under AASB 15
Commercial sales of goods	Commercial sale of SCENESSE® implants in Europe. Performance obligation: Delivery of goods to customer	Point in time
Sales reimbursements	Distribution of SCENESSE® implants under special access reimbursement schemes Performance obligation: Delivery of goods to customer	Point in time

The new Standard has been applied as at 1 July 2018 using the modified retrospective approach. The Group has assessed of the impact of AASB 15's changes and there is no impact on the Revenue from Contracts with Customers transactions and balances recognised in the financial statements.

Seasonal nature of revenue from contracts with suppliers

Due to patients seeking treatment in the spring, summer and autumn months, there remains a seasonal demand for SCENESSE®. As such, fluctuations caused by seasonal demand impact the Group's operations

Note "Revenue" provides additional disclosures disaggregating revenue by geographical market and the timing of revenue recognition.

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 dividend for 2018 of 2.0 cents per share, unfranked, was paid 8 October 2018 (2017: Nil)

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.

The Group's objective to grow earnings per share was achieved again in the period ended 31 December 2018. Basic earnings per share were $0.085 on a weighted average number of 47,845,584 issued ordinary shares. This compares with basic earnings per share of $0.03 as at 31 December 2017 on a weighted average number of 47,735,227 issued ordinary shares, a 188% increase.

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 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**

Six months to 31 December 2017			
	Commercial sales of goods	**Sales reimburse-ments**	**Total**
	$'000	$'000	$'000
Europe	5,332	43	5,375
Switzerland	-	1,694	1,694
Total	**5,332**	**1,737**	**7,069**

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 2018, 100% of the commercial sales and supply from special access reimbursement schemes is generated from supply to European countries including Switzerland (31 December 2017: 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 2018 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, 2019

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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 half-year ended 31 December 2018. 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 2019