APPENDIX 4D ASX Listing Rule 4.2A.3

HALF YEARLY REPORT

HALF YEAR ENDED 31 DECEMBER 2016

CLINUVEL PHARMACEUTICALS LTD

ABN 88 089 644 119

PREVIOUS CORRESPONDING PERIOD: HALF YEAR ENDED 31 DECEMBER 2015

RESULTS FOR ANNOUNCEMENT TO THE MARKET

				($A'000)
Revenues from continuing activities	Increased	395%	to	6,991
Profit from continuing activities after tax attributed to members	Increased	177%	to	2,523
Net Profit for the period attributed to members	Increased	179%	to	2,552

DIVIDENDS (DISTRIBUTION)

	Amount per security	Franked amount per security
Final dividend*	*Nil ¢	*Nil ¢
Interim dividend	*Nil ¢	*Nil ¢
***CLINUVEL PHARMACEUTICALS LIMITED has not paid any dividends during the 2016/17 financial year**		
Previous corresponding period (31 December 2015)	*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:
* Not applicable

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	$0.43	$0.20

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 2016

DIRECTORS' REPORT

Your Directors present their report on the Company and its controlled entities for the half year ended 31 December 2016.

DIRECTORS

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

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

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

REVIEW AND RESULTS OF OPERATIONS

The result from ordinary activities attributable to CLINUVEL PHARMACEUTICALS LIMITED for the half year was a net profit of $2,522,519, representing a 177% improvement to the financial result for the same period last year (a net loss of $3,261,046).

Key highlights of the financial activities of the consolidated entity for the six months to 31 December 2016 include:

FINANCIAL HIGHLIGHTS

Cash & Equivalents

Cash and Other Financial Assets amounted to $19,550,345 (30 June 2016: $13,844,703). Total Net Assets equalled $20,552,622 and net tangible assets at balance date were $0.437 per share.

Revenue from Sale of Goods, Sales Reimbursements, Interest Income & Other Income

Commercial sales of SCENESSE® (afamelanotide 16mg) commenced in June 2016 and the Company recorded its first full six months of sales under its marketing authorisation. Commercial sales for the half year ended 31 December 2016 was $4,180,724, with sales to centres in the Netherlands, Germany, Austria and Italy. The subsidised supply of SCENESSE® implants under the special access reimbursement schemes of Italy and Switzerland generated $2,669,292 in revenue for the six months to 31 December 2016. This is compared to revenue of $1,317,195 for the six months to 31 December 2015, a 103% increase. Since 1 January 2016 the subsidised price of SCENESSE® under the special access reimbursement schemes increased to be equivalent to the commercial price of SCENESSE®. The increase in price occurred in a period when a 24% decline in sales units was recorded in Italy and Switzerland. From November 2016 onwards, supply of SCENESSE® in Italy provided is recorded as a commercial sale under the European marketing authorisation as opposed to a subsidised supply under a special access reimbursement scheme.

CLINUVEL's cash and cash equivalents generated interest income of $140,650, up from $94,463 in interest income generated for the same period last year. The increase in interest revenue is due to higher average level of cash reserves held over the six months in interest-yielding Australian dollars and which were available for working capital deployment. The higher average level of cash reserves generating interest revenue was primarily sourced from capital raised in a private placement to existing and new institutional and professional investors in March 2016. The interest income result was in a period of lower average rates of return from term deposit holdings throughout the six months compared to the same period 12 months ago. As a result of decreasing eligible research and development incentive expenditures, the Company is reporting a $38,266 Australian R&D tax incentive refund for the six months ended 31 December 2016. This compares to a reported tax refund result relating to activities conducted in the half year to 31 December 2015 of $312,850. There were no financial assets held for trading during the reporting period.

Clinical Development

Clinical development costs increased 17% to $115,815 compared to the same period last year (31 December 2015: $99,028). The result is due to after-trial expenditures including data management and study reporting for the CUV103 Phase II study in vitiligo and with other completed SCENESSE® clinical studies.

Drug formulation R&D, Manufacture & Distribution

The costs towards drug formulation development, manufacture and distribution to treating centres for the six months to 31 December 2016 is $285,290 a 51% reduction to the same period to 31 December 2015 of $584,969. The prior reporting period included the cost of manufacturing placebo implants for clinical trial use as well as distribution set-up costs which were incurred prior to the 2016 commercial launch in Europe. There were ongoing manufacturing and implant development costs to support sales and subsidised supply but at reduced levels when compared to the prior period leading up to commercial launch. The current period included first time royalty expenses to CLINUVEL's implant contract manufacturer.

Non-Clinical and Regulatory (Pre & Post Marketing)

Regulatory and non-clinical development costs decreased 9% from $533,518 for the six months to 31

December 2015 to $487,738 for the six months to 31 December 2016. The costs incurred in the current period were primarily associated with the Company meeting its post-marketing and pharmacovigilance program commitments consequent to the European Medicines Agency (EMA) approval of SCENESSE® to treat patients with erythropoietic protoporphyria (EPP), including European EPP Disease Registry implementation and use, pharmacovigilance system oversight and audit, consultant and fees associated with regulatory activities. An improved result from the prior period was largely due to $286,495 incurred in the prior period that was related to the non-clinical study to examine the effect of SCENESSE® in combination with narrowband UVB therapy of which $nil was incurred in the current period.

Clinical, Regulatory & Commercial Overheads

Clinical, regulatory and commercial overheads increased 16% to $842,981 compared to the six months ended 31 December 2015 of $724,789, reflecting a continuing increase to head count in the regulatory, pharmacovigilance, medical monitoring, complementary product and quality assurance staffing primarily as a result of obtaining European marketing authorisation and also establishing the VALLAURIX PTE LTD joint venture.

Business Marketing & Listing, and Patent & Trademarks

Expenses towards business marketing and listing fees decreased 11% to $410,433 (31 December 2015: $459,388). An increase in communications and website staffing was balanced out by reductions in expenditures towards independent pricing modelling fees which was completed in the prior reporting period and in hosting key expert meetings. Patent and trademark fee charges also reduced 11%, from $114,163 for the six months ended 31 December 2015 to $101,825 for the same period this year. CLINUVEL continues to fortify its patent protection by applying for new patents and methodically renewing its existing patents across a range of methods, indications and territories.

General Operations

Expenses from general operations decreased 16% to $2,153,227 (31 December 2015: $2,566,084). The primary reason for the decrease was a reduction of $615,566 in the non-cash charge to share based payments when compared to the prior reporting period, mostly related to the issue of performance rights to Directors upon shareholder approval at the Company's 28 November 2014 AGM and the subsequent achievement of performance conditions attached to these performance rights. If the share based payment charge was removed from both reporting periods, the expenses from general operations increased 11% ($1,971,997 for the 6 months to 31 December 2016 compared to $1,769,288 for the 6 months to 31 December 2015). The key drivers to the 11% increase in general operations excluding share-based payments is recruitment costs to support additional headcount in the UK and Singapore, rental and general office costs for the recently established UK office and office relocation costs for moving offices in other CLINUVEL locations. The restatement of foreign currency debtor and creditor balances and currencies held resulted in a loss of $95,471 compared to a $96,562 gain for the six months to 31 December 2015.

At 31 December 2016 basic earnings per share were $0.053 calculated on a weighted average number of 47,609,621 issued ordinary shares. This is compared to basic earnings per share of ($0.073) as at 31 December 2015 on a weighted average number of 44,554,787 issued ordinary shares.

The Company made a number of announcements throughout the six months ended 31 December 2016 describing the progress of, and developments within, the business.

REVIEW OF OPERATIONS

On 6 July 2016, the Company announced that the US Food and Drug Administration (FDA) has granted SCENESSE® Fast Track designation for the treatment of EPP. This designation recognises the severity of EPP and the unmet medical need of the disorder in the US. The Fast Track designation enables CLINUVEL to file a New Drug Application (NDA) on a rolling basis for US regulatory assessment.

On 18 July 2016 it was announced that the US FDA had concluded an initial four-month review of CLINUVEL'S clinical data package for SCENESSE® in patients with EPP. The basis behind the FDA's request for the clinical data package was to understand the impact and severity of EPP symptoms and the clinical effectiveness of SCENESSE®. The FDA deemed CLINUVEL's clinical data package satisfactory for submitting a New Drug Application (NDA).

On 3 August 2016 it was announced that CLINUVEL had fulfilled the FDA requirement to demonstrate safety in a pre-clinical model prior to progressing further with the clinical development of the combination therapy of SCENESSE® and narrowband UVB (NB-UVB) light in the pigmentation disorder vitiligo. CLINUVEL has completed one US Phase II clinical trial of SCENESSE® in vitiligo patients (CUV102), with a second study (CUV103) in Singapore. In both studies the drug has been used in combination with NB-UVB light to evaluate its safety profile and ability to repigment skin in vitiligo patients. The results of CUV102 and preliminary results in CUV103 show that SCENESSE® in combination with NB-UVB light administered twice or thrice weekly had a good safety profile, and the optimal effectiveness of the combination was identified in patients of darker skin complexion (Fitzpatrick skin types IV, V and VI). The FDA communicated to CLINUVEL that – prior to pursuing later stage clinical trials and seeking marketing authorisation for SCENESSE® in vitiligo in the US – the Company would need to demonstrate the safety of the drug in combination with NB-UVB light, simulating the proposed human dose regimen in a pre-clinical model. This requirement is now considered completed.

On 18 October 2016 CLINUVEL announced an update to the review by the National Institute for Health and Care Excellence (NICE) regarding SCENESSE® for adult patients with EPP in England. CLINUVEL had previously announced it had participated in a public workshop with NICE where SCENESSE® was proposed to be evaluated under the Highly Specialised Technology (HST) Programme for its introduction in

England. NICE responded by making a recommendation to the UK Department of Health that SCENESSE® is to be evaluated under the Single Technology Appraisal (STA) procedure. Discussions between the Company and NICE on the evaluation procedures are ongoing.

On 9 November 2016 the company announced that it had met on 7 November with the US FDA's Division of Dermatology and Dental Products (DDDP) to discuss the content and format of a NDA submission as part of the US regulatory pathway for SCENESSE®. The pre-NDA meeting allowed both parties to discuss expectations on timelines and the sequence of submissions of the NDA modules. CLINUVEL will submit the modular dossier on SCENESSE® on a rolling basis during the first half of 2017 and after the completion of the submission of the dossier the FDA will observe a validation period of two months. Further interactions between the DDDP and CLINUVEL will take place as the submission progresses.

Throughout the six months between 1 July and 31 December 2016 substantial shareholder notice filings were disclosed including a notice of becoming a substantial shareholder by CLINUVEL PHARMACEUTICALS LTD by virtue of its control of A.C.N. 108 768 896 Pty Ltd in which it has a relevant interest in the company's shares as the registered holder, along with Dr Philippe Wolgen on 10 August 2016.

Included here 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 2016.

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 2016.

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.

PHILIPPE WOLGEN
MANAGING DIRECTOR
Dated this 24th day of February, 2017

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Independent Auditor's Review Report
To The Members of Clinuvel Pharmaceuticals Limited

We have reviewed the accompanying half-year financial report of Clinuvel Pharmaceuticals Limited (the Company), which comprises the consolidated financial statements being the statement of financial position as at 31 December 2016, and the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a statement or description of accounting policies, other explanatory information and the directors' declaration of the consolidated entity, comprising both the Company and the entities it controlled at the half-year's end or from time to time during the half-year.

Directors' Responsibility for the Half-year Financial Report

The Directors of Clinuvel Pharmaceuticals Limited 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 controls as the Directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express a conclusion on the consolidated half-year financial report based on our review. We conducted our review in accordance with the 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 Clinuvel Pharmaceuticals Limited consolidated entity's financial position as at 31 December 2016 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 complied with the independence requirements of the *Corporations Act 2001*.

Conclusion

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

a giving a true and fair view of the consolidated entity's financial position as at 31 December 2016 and of its performance for the half-year ended on that date; and

b complying with Accounting Standard AASB 134 *Interim Financial Reporting* and *Corporations Regulations 2001*.

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

B. A. Mackenzie
Partner - Audit & Assurance

Melbourne, 24 February 2017

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE HALF YEAR ENDED 31 DECEMBER 2016

	CONSOLIDATED	
	31 December 2016 $	31 December 2015 $
Revenues		
Interest received	140,650	94,463
Sales reimbursements	2,669,292	1,317,195
Commercial sales	4,180,724	-
Total revenues	**6,990,666**	**1,411,658**
Other income		
Government R&D tax incentive	38,266	312,850
Total other income	**38,266**	**312,850**
Expenses		
Clinical development costs	(115,815)	(99,028)
Drug formulation R&D, manufacture & distribution	(285,290)	(584,969)
Regulatory (Pre & Post Marketing) & Non-clinical	(487,738)	(533,518)
Clinical, Regulatory & Commercial overheads	(842,981)	(724,789)
Business marketing & listing	(410,433)	(459,388)
Patents and trademarks	(101,825)	(114,163)
General Operations (incl Board)	(2,153,228)	(2,566,084)
Foreign currency translation gain/(loss)	(95,471)	96,562
Realised net currency loss on transactions	(13,632)	(177)
Total expenses	**(4,506,413)**	**(4,985,554)**
Profit/(loss) before related income tax expenses	**2,522,519**	**(3,261,046)**
Income tax expense (benefit)	-	-
Profit/(loss) after related income tax expense	2,522,519	(3,261,046)
Profit/(loss) for the period	**2,522,519**	**(3,261,046)**
Other comprehensive income:		
Items that may be re-classified subsequently to profit and loss:		
Losses arising from the conversion of foreign operations	(71,658)	(41,626)
Income tax relating to other comprehensive income	-	-
Other comprehensive loss for the period after income tax	(71,658)	(41,626)
Total comprehensive income/(loss) for the period	**2,450,861**	**(3,302,672)**
Profit for the year attributable to:		
Non-controlling interest	(29,545)	(14,016)
Owners of the parent	2,552,064	(3,247,030)
	2,522,519	**(3,261,046)**
Total comprehensive income/(loss) attributable to:		
Non-controlling interest	(29,545)	(14,016)
Owners of the parent	2,480,406	(3,288,656)
	2,450,861	**(3,302,672)**
Basic & diluted earnings per share – cents per share	**5.3**	**(7.3)**

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 2016

	CONSOLIDATED	
	31 December 2016 $	30 June 2016 $
Current assets		
Cash and cash equivalents	19,550,345	13,844,703
Trade and other receivables	1,509,152	4,823,770
Inventory	1,353,602	1,082,163
Other	256,349	222,961
Total current assets	**22,669,448**	**19,973,597**
Non-current assets		
Property, plant and equipment	171,233	164,670
Total non-current assets	**171,233**	**164,670**
Total assets	**22,840,681**	**20,138,267**
Current liabilities		
Trade and other payables	1,509,567	1,573,361
Provisions	763,832	715,017
Total current liabilities	**2,273,399**	**2,288,378**
Non-current liabilities		
Provisions	14,660	15,369
Total non-current liabilities	**14,660**	**15,369**
Total liabilities	**2,288,059**	**2,303,747**
Net assets	**20,552,622**	**17,834,520**
Equity		
Equity attributable to the owners of the parent:		
Contributed equity	148,396,095	146,764,500
Reserves	2,568,336	4,094,977
Accumulated losses	(130,506,547)	(133,063,239)
Equity attributable to the owners of the parent	**20,457,884**	**17,796,238**
Equity attributable to non-controlling (minority equity) interest	**94,738**	**38,282**
Total equity	**20,552,622**	**17,834,520**

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 2016

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 2015 (44,554,787 fully paid shares)	**138,465,335**	**2,313,678**	**384,660**	**(129,942,039)**	**11,221,634**	**(16,343)**	**11,205,291**
Equity contribution by subsidiary non-controlling interest	-	-	-	-	-	87,143	**87,143**
Employee share-based payment options	-	796,796	-	-	796,796	-	**796,796**
Transactions with owners	**138,465,335**	**3,110,474**	**384,660**	**(129,942,039)**	**12,018,430**	**70,800**	**12,089,230**
Loss for the period	-	-	-	(3,247,030)	(3,247,030)	(14,016)	**(3,261,046)**
Other comprehensive income:							
Exchange differences of foreign exchange translation of foreign operations	-	-	(41,626)	-	(41,626)	-	**(41,626)**
Balance at 31 December 2015 (44,554,787 fully paid shares)	**138,465,335**	**3,110,474**	**343,034**	**(133,189,069)**	**8,729,774**	**56,784**	**8,786,558**
Balance at 1 July 2016 (47,080,637 fully paid shares)	**146,764,500**	**3,984,103**	**110,874**	**(133,063,239)**	**17,796,238**	**38,282**	**17,834,520**
Equity contribution by subsidiary non-controlling interest	-	-	-	-	-	86,001	**86,001**
Issue of Share Capital under share-based payment	1,631,595	(1,631,595)	-	-	-	-	-
Employee share-based payment options	-	176,612	-	4,628	181,240	-	**181,240**
Transactions with owners	**148,396,095**	**2,529,120**	**110,874**	**(133,058,611)**	**17,977,478**	**124,283**	**18,101,761**
Profit/(loss) for the period	-	-	-	2,552,064	2,552,064	(29,545)	**2,522,519**
Other comprehensive income:							
Exchange differences of foreign exchange translation of foreign operations	-	-	(71,658)	-	(71,658)	-	**(71,658)**
Balance at 31 December 2016 (47,725,227 fully paid shares)	**148,396,095**	**2,529,120**	**39,216**	**(130,506,547)**	**20,457,884**	**94,738**	**20,552,622**

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 2016

	CONSOLIDATED	
	31 December 2016 $	31 December 2015 $
Cash flows from operating activities		
GST and VAT refunds	153,188	92,061
Receipts from customers	10,080,459	1,592,409
Interest received	124,987	91,404
Payments to suppliers and employees	(4,688,116)	(4,945,664)
Net cash provided by (used in) operating activities	**5,670,518**	**(3,169,790)**
Cash flows from investing activities		
Payments for property, plant and equipment	(41,658)	(4,809)
Net cash provided by (used in) investing activities	**(41,658)**	**(4,809)**
Cash flows from financing activities		
Equity contribution by subsidiary non-controlling interest	85,082	89,118
Net cash provided by (used in) financing activities	**85,082**	**89,118**
Net increase/(decrease) in cash held	**5,713,942**	**(3,085,481)**
Cash and cash equivalents at beginning of the period	**13,844,703**	**10,572,295**
Effect of exchange rate changes on foreign currency held	(8,300)	11,953
Cash and cash equivalents at end of the period	**19,550,345**	**7,498,767**

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 2016

STATEMENT OF ACCOUNTING POLICIES 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 2016 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 2016.

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.

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

No dividends were paid or declared during the interim reporting period.

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.

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 subsidised 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 2016, 100% of the commercial sales and subsidised supply from special access reimbursement schemes is generated from five countries (31 December 2015: two countries).

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 2016 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.

PHILIPPE WOLGEN
Director
Dated this 24th day of February, 2017

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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 2016, 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, 24 February 2017