

APPENDIX 4D

ASX Listing Rule 4.2A.3

HALF YEARLY REPORT

HALF YEAR ENDED 31 DECEMBER 2015

CLINUVEL PHARMACEUTICALS LTD

ABN 88 089 644 119

PREVIOUS CORRESPONDING PERIOD: HALF YEAR ENDED 31 DECEMBER 2014

RESULTS FOR ANNOUNCEMENT TO THE MARKET

				(\$A'000)
Revenues from continuing activities	Increased	32%	to	1,412
Loss from continuing activities after tax attributed to members	Decreased	56%	to	(3,261)
Net Loss for the period attributed to members	Decreased	56%	to	(3,261)

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 2015/16 financial year**

Previous corresponding period (31 December 2014)	*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	\$0.20	\$0.30

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 CHESSE approved, or security holding balances established by 5.00pm or such later time permitted by SCH business Rules if securities are CHESSE 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 FINANCIAL REPORT HALF YEAR ENDED 31 DECEMBER 2015

DIRECTORS' REPORT

Your Directors present their report on the company and its controlled entities for the half year ended 31 December 2015.

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 consolidated loss from ordinary activities for the half year was \$3,261,046, representing a 56% improvement on the loss sustained for the same period last year (\$7,347,382).

Key highlights of the financial activities of the consolidated entity for the six months to 31 December 2015 include:

1. Cash and Other Financial Assets amounted to \$7,498,767 (30 June 2015: \$10,572,295). Total Net Assets equalled \$8,786,558 and net tangible assets at balance date were \$0.197 per share.

2. Clinuvel's cash and cash equivalents, generated interest income of \$94,463, down from \$203,785 in interest income generated for the same period last year. The decrease in revenue is due to a combination of a lower average level of cash reserves available for working capital deployment and lower average rates of return from term deposit holdings throughout the six months compared to the same period 12 months ago. The supply of SCENESSE® (afamelanotide 16mg) implants under the reimbursement schemes of Italy and Switzerland generated \$1,317,195 in revenue for the six months to 31 December 2015. This is compared to revenue of \$865,080 for the six months to 31 December 2014, a 52% increase. Whilst the number of implants supplied under the reimbursement schemes increased period-on-period, reflecting the increasing awareness and demand for the drug within the patient communities, the revenue result benefited from a stronger Euro and Swiss Franc relative to the Australian dollar. There were no financial assets held for trading during the reporting period. The company is projecting a \$312,850 Australian R&D tax incentive refund for the six months ended 31

December 2015 resulting from an increase in eligible research and development expenditures. This compares to a reported tax refund result relating to activities conducted in the half year to 31 December 2014 of \$207,136.

3. Clinical development costs decreased 41% to \$99,028 compared to the same period last year (31 December 2014: \$167,488). The continuing decline in clinical development costs reflects the concluding of its clinical trial program into erythropoietic protoporphyria (EPP) and furthering its focus on the CUV103 Phase II study in vitiligo.

4. Drug delivery research costs for the six months to 31 December 2015 is \$504,161 which is broadly in line with the same period to 31 December 2014 (\$512,765). In the current reporting period implants were required to supply a preclinical study mimicking the future human dosing in vitiligo, a US Food and Drug Administration (FDA) imposed requirement whereas the drug delivery research costs in the previous period was related to meeting future supply requirements.

5. Regulatory and non-clinical development costs increased 245% from \$178,313 for the six months to 31 December 2014 to \$614,326 for the six months to 31 December 2015. Approximately two-thirds of the increase relates to costs incurred from conducting the aforementioned preclinical study to examine the effect of SCENESSE® in combination with narrowband UVB therapy. Other reasons for the increase included fees from external consultants assisting the company in meeting its post-marketing and pharmacovigilance program commitments consequent to the European Medicines Agency (EMA) approval of SCENESSE® to treat patients with EPP, along with the costs attached to establishing a distribution system to facilitate product release in Europe. The expenditures in the prior reporting period were contained to fees towards third-party regulatory experts to assist the company in answering questions received from the EMA in the final stages of the EMA's review of the company's marketing authorisation application (MAA).

6. Research, development and distribution overheads increased 24% to \$724,789 compared to the six months ended 31 December 2014 of \$584,485, reflecting an increased head count in regulatory, complementary product and quality assurance staffing as a result of obtaining MAA approval and establishing the Vallaurix Pte Ltd joint venture.

7. Expenses towards business marketing and listing fees increased 21% to \$459,388 (31 December 2014: \$380,541). The increase in these expenses was due to a combination of pricing modelling fees, hosting key

expert meetings, website and database management costs and increased personnel costs. Patent, trademark and sub-license maintenance fee charges reduced 18%, from \$138,426 for the six months ended 31 December 2014 to \$114,163 for the same period this year. The decrease was largely due to the expenditures incurred in the prior reporting period in validating European patents in all European member states in the week's consequent to the EMA's approval of Clinuvel's MAA in EPP.

8. Expenses from general operations decreased 62% to \$2,566,084 (31 December 2014: \$6,764,516). The primary reason for the decrease was the \$4,413,421 non-cash charge to share based payments in the prior reporting period, mostly related to the issue of performance rights to Directors upon shareholder approval at the company's 28 November AGM and the subsequent achievement of performance conditions attached to these performance rights. For the six months to 31 December 2015, the non-cash charge to share based payments was \$796,796. If the share based payment charge was removed from both reporting periods, the expenses from general operations improved 25% (\$1,769,288 for the 6 months to 31 December 2015 compared to \$2,351,095 for the 6 months to 31 December 2014). Along with a general reduction in general overseas travel expenditures, the reason for this improvement is the absence of legal and corporate advisory fees which were incurred in the prior reporting period in Clinuvel responding to Retrophin Inc's unsolicited bid proposal in July 2014 to acquire all the issued ordinary shares in the company. The restatement of foreign currency debtor and creditor balances and currencies held resulted in a gain of \$96,562 compared to a \$104,138 gain for the six months to 31 December 2014. The degree of weakening in the Australian dollar for the July to December 2015 was less than the same period 12 months ago.

At 31 December 2015 basic earnings per share were (\$0.073) calculated on a weighted average number of 44,554,787 issued ordinary shares. This is compared to basic earnings per share of (\$0.173) as at 31 December 2014 on a weighted average number of 42,454,604 issued ordinary shares.

The company made a number of announcements throughout the six months ended 31 December 2015 describing the progress of, and developments within, the business.

On 2 July 2015, the company announced that results from its pivotal Phase III studies of SCENESSE® in EPP were published in *the New England Journal of Medicine*, a world leading medical periodical publication.

On 27 August 2015 it was announced that Clinuvel will meet the US (FDA) to discuss the overall development of SCENESSE® and the filing requirements for a New Drug Application for the treatment of adult patients diagnosed with EPP. It was further announced on 5 October 2015 that the company had met with the US FDA's Division for Dermatology and Dental Products (DDDP) and representatives of the Center of Drug Evaluation and Research. The DDDP stated that it was seeking a regulatory pathway to make SCENESSE® available in the USA, and the regulatory avenue of Accelerated Approval was suggested, pending further review, analyses and discussions on available

photoprovocation and data on quality of life in EPP patients by the FDA.

On 21 September 2015 it was announced that the EMA's Pharmacovigilance and Risk Committee had agreed to a Post Authorisation Safety Study protocol, allowing SCENESSE® to be released for the commercial supply to adult patients diagnosed with EPP.

Throughout the six months between 1 July and 31 December 2015 a number of substantial shareholder notice filings were disclosed including a notice of becoming a substantial shareholder by Lagoda Investment Management LLC (23 September), subsequent notice of changes to their shareholding interests in Clinuvel (7 October, 4 November) and also a notice of ceasing to be a substantial shareholder by Retrophin Inc (30 July).

Following is the Half Year Report Appendix 4D, together with the Financial Report, Directors' Report and Declaration and Audit Independent Review Report relating to the half year ended 31 December 2015.

This letter and attached 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 2015.

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 19th day of February, 2016

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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 2015, 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, 19 February 2016

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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 ("Company"), which comprises the consolidated financial statements being the statement of financial position as at 31 December 2015, 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 2015 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.

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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 Clinuvet 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 2015 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, 19 February 2016

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE HALF YEAR ENDED 31 DECEMBER 2015

	CONSOLIDATED	
	31 December 2015 \$	31 December 2014 \$
Revenues		
Interest received	94,463	203,785
Sales reimbursements	1,317,195	865,080
Total revenues	1,411,658	1,068,865
Other income		
Government R&D tax incentive	312,850	207,136
Total other income	312,850	207,136
Expenses		
Clinical development costs	(99,028)	(167,488)
Drug delivery research costs	(504,161)	(512,765)
Regulatory and non-clinical development costs	(614,326)	(178,313)
Research, development, distribution overheads	(724,789)	(584,485)
Business marketing & listing	(459,388)	(380,541)
Licenses, patents and trademarks	(114,163)	(138,426)
General operations	(2,566,084)	(6,764,516)
Foreign currency translation gains (losses)	96,562	104,138
Realised net currency gain (loss) on transactions	(177)	(987)
Total expenses	(4,985,554)	(8,623,383)
Profit (loss) before related income tax expenses	(3,261,046)	(7,347,382)
Income tax expense (benefit)	-	-
Profit (loss) after related income tax expense	(3,261,046)	(7,347,382)
Profit (loss) for the period	(3,261,046)	(7,347,382)
Other comprehensive income:		
Items that may be re-classified subsequently to profit and loss:		
Gains (losses) arising from the conversion of foreign operations	(41,626)	40,422
Income tax relating to other comprehensive income	-	-
Other comprehensive income/(loss) for the period after income tax	(41,626)	40,422
Total comprehensive income/(loss) for the period	(3,302,672)	(7,306,960)
Profit for the year attributable to:		
Non-controlling interest	(14,016)	-
Owners of the parent	(3,247,030)	(7,347,382)
	(3,261,046)	(7,347,382)
Total comprehensive income/(loss) attributable to:		
Non-controlling interest	(14,016)	-
Owners of the parent	(3,288,656)	(7,306,960)
	(3,302,672)	(7,306,960)
Basic & diluted earnings per share – cents per share	(7.3)	(17.3)

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 FOR THE HALF YEAR ENDED 31 DECEMBER 2015

	CONSOLIDATED	
	31 December 2015 \$	30 June 2015 \$
Current assets		
Cash and cash equivalents	7,498,767	10,572,295
Trade and other receivables	2,069,112	1,960,453
Inventory	1,357,959	837,135
Other	287,005	204,623
Total current assets	11,212,843	13,574,506
Non-current assets		
Property, plant and equipment	67,852	69,369
Total non-current assets	67,852	69,369
Total assets	11,280,695	13,643,875
Current liabilities		
Trade and other payables	1,847,982	1,860,636
Provisions	642,259	574,640
Total current liabilities	2,490,241	2,435,276
Non-current liabilities		
Provisions	3,896	3,308
Total non-current liabilities	3,896	3,308
Total liabilities	2,494,137	2,438,584
Net assets	8,786,558	11,205,291
Equity		
Equity attributable to the owners of the parent:		
Issued capital equity	138,465,335	138,465,335
Reserves	3,453,508	2,698,338
Accumulated losses	(133,189,069)	(129,942,039)
Total equity attributable to the owners of the parent	8,729,774	11,221,634
Non-controlling interest:	56,784	(16,343)
Total equity	8,786,558	11,205,291

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 2015

CONSOLIDATED	Share capital \$	Share option reserve \$	Performance rights reserve \$	Foreign currency translation reserve \$	Retained earnings \$	Total attributable to Owners of parent \$	Non-controlling interest \$	Total equity \$
Balance at 1 July 2014 (42,391,435 fully paid shares)	133,567,056	-	1,321,529	116,517	(119,577,370)	15,427,732	-	15,427,732
Issue of share capital under private placement	250,000	-	-	-	-	250,000	-	250,000
Employee share-based payment options	-	-	4,380,058	-	33,364	4,413,422	-	4,413,422
Transactions with owners	133,817,056	-	5,701,587	116,517	(119,544,006)	20,091,154	-	20,091,154
Profit/(loss) for the year	-	-	-	-	(7,347,382)	(7,347,382)	-	(7,347,382)
Other comprehensive income:								
Exchange differences of foreign exchange translation of foreign operations	-	-	-	40,422	-	40,422	-	40,422
Balance at 31 December 2014 (42,526,425 fully paid shares)	133,817,056	-	5,701,587	156,939	(126,891,388)	12,784,194	-	12,784,194
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
Acquisition of joint venture subsidiary with non-controlling interests	-	-	-	-	-	-	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
Profit/(loss) for the year	-	-	-	-	(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

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 2015

	CONSOLIDATED	
	31 December 2015 \$	31 December 2014 \$
Cash flows from operating activities		
GST and VAT refunds	92,061	75,694
Receipts from customers	1,592,409	1,101,487
Interest received	91,404	190,040
Payments to suppliers and employees	(4,945,664)	(4,293,860)
Net cash provided by (used in) operating activities	(3,169,790)	(2,926,639)
Cash flows from investing activities		
Payments for property, plant and equipment	(4,809)	(2,749)
Net cash provided by (used in) investing activities	(4,809)	(2,749)
Cash flows from financing activities		
Proceeds from issue of ordinary shares	-	250,000
Proceeds from acquisition of joint venture subsidiary with non-controlling interests	89,118	-
Payment of share issue costs	-	(25,008)
Net cash provided by (used in) financing activities	89,118	224,992
Net increase/(decrease) in cash held	(3,085,481)	(2,704,396)
Cash at beginning of the period	10,572,295	14,625,583
Effect of exchange rate changes on foreign currency held	11,953	58,153
Cash at end of the period	7,498,767	11,979,340

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 2015

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 2015 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 2015.

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 reports 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 is concentrated in researching

and developing a sole asset, being its leading drug candidate.

It has established entities in more than one geographical area. Revenues from reimbursement revenue 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 2015, 100% of the revenue from sales reimbursements is generated from six customers (six months to 31 December 2014: five customers).

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 company's and the consolidated entity's financial position as at 31 December 2015 and of their 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 19th day of February, 2016