

Appendix 4D

CLINUVEL PHARMACEUTICALS LIMITED

ABN: 88 089 644 119

Half Yearly Report Half Year Ended 31 December 2009

(Previous Corresponding Period : Half year ended 31 December 2008)

Results for announcement to the market

\$A'000

Revenues from ordinary activities	Decreased 4%	to	2,693
Loss from ordinary activities after tax attributable to members	Decreased 51%	to	(4,434)
Net loss for the period attributable to members	Decreased 51%	to	(4,434)

Dividends (distributions)	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 2010 financial year.

Previous corresponding period (30 December 2008)	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.

Ratios and Other measures**NTA backing**

Net tangible asset backing per ordinary security

Current period	Previous corresponding Period
11 cents	14 cents

Additional Disclosure

As per ASX listing rule 4.2A.3, for the six month period ending 31 December 2009:

Control gained over entities having material effect

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

Loss of control of entities having material effect

Name of entity (or group of entities)	N/A
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Consolidated profit (loss) from ordinary activities and extraordinary items after tax of the controlled entity (or group of entities) for the current period to the date of loss of control	N/A
Date to which the profit (loss) has been calculated	N/A
Consolidated profit (loss) from ordinary activities and extra ordinary items after tax of the controlled entity(or group of entities) while controlled during 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 +CHES approved, or security holding balances established by 5.00pm or such later time permitted by SCH business Rules if +securities are +CHES approved)	N/A
If it is a final dividend, has it been declared?	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 ordinary activities Before tax	N/A	N/A
Income tax on ordinary activities	N/A	N/A
Profit (loss) from ordinary 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 2009**

CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES

DIRECTORS' REPORT

Your Directors present their report on the company and its controlled entity for the half year ended 31 December 2009.

DIRECTORS

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

Mrs B. M. Shanahan
Dr P.J. Wolgen
Dr H.P.K. Agersborg

Dr R. Aston
Mr S.R. McLiesh
Mr L. J. Wood

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 \$4,434,473, representing a 51% decrease to the loss sustained for the same period last year (\$9,041,848).

Key highlights of the financial activities of the consolidated entity for the six months to 31 December 2009 include:

1. Cash and Other Financial Assets amounted to \$32,477,942 (30 June 2009: \$37,754,141). Total Net Assets equalled \$32,952,023 and net tangible assets at balance date were \$0.108 per share.
2. Clinuvel's portfolio of cash and financial assets, primarily fixed income securities, generated interest income of \$776,782, down from \$1,718,390 for the same period last year. Movements in Australian dollar exchange rates resulted in foreign currency gains on expenditures in foreign currency of \$391,166 (31 December 2008: \$29,699 loss). An unrealised gain of \$1,525,718 was recorded in the revaluation of financial assets (31 December 2008: \$2,508,691 loss).
3. Research and development expenditures decreased 33% to \$3,693,816, compared to the same period last year (to Dec 31 2008: \$5,521,885). The cost of supplying implants to meet clinical trial requirements and the scaling up of the implant manufacturing process was \$1,878,949 less than the same period last year. Increases in clinical and regulatory staffing costs to meet the demands of managing the clinical trial program were largely offset by the absence of regulatory expenditures incurred in the successful IND application in December 2008.
4. Expenditure from general operations decreased 12% to \$2,437,898 (31 December 2008: \$2,777,231). The major reasons for the improvement in the general operations result was due to the relocation of the US office, reduced non-clinical staffing and reduced travel costs (a \$271,988 gain compared to the same period last year), reflecting the company's continuing emphasis on concentrating its resources on its core clinical research and development and regulatory activities. Spending on corporate communications, investor marketing and company listing activities were comparable between the two reporting periods (\$437,093 compared to \$449,746 for the same period last year).

During the six months to December 31 2009 Clinuvel achieved a number of milestones in its clinical and regulatory program for the first-in-class photoprotective drug afamelanotide.

The company released preliminary results from its lead Phase III trial in porphyria (EPP). This trial (CUV017) was completed in 100 patients in Europe and Australia in late December. Clinuvel successfully completed Phase II trials for the orphan indication Solar Urticaria (SU), as well as positive results in a Phase II pilot study of afamelanotide as an adjunctive therapy in systemic photodynamic therapy (PDT). Preliminary results were published from a Phase III trial in polymorphic light eruption (PLE) and Phase II trials to determine afamelanotide's photoprotective effect in preventing actinic keratoses (AKs) and SCC skin cancer in organ transplant recipients (OTRs) were advanced in Europe and Australia. The company also conducted its first US trial of afamelanotide, a confirmatory pharmacokinetic study conducted under the IND granted in January 2009.

Further regulatory acknowledgement was received with the FDA granting afamelanotide its second orphan drug designation (ODD) for SU and the European Medicines Agency (EMA, formerly EMEA) granting Clinuvel Small and Medium Enterprise status.

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 2009.

This letter and attached Half Year Report forms part of this announcement to the Australian Stock Exchange Limited, and should be read in conjunction with Clinuvel's Annual Report for the year ended 30 June 2009.

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.

A handwritten signature in black ink, appearing to read 'Philippe Wolgen', written in a cursive style.

PHILIPPE WOLGEN
MANAGING DIRECTOR

Dated this 5th day of February, 2010

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Independent Auditor's Review Report To the Members of Clinuvel Pharmaceuticals Ltd

We have reviewed the accompanying half-year financial report of Clinuvel Pharmaceuticals Ltd ("the Company"), which comprises the consolidated financial statements being the statement of financial position as at 31 December 2009, and the statement of comprehensive income, condensed statement of changes in equity and condensed statement of cash flows for the half-year ended on that date, a statement of accounting policies, other selected explanatory notes 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 the Company are responsible for the preparation and fair presentation of the half-year financial report in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the Corporations Act 2001. This responsibility includes establishing and maintaining internal controls relevant to the preparation and fair presentation of the half-year financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

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 Auditing Standard on Review Engagement ASRE 2410: Review of Interim and Other Financial Reports 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 financial report is not in accordance with the Corporations Act 2001 including giving a true and fair view of the consolidated entity's financial position as at 31 December 2009 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 Ltd, 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.

Electronic presentation of reviewed financial report

This auditor's review report relates to the financial report of Clinuvel Pharmaceuticals Ltd for the half-year ended 31 December 2009 included on Clinuvel Pharmaceuticals Ltd's web site. The Company's directors are responsible for the integrity of Clinuvel Pharmaceuticals Ltd's web site. We have not been engaged to report on the integrity of Clinuvel Pharmaceuticals Ltd's web site. The auditor's review report refers only to the statements named above. It does not provide an opinion on any other information which may have been hyperlinked to/from these statements. If users of this report are concerned with the inherent risks arising from electronic data communications, they are advised to refer to the hard copy of the reviewed financial report to confirm the information included in the reviewed financial report presented on this web site.

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 Company's financial position as at 31 December 2009 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



D. A. Ashmore
Director - Audit & Assurance Services
Melbourne, 5 February 2010

CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES

CONDENSED STATEMENT OF COMPREHENSIVE INCOME
FOR THE HALF YEAR ENDED 31 DECEMBER 2009

		Consolidated	
		31 December 2009 \$	31 December 2008 \$
Revenues from ordinary activities	See notes	2,693,666	2,800,852
Total expenses from ordinary activities	See notes	(7,128,139)	(11,842,700)
Profit(loss) from ordinary activities before related income tax expense		(4,434,473)	(9,041,848)
Income tax expense (benefit) relating to ordinary activities			-
Profit(loss) from ordinary activities after related income tax expense		(4,434,473)	(9,041,848)
Net profit(loss)		(4,434,473)	(9,041,848)
Other comprehensive income:			
Losses arising from the conversion of foreign operations		(2,585)	(546,041)
Income tax relating to other comprehensive income		-	-
Other comprehensive income for the period after income tax		(2,585)	(546,041)
Total comprehensive income for the period		(4,437,058)	(9,587,889)
Basic earnings per share - cents per share		(1.5)	(3.0)

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

CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES

CONDENSED STATEMENT OF FINANCIAL POSITION
FOR THE HALF YEAR ENDED 31 DECEMBER 2009

Consolidated

	31 December 2009 \$	30 June 2009 \$
CURRENT ASSETS		
Cash Assets	16,818,259	21,710,643
Receivables	268,672	211,787
Other Financial Assets	15,659,683	16,043,498
Other	2,376,849	2,627,585
TOTAL CURRENT ASSETS	35,123,463	40,593,513
NON CURRENT ASSETS		
Property, plant and equipment	339,308	357,135
Intangible assets	284,866	663,114
TOTAL NON CURRENT ASSETS	624,174	1,020,249
TOTAL ASSETS	35,747,637	41,613,762
CURRENT LIABILITIES		
Payables	2,571,798	4,369,406
Provisions	189,084	174,646
TOTAL CURRENT LIABILITIES	2,760,882	4,544,052
NON CURRENT LIABILITIES		
Provisions	34,732	18,526
TOTAL NON CURRENT LIABILITIES	34,732	18,526
TOTAL LIABILITIES	2,795,614	4,562,578
NET ASSETS	32,952,023	37,051,184
EQUITY		
Contributed equity	113,221,065	113,221,065
Reserves	1,887,760	2,167,446
Accumulated losses	(82,156,802)	(78,337,327)
TOTAL EQUITY	32,952,023	37,051,184

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

CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES

CONDENSED STATEMENT OF CHANGES IN EQUITY
FOR THE HALF YEAR ENDED 31 DECEMBER 2009

Consolidated

	31 December 2009 \$	31 December 2008 \$
RETAINED EARNINGS		
Retained Earnings at the beginning of period	(78,337,327)	(63,171,776)
Transfer from share option reserve of lapsed, expired share options	614,998	37,763
Net profit/(loss) for the period	(4,434,473)	(9,041,848)
Retained earnings at the end of period	(82,156,802)	(72,175,861)
RESERVES		
Reserves at the beginning of period	2,167,446	1,763,836
Other comprehensive income	(2,585)	(546,041)
Movement in Share Option reserve	(277,101)	301,441
Reserves at the end of period	1,887,760	1,519,236
SHARE CAPITAL		
Share Capital at the beginning of period 303,148,665 fully paid shares	113,221,065	113,222,456
Capital Raising Costs	0	(1,391)
Share Capital at the end of period 303,148,665 fully paid shares	113,221,065	113,221,065

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

CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES

CONDENSED CASH FLOW STATEMENT
FOR THE HALF YEAR ENDED 31 DECEMBER 2009

	Consolidated	
	31 December 2009	31 December 2008
	\$	\$
CASH FLOWS FROM OPERATING ACTIVITIES		
Refund from ATO	81,812	119,088
Receipts from customers	0	0
Payments to suppliers and employees	(7,263,943)	(6,826,879)
Interest received	756,805	1,824,739
Net cash provided by (used in) operating activities	(6,425,326)	(4,883,052)
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for property, plant and equipment	(25,062)	(16,944)
Payments received property, plant and equipment	0	0
Proceeds upon disposal of financial instruments	1,655,621	4,742,410
Net cash provided by (used in) investing activities	1,630,559	4,725,466
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issue of ordinary shares	0	145,000
Payment of share issue costs	0	(1,391)
Net cash provided by (used in) financing activities	0	143,609
Net increase/(decrease) in cash held	(4,794,767)	(13,977)
Cash at beginning of the year	21,710,643	25,752,193
Effect of exchange rate changes on foreign currency held	(97,617)	352,635
Cash at end of the year	16,818,259	26,090,851

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

**CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS
FOR THE HALF YEAR ENDED 31 DECEMBER 2009**

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 set out below have been applied preparing the financial statements for the half year ended 31 December 2009, and in the preparation of the comparative income statement for the financial half year ending 31 December 2008 and the comparative balance sheet as at 30 June 2009. The accounting standards, policies, estimation methods and measurement bases used in this report is the same as those used in the last Clinuvel Pharmaceuticals Ltd Annual Report. When required by accounting standards, comparative figures have been adjusted to conform to changes in presentation for the current year.

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, other than announcements to the market referred below:

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.

CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES

NOTES TO THE CONDENSED FINANCIAL STATEMENTS
FOR THE HALF YEAR ENDED 31 DECEMBER 2009

STATEMENT OF ACCOUNTING POLICIES (CONT'D)

NOTE TO CONDENSED STATEMENT OF COMPREHENSIVE INCOME

		Consolidated	
		31 December 2009 \$	31 December 2008 \$
Revenues from ordinary activities			
(A) Specific Items			
- Interest revenue		776,782	1,718,390
- Net foreign currency translation gains		391,166	1,082,462
- Net gains on revaluation of financial assets held at fair value through profit and loss		1,525,718	0
Expenses from ordinary activities			
- Depreciation and amortisation of sub-license and intangibles		(411,301)	(415,168)
- Research and development costs		(3,693,816)	(5,521,885)
- Operations		(2,437,898)	(2,777,231)
- Foreign currency translation losses		(348,892)	(29,699)
- Realised loss on disposal of investments		(236,230)	(590,426)
- Net losses on revaluation of financial assets held at fair value through profit and loss		0	(2,508,291)

CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES

NOTES TO THE CONDENSED FINANCIAL STATEMENTS
FOR THE HALF YEAR ENDED 31 DECEMBER 2009

SEGMENT REPORTING

A segment is a component of the consolidated entity that engages in business activities to provide products or services within a particular economic environment. The consolidated entity operates in one business segment, being the biopharmaceutical sector. It has established non-revenue generating entities in more than one geographical area, however the activities from these entities comparative to the consolidated entity are considered immaterial for the purposes of segment reporting. Furthermore, although clinical trials are conducted in a number of countries, the core business functions supporting the trials are located in Australia.

**CLINUVEL PHARMACEUTICALS LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITIES**

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 2009 and of their performance for the half year ended on that date;
 - (b) complying with Accounting Standards 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 5th day of February, 2010

Grant Thornton Audit Pty Ltd
ACN 130 913 594

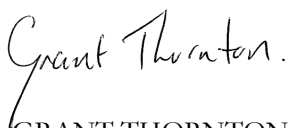
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**Auditor's Independence Declaration
To The Directors of Clinuvel Pharmaceuticals Limited**

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 2009, 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



D. Ashmore
Director - Audit & Assurance Services

Melbourne, 1 February 2010