Appendix 4D

CLINUVEL PHARMACEUTICALS LIMITED

ABN: 88 089 644 119

Half Yearly Report
Half Year Ended 31 December 2008

(Previous Corresponding Period : Half year ended 31 December 2007)

Results for announcement to the market

				$A'000
Revenues from ordinary activities	Increased	30%	to	2,801
Loss from ordinary activities after tax attributable to members	Increased	39%	to	(9,048)
Net loss for the period attributable to members	Increased	39%	to	(9,048)

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 2007 financial year.***

Previous corresponding period (30 December 2007)	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 Director's 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	Current period	Previous corresponding Period
Net tangible asset backing per ordinary security	14 cents	19 cents

Additional Disclosure

As per ASX listing rule 4.2A.3, for the six month period ending 31 December 2008:

Control gained over entities having material effect

Name of entity (or group of entities)	N/A

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

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 +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?	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 2008

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 2008.

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 (since 11 July 2008)

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 $9,041,848, representing a 39% increase to the loss sustained for the same period last year ($6,481,402).

Key highlights of the financial activities of the consolidated entity for the six months to 31 December 2008 include:

1. Cash and Other Financial Assets amounted to $43,298,110 (30 June 2008: $50,800,580). Total Net Assets equalled $42,564,440 and net tangible assets at balance date were $0.14 per share.

2. Clinuvel's portfolio of cash and financial assets, primarily fixed income securities, generated interest income of $1,718,390, down from $2,129,223 for the same period last year. The depreciation of the Australian dollar has resulted in unrealised foreign currency gains from currencies held, from loans to its US and Swiss subsidiaries and foreign trade creditor balances at reporting date, amounting to $1,082,462. On financial assets held an unrealised mark-to-market charge of $2,508,291 was recorded. Cash and financial assets are currently deemed sufficient to obtain registration for afamelanotide.

3. Research and development expenditures increased 33% to $5,521,885, compared to the same period last year (to Dec 31 2007: $4,136,636). Compared to the December 2007 period, the increase is primarily due to the scaling up of implant manufacture and the greater number of implants produced to support the progression in Clinuvel's clinical trial program. In particular, the commencement of a Phase II trial in Photodynamic Therapy, announced 23rd September 2008, and the progress made in the Phase III clinical trials on Erythropoietic Protoporphyria (EPP) resulting in an announcement on 21st January 2009 of positive interim results, significantly contributed to the increase.

4. Expenditure from general operations increased 16% to $2,777,231 (to December 2007: $2,402,442). Excluding employee share option valuations, expenditure from general operations fell 3%. The key differences between the two reporting periods is a reduction in expenditures arising from corporate communications, IT development and investor marketing activities from the

December 2007 period as the company maintained focus on its core clinical activities, offset by six months of Zurich office support activities. The Zurich office opened November 2007.

During the six months to December 31 2008 Clinuvel achieved a number of significant highlights in the progression of its photoprotective drug afamelanotide. The company received regulatory acknowledgement from the US Food and Drug Administration (FDA) by being granted an Orphan Drug Designation (ODD) for the use of afamelanotide in the treatment of EPP. An Investigational New Drug (IND) application was submitted (and subsequently approved after December 31) to the FDA, paving the way for Clinuvel to conduct clinical trials in the world's largest pharmaceutical market to support an eventual marketing application. A 5th clinical application was identified, being the use of afamelanotide as an adjunct therapy for patients undergoing PDT. Phase III clinical trials continued to progress in polymorphic light eruption (PLE), along with Phase II trials in Actinic Keratosis (AK) and Solar Urticaria (SU).

Following is the Half Year Report Appendix 4D, together with the Financial Report, Director's Report and Declaration and Audit Independent Review Report relating to the half year ended 31 December 2008.

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 2008.

AUDITOR INDEPENDENCE DECLARATION

The independence declaration of our auditor as per section 307C of the Corporations Act is attached and forms part of the Director's 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 25th day of February, 2009

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INDEPENDENT AUDITOR'S REVIEW REPORT TO THE MEMBERS OF CLINUVEL PHARMACEUTICALS LIMITED

Report on the half-year financial report

We have reviewed the accompanying half-year financial report of Clinuvel Pharmaceuticals Limited (the Company) and consolidated entity, which comprises the balance sheet as at 31 December 2008 and the income statement, statement of changes in equity and cash flow statement for the half-year ended on that date, other selected explanatory notes and the directors' declaration. The consolidated entity comprises both the Company and the entities it controlled at the half-year's end or from time to time during that 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 control 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 an 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 2008 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.

Electronic presentation of audited financial report

This auditor's report relates to the financial report of Clinuvel Pharmaceuticals Limited for the year ended 31 December 2008 included on Clinuvel Pharmaceuticals Limited web site. The Company's directors are responsible for the integrity of the Clinuvel Pharmaceuticals Limited web site. We have not been engaged to report on the integrity of the Clinuvel Pharmaceuticals Limited web site. The auditor's 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 audited financial report to confirm the information included in the audited 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:

1 giving a true and fair view of the Clinuvel Pharmaceuticals Limited financial position as at 31 December 2008 and of its performance for the half-year ended on that date; and

2 complying with Accounting Standard AASB 134: Interim Financial Reporting and Corporations Regulations 2001.

Grant Thornton.

GRANT THORNTON
Chartered Accountants

D.A. Ashmore
Partner

Melbourne, 25 February 2009

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

CONDENSED INCOME STATEMENT
FOR THE HALF YEAR ENDED 31 DECEMBER 2008

		Consolidated	
		31 December 2008 $	**31 December 2007 $**
Revenues from ordinary activities	See notes	2,800,852	2,129,223
Total expenses from ordinary activities	See notes	(11,842,700)	(8,610,625)
Profit(loss) from ordinary activities before related income tax expense		**(9,041,848)**	**(6,481,402)**
Income tax expense (benefit) relating to ordinary activities			-
Profit(loss) from ordinary activities after related income tax expense		(9,041,848)	(6,481,402)
Net profit(loss)		**(9,041,848)**	**(6,481,402)**
Net profit(loss) attributable to members of Clinuvel Pharmaceuticals Limited		(9,041,848)	(6,481,402)
Basic earnings per share - cents per share		(3.0)	(2.1)

This condensed income 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

CONDENSED BALANCE SHEET
FOR THE HALF YEAR ENDED 31 DECEMBER 2008

	Consolidated	
	31 December 2008 $	**30 June 2008 $**
CURRENT ASSETS		
Cash Assets	26,090,851	25,752,193
Receivables	363,251	616,136
Other Financial Assets	17,207,259	25,048,387
Other	2,820,087	1,703,396
TOTAL CURRENT ASSETS	**46,481,448**	**53,120,112**
NON CURRENT ASSETS		
Property, plant and equipment	417,734	431,034
Intangible assets	1,041,363	1,419,612
TOTAL NON CURRENT ASSETS	**1,459,097**	**1,850,646**
TOTAL ASSETS	**47,940,545**	**54,970,758**
CURRENT LIABILITIES		
Payables	5,246,534	2,968,356
Provisions	122,006	178,576
TOTAL CURRENT LIABILITIES	**5,368,540**	**3,146,932**
NON CURRENT LIABILITIES		
Provisions	7,565	9,310
TOTAL NON CURRENT LIABILITIES	**7,565**	**9,310**
TOTAL LIABILITIES	**5,376,105**	**3,156,242**
NET ASSETS	**42,564,440**	**51,814,516**
EQUITY		
Contributed equity	113,221,065	113,222,456
Reserves	1,519,236	1,763,836
Accumulated losses	(72,175,861)	(63,171,776)
TOTAL EQUITY	**42,564,440**	**51,814,516**

This condensed balance sheet 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 2008

	Consolidated	
	31 December 2008 $	**31 December 2007 $**
RETAINED EARNINGS		
Retained Earnings at the beginning of period	(63,171,776)	(49,066,474)
Transfer from Share Option Reserve of Lapsed, Expired Share Options	37,763	0
Net profit/(loss) attributable to members of Clinuvel Pharmaceuticals Ltd	(9,041,848)	(6,086,787)
Retained earnings at the end of period	**(72,175,861)**	**(55,153,261)**
RESERVES		
Reserves at the beginning of period	1,763,836	1,644,837
Exchange difference on translating foreign operations	(546,041)	7,147
Movement in Share Option reserve	301,441	(107,792)
Reserves at the end of period	**1,519,236**	**1,544,192**
SHARE CAPITAL		
Share Capital at the beginning of period 303,148,665 fully paid shares	113,222,456	112,813,470
Issue of shares via investor share purchase plan	0	0
Issue of shares through institutional placement	0	0
Share options exercised	0	0
Capital Raising Costs	(1,391)	0
Share Capital at the end of period 303,148,665 fully paid shares	**113,221,065**	**112,813,470**

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 2008

	Consolidated	
	31 December 2008	31 December 2007
	$	$
CASH FLOWS FROM OPERATING ACTIVITIES		
Refund from ATO	119,088	176,263
Receipts from customers	0	0
Payments to suppliers and employees	(6,826,879)	(5,857,921)
Interest received	1,824,739	2,053,080
Net cash provided by (used in) operating activities	**(4,883,052)**	**(3,628,578)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for property, plant and equipment	(16,944)	(79,473)
Payments for trademarks		
Payments for licenses & production distribution rights	0	0
Payments for financial instruments	0	(21,965,276)
Payments received property, plant and equipment	0	2,285
Payments received financial instruments	4,742,410	18,360,072
Net cash provided by (used in) investing activities	**4,725,466**	**(3,682,392)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issue of ordinary shares	145,000	0
Payment of share issue costs	(1,391)	(77,750)
Net cash provided by (used in) financing activities	**143,609**	**(77,750)**
Net increase/(decrease) in cash held	**(13,977)**	**(7,388,720)**
Cash at beginning of the year	**25,752,193**	**33,841,849**
Effect of exchange rate changes on foreign currency held	352,635	(32,989)
Cash at end of the year	**26,090,851**	**26,420,140**

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 2008

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 2008, and in the preparation of the comparative income statement for the financial half year ending 31 December 2007 and the comparative balance sheet as at 30 June 2008. 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.

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:

- On 21 January the consolidated entity announced positive interim results of its photoprotective drug, afamelanotide, in a Phase III trial conducted in Switzerland. The trial investigated the medical benefits of afamelanotide in the orphan disease Erythropoietic photoporphyria (EPP), a severe genetic disorder causing absolute ultraviolet radiation (UV) and light intolerance of the skin. The trial is due to be completed later in 2009.

- On 29 January the consolidated entity announced it had obtained Investigational New Drug (IND) status for its photoprotective drug afamelanotide from the USA Food and Drug Administration (FDA), allowing it to conduct clinical trials in the USA, the world's largest pharmaceutical market.

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 2008

STATEMENT OF ACCOUNTING POLICIES (CONT'D)

NOTE TO CONDENSED INCOME STATEMENT

		Consolidated	
		31 December 2008 $	**31 December 2007 $**
Revenues from ordinary activities			
(A) Specific Items			
- Interest revenue		1,718,390	2,129,223
- Net unrealised foreign currency gains (including loans to overseas subsidiaries):		1,082,462	0
- Realised foreign currency gain		0	25,302
Expenses from ordinary activities			
- Depreciation and amortisation of sub-license and intangibles		(415,168)	(452,763)
- Research and development costs		(5,521,885)	(4,136,636)
- Operations		(2,777,231)	(2,402,442)
- Realised foreign currency loss		(29,699)	0
- Net unrealised foreign currency loss (including loans to overseas subsidiaries):		0	(45,927)
- Realised loss on disposal of investments		(590,426)	(660,585)
- Unrealised mark-to-market valuation of investments		(2,508,291)	(937,574)

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 2008

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.

In previous reporting periods, the consolidated entity reported a second business segment being Pharmaceuticals Products. This business segment relates to a non-strategic discontinued operation and is therefore no longer a business segment for the purposes of segment reporting.

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 2008 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 25th day of February, 2009

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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 2008, 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.

GRANT THORNTON
Chartered Accountants

D.A. Ashmore
Partner

Melbourne, 25 February 2009