



CLINUVEL

Company Announcement

ASX:

CUV

XETRA-DAX:

UR9

NASDAQ INTERNATIONAL DESIGNATION: CLVLY

APPENDIX 4C

Melbourne, Australia and Leatherhead, UK, 31 October 2018

CLINUVEL PHARMACEUTICALS LTD, a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders, today announced its Appendix 4C – Quarterly Cashflow report for the period 01 July to 30 September 2018. All figures are rounded and reported in Australian dollars.

Cash receipts from customers for the quarter were \$10,705,000, an 89% increase compared to the same quarter last year (\$5,638,000 for the July to September 2017 quarter) and a 3% increase compared to the previous quarter (\$10,388,000 for the April to June 2018 quarter). Orders received from European Erythropoietic Protoporphyria (EPP) Expert Centres (EEECs) continue to reflect the seasonal demand for SCENESSE® (afamelanotide 16mg) in the northern hemisphere where orders for SCENESSE® increase in spring, summer and autumn when EPP patients are at a heightened risk of phototoxic and anaphylactoid reactions.¹

Cash receipts are expected to continue to fluctuate in the quarterly reporting periods owing to the timing of customer payments following cyclical sales orders received for SCENESSE®. All revenues in the quarter were generated from the CLINUVEL Group's innovative technology being used to treat an "orphan" indication, whilst the Group continued to focus on managing its overall cost base.

The cash balance as of 30 September 2018 was \$44,391,000, an increase of \$8,193,000 to the 30 June 2018 cash balance and an increase of \$16,452,000 to the 31 December 2017 cash balance.

Net operating payments for the quarter decreased 12% to \$2,864,000 compared to \$3,268,000 for the same quarter last year and compared to \$3,090,000 for the previous quarter, a 7% reduction. The net operating payments were characterised by expenditures in meeting annual listing, audit, travel and tax fees, work towards the US FDA drug filing, legal and intellectual property work, and personnel-related payments. Planning and management of key expenditures is a major reason for the decline in expenditures.

The combination of cash receipts and expenditures contributed to a net operating activity positive cash flow of \$7,873,000 for the quarter ended 30 September 2018. The increase in cash reserves is primarily generated from the Company's operations, reflecting its sustained progress.

The CLINUVEL Group has incurred costs of over \$185 million to date on developing and commercialising its novel drug SCENESSE®, with the product approved in the European Union as the only available and first-line therapy for the treatment of EPP.

COMMENTARY

"At this stage of the company's evolution, we are striving for growth which enables us to invest in new technologies and in new products," CLINUVEL's Chief Financial Officer Mr Darren Keamy said. "As we move towards the darker months in the northern hemisphere some downward fluctuation in customer payments from SCENESSE® sales is expected each year. We remain vigilant in managing and controlling the Company's expenditure base in a period where activity levels from US filing, European distribution and product development continue to rise. As CLINUVEL grows, the constant attention to cost management will continue to support the foundation for future success."

- End -

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

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatment(s) for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at <http://www.epp.care>. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Switzerland, the US and Singapore. For more information go to <http://www.clinuvel.com>.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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Forward-Looking Statements

This release to the Australian Securities Exchange and to press may contain forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause CLINUVEL's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for SCENESSE®; that the FDA may not provide regulatory approval for any use of SCENESSE® or that the approval may be limited; that the Company may not be able to access adequate capital to advance its vitiligo programs; that the Company may not be able to retain its current pharmaceutical and biotechnology key personnel and knowhow for further development of its product candidates or may not reach favourable agreements with potential pricing and reimbursement agencies in Europe and the US; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE® which may lead to it being unable to supply its commercial markets and/or clinical trial programs.

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Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

CLINUVEL PHARMACEUTICALS LIMITED

ABN

88 089 644 119

Quarter ended ("current quarter")

30 SEPTEMBER 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	10,705	10,705
1.2 Payments for		
(a) research and development	(105)	(105)
(b) product manufacturing and operating costs	(186)	(186)
(c) advertising and marketing	(57)	(57)
(d) leased assets	(101)	(101)
(e) staff costs	(1,800)	(1,800)
(f) administration and corporate costs	(674)	(674)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	32	32
1.5 Interest and other costs of finance paid	(3)	(3)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other/including GST & VAT	62	62
1.9 Net cash from / (used in) operating activities	7,873	7,873
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(40)	(40)
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(40)	(40)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	-	-
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	36,198	36,198
4.2	Net cash from / (used in) operating activities (item 1.9 above)	7,873	7,873
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(40)	(40)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	360	360
4.6	Cash and cash equivalents at end of quarter	44,391	44,391

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	26,080	22,140
5.2	Call deposits	18,225	13,975
5.3	Bank overdrafts		
5.4	Other (Security Deposits)	86	83
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	44,391	36,198

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	769
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	
Non-Executive Directors' fees and Managing Director salary including short term incentive payment		

7.	Payments to related entities of the entity and their associates	Current quarter \$A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	-
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
7.3	Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

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8.	Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1	Loan facilities	-	-
8.2	Credit standby arrangements	-	-
8.3	Other (please specify)	-	-
8.4	Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

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9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	(100)
9.2	Product manufacturing and operating costs	(1,300)
9.3	Advertising and marketing	(70)
9.4	Leased assets	(110)
9.5	Staff costs	(1,360)
9.6	Administration and corporate costs	(725)
9.7	Other/including GST & VAT	40
9.8	Total estimated cash outflows	(3,625)

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.



Sign here:
(Director/Company secretary)

Date: 31 October 2018

Print name: DARREN KEAMY

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.