

Appendix 4C & Activity Report

CLINUVEL delivers strong positive cash flow in June Quarter 2022

Melbourne, Australia, 25 July 2022

ASX:
XETRA-DAX:
ADR Level 1:

CUV
UR9
CLVLY

CLINUVEL PHARMACEUTICALS LTD released its Appendix 4C – Quarterly Cashflow Report and Activity Report for the period 01 April to 30 June 2022.

HIGHLIGHTS CASH FLOW

Q4 FY2022¹

Cash receipts ²	\$24,053,000
Operating cash expenditures	\$5,624,000
Net operating cash flow ³	+\$18,478,000
Cash reserves ⁴	+19.3%
Debt-free	

1. Period 01 April to 30 June 2022. All dollar figures in this release are rounded and reported in Australian dollars.

2. Excludes interest income.

3. Operating cash flow excludes non-cash items.

4. % increase in cash reserves compared to previous quarter.

STRONG OPERATING CASH FLOW

CLINUVEL's customer receipts were strong in the final quarter of the 2022 financial year (ended 30 June), driven by rising clinical demand for SCENESSE[®] (afamelanotide 16mg) treatment.¹ The Company continued active management of expenditures across the Group, resulting in a considerable increase in net cash from operating activities. During the quarter ended 30 June 2022, more treatment centres facilitated access to SCENESSE[®] for a larger pool of patients, as CLINUVEL personnel worked closely with insurers and government agencies enabling wider reimbursement for treatment.

"Our operating systems are getting to an optimum level following years of building the foundations for self-distribution and commercial market access," CLINUVEL's Chief Financial Officer, Darren Keamy said. "Of course we are pleased with the strong financial result, placing the Company in an ideal position to realise its growth plans: increasing access to SCENESSE[®] in response to demand, expanding our product portfolio, and seizing value-adding opportunities."

In 2021, CLINUVEL outlined a growth strategy which would see the Group spend \$175m over five years (to 30 June 2025). The Company is nigh on track against this forecast and is steadily increasing expenditure in its Pharmaceutical and Healthcare Solutions Divisions with the aim to expand clinical use of SCENESSE® and add new products.

All of CLINUVEL’s cash receipts are generated from its operations, without reliance on debt or equity funding.

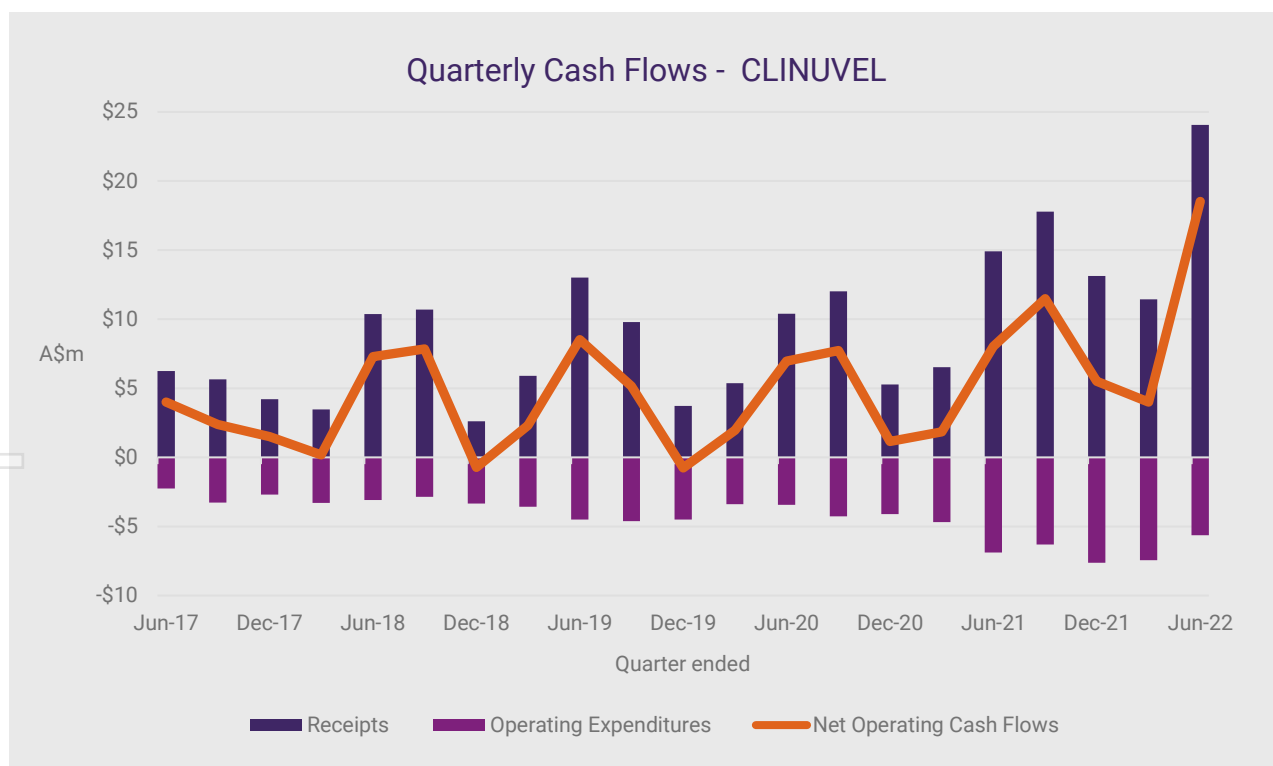
“CLINUVEL is one of the few life sciences companies on the ASX to generate positive cash flows and profit and seeks to set an example of prudent financial management. Part of this approach is ensuring we can protect the Company from environmental and market pressures, while we execute our long-term plans,” Mr Keamy said.

CASH RECEIPTS AND OPERATING EXPENDITURES – JUNE QUARTER 2022

CLINUVEL recorded Q4 FY2022 cash receipts of \$24,503,000, a 64% increase on the same quarter of 2021.

Operating expenditures totalled \$5,624,000 for the quarter, less than the previous four quarters and largely due to a temporary decline in supply chain and manufacturing costs. Overall costs are expected to trend back to previous levels in the near term to meet ongoing clinical demand. Increase in staff has been required to manage and implement various ongoing programs within the Pharmaceuticals and Healthcare Solutions Divisions.

The net operating cash flow for the quarter was \$18,478,000.



KEY ACTIVITIES – JUNE QUARTER 2022

Commercial Operations

CLINUVEL’s distribution of SCENESSE® to the EPP community in Europe, the USA, and Israel continued under commercial and special access programs during the June quarter 2022 to meet ongoing and growing patient demand.

Progress of Clinical Programs

CLINUVEL has expanded targeted clinical development programs evaluating safety and efficacy of melanocortins – including afamelanotide – for patients with genetic, metabolic, life-threatening and acute disorders.

The last update on the Company's programs was provided in [News Communiqué III](#), released on 23 June 2022. For ease of reference, a summary is provided below.

DNA Repair Program:

assessing the ability of afamelanotide to assist the repair of DNA of skin damaged by ultraviolet (UV) radiation and High Energy Visible (HEV) light. The clinical focus is relevant to over two billion people worldwide who show some inefficiency in their biological DNA reparative processes (nucleotide excision repair and basic excision repair).

<i>Study</i>	<i>Status</i>
CUV156 adult xeroderma pigmentosum C (XP-C) patients	Study ongoing. Results expected in 2022.
CUV151 disease free adult subjects	First subject dosed in February 2022. Results expected in 2022.
CUV152 adult xeroderma pigmentosum V & C (XP-V/XP-C) patients	First XP-V patient dosed in March 2022. Results expected in 2022.

Arterial Ischaemic Stroke (AIS) Program:

assessing the ability of afamelanotide to improve blood flow and increase the delivery of oxygen and nutrients to deprived brain tissue in acute stroke patients. An estimated 15 million strokes are suffered each year.

<i>Study</i>	<i>Status</i>
CUV801 adult stroke patients	Study complete, results announced. Afamelanotide was evaluated as safe in mild to moderate AIS. Neurological function, as measured by the National Institutes of Health Stroke Scale (NIHSS) improved in five patients, brain scans (MRI-FLAIR) in all six patients showed reduction of affected tissue, and there was strong functional recovery in all five surviving patients.
CUV803 adult stroke patients	A new study , evaluating the safety and efficacy of a higher, more frequent dosing regimen, is expected to commence in 2022.

Vitiligo Program:

assess the ability of afamelanotide to repigment skin in pigment loss disorder. Focus on patients with darker skin complexion (Fitzpatrick IV-VI), an estimated 563,000 of whom live in Europe-UK-North America.

<i>Study</i>	<i>Status</i>
CUV104 adult vitiligo patients with darker skin complexion (Fitzpatrick IV-VI)	Study design agreed with the US Food and Drug Administration (FDA). Institutional Review Board approved CUV104 study to focus on patients of darker skin complexion (Fitzpatrick types IV-VI). Afamelanotide to be assessed as a monotherapy for systemic repigmentation of vitiligo patients. Recruitment of CUV104 is to commence at a North American vitiligo expert centre in 2022.

Healthcare Solutions

CLINUVEL is committed to translating its expertise in the role of melanocortins in the human body from the Pharmaceuticals Division to the general population through its Healthcare Solutions Division. A range of over-the-counter topical products is being developed and commercialised for targeted audiences at the highest risk from exposure to ultraviolet (UV) and high energy visible (HEV) light.

The first product will provide polychromatic protection across a wider spectrum of light. Future dermatocosmetic products will assist in DNA repair of the skin and the stabilisation of melanogenesis, drawing on the technology and learnings from the Pharmaceutical Division programs.

Ahead of formal product launch, an extensive digital marketing campaign is being deployed to build a following amongst targeted audiences. New digital platforms, including [LightSkinScience.com](https://www.lightskinscience.com) and dedicated social media channels have been launched, with a team of CLINUVEL Ambassadors (CUVAs) engaged to educate and build connectivity with the targeted audiences.

Other Activities and Announcements

CLINUVEL announced its Strategic Update IV in May 2022, which can be accessed on [the Company's website](#). The Company's announcements in the June quarter 2022 are available on the [CLINUVEL website](#), with other updates available on the [CLINUVEL News website](#).

Although the Company is no longer obligated under ASX Listing Rules to publish quarterly cash flow results, it elects to continue to do so to keep its global investors updated regularly. A copy of the Appendix 4C – Quarterly Cash Flow Report for the final quarter of FY2022 is attached.

Pursuant to Listing Rule 4.7C and as disclosed in Item 6.1 to the attached Appendix 4C, \$1,065,000 were recorded in respect to Non-Executive Directors' fees, Managing Director's fees and non-monetary benefits (inclusive of non-monetary and non-cash benefits and unused and long accrued annual leave entitlement to Managing Director).

– End –

¹ SCENESSE® (afamelanotide 16mg) is approved in the European Union and Australia as an orphan medicinal product for the prevention of prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). SCENESSE® is approved in the USA to increase "pain-free" light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; XETRA-DAX: UR9) is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to <https://www.clinuvel.com>.

SCENESSE®, PRÉNUMBRA®, and NEURACTHEL® are registered trademarks of CLINUVEL.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD

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Investor Enquiries

<https://www.clinuvel.com/investors/contact-us>

Forward-Looking Statements

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products; the COVID-19 pandemic and/or other world, regional or national events affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg), PRÉNUMBRA® or NEURACTHEL®; our ability to achieve expected safety and efficacy results in a timely manner through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe, Israel, China and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE®, PRÉNUMBRA® or NEURACTHEL® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; our ability to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2021 Annual Report. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

www.clinuvel.com

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

CLINUVEL PHARMACEUTICALS LIMITED

ABN

88 089 644 119

Quarter ended ("current quarter")

30 JUNE 2022

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	24,053	66,400
1.2	Payments for		
	research and development	(332)	(1,213)
	product manufacturing and operating costs	(1,128)	(9,665)
	advertising and marketing	(37)	(291)
	leased assets	(87)	(321)
	staff costs	(3,095)	(11,732)
	administration and corporate costs	(894)	(3,908)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	46	249
1.5	Interest and other costs of finance paid	(8)	(35)
1.6	Income taxes paid	(90)	(183)
1.7	Government grants and tax incentives	3	213
1.8	Other (provide details if material)	47	356
1.9	Net cash from / (used in) operating activities	18,478	39,872
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) Entities	-	-
	Businesses	-	-
	property, plant and equipment	(197)	(434)
	Investments	-	-
	intellectual property	-	-
	other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(b) Entities	-	-
	Businesses	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
	property, plant and equipment	-	-
	Investments	-	-
	intellectual property	-	-
	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	(197)	(434)
3. Cash flows from financing activities			
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(80)	(269)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	(1,235)
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	(80)	(1,504)
4. Net increase / (decrease) in cash and cash equivalents for the period			
4.1	Cash and cash equivalents at beginning of period	101,851	82,691
4.2	Net cash from / (used in) operating activities (item 1.9 above)	18,478	39,872
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(197)	(434)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(80)	(1,504)
4.5	Effect of movement in exchange rates on cash held	1,457	884
4.6	Cash and cash equivalents at end of period	121,509	121,509

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	27,066	37,486
5.2	Call deposits	94,100	64,050
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	343	315
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	121,509	101,851

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	1,065
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	Total financing facilities		
7.5	Unused financing facilities available at quarter end		
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	39,874
8.2	Cash and cash equivalents at quarter end (item 4.6)	121,509
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (item 8.2 + item 8.3)	121,509
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

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8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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.

Date: 25 July 2022

Authorised by: MR DARREN KEAMY

(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.