CLINUVEL

COMPANY ANNOUNCEMENT

CLINUVEL tracking on its financial objectives in Q2 FY23

Appendix 4C & Activity Report

Melbourne, Australia, 31 January 2023	ASX:	CUV
	Börse Frankfurt:	UR9
	ADR Level 1:	CLVLY

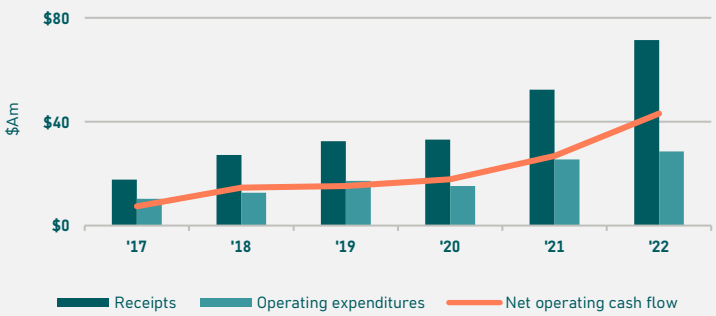
Executive summary

- Increased annual cash receipts (+36% year-on-year), net operating cash flow and assets
- Decrease in cash used in opex (-12.7% compared to Q1 FY23)
- Commercial performance in an inflationary environment
- Financial discipline in support of diversification

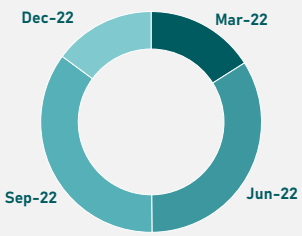
HIGHLIGHTS CASH FLOW
01 October – 31 December 2022

	Q2 FY2023[1]	CY2022[2]
Cash receipts[3]	$10,623,000	$71,371,000
Operating cash expenditures	$7,227,000	$28,514,000
Net operating cash flow[4]	$3,726,000	$43,120,000
Cash reserves[5]	+2.2%	+42.1%

Annual cash flow (CY)



Cash receipts by quarter, CY2022

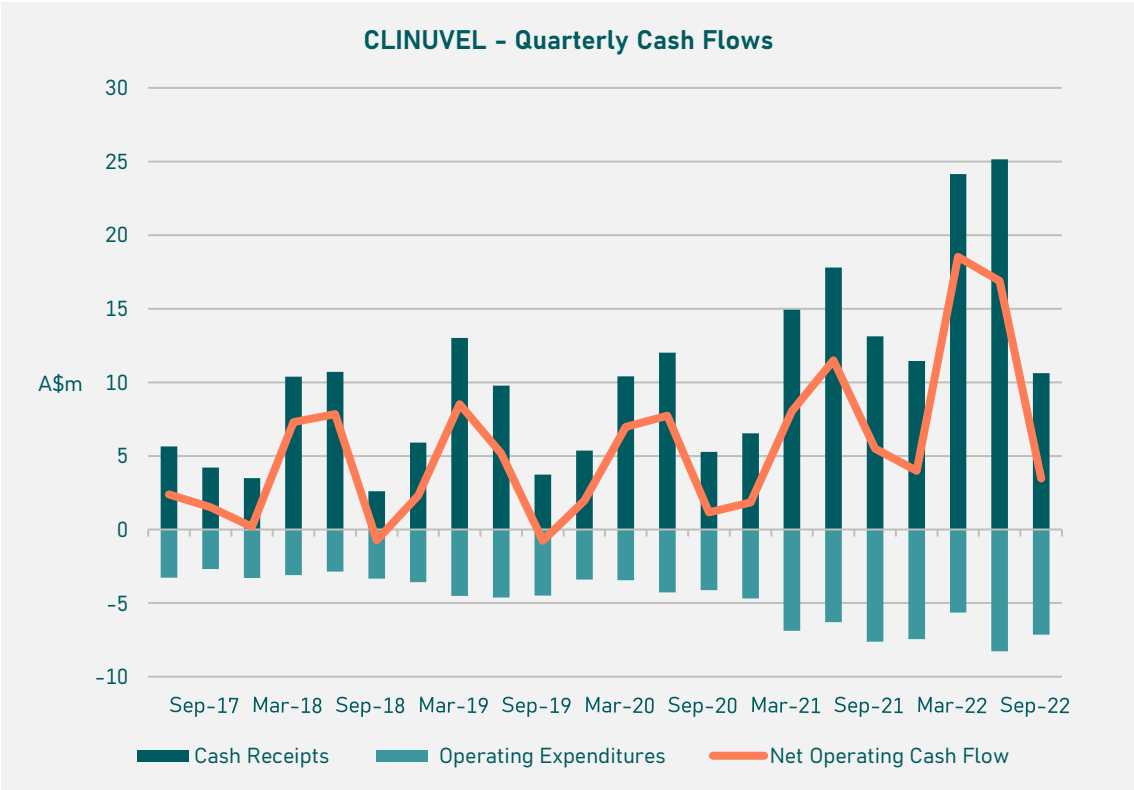


1. Period 01 October to 31 December 2022, "the December quarter". All Australian dollar figures in this release are rounded.
2. Period 01 January to 31 December 2022.
3. Excludes interest income.
4. Operating cash flow excludes non-cash items.
5. % increase in cash reserves compared to previous quarter/12 month period.

Positive cash balance, annual increase in receipts

Cash receipts are generated from the commercial supply of CLINUVEL's pharmaceutical product SCENESSE® (afamelanotide 16mg) for the genetic metabolic disorder erythropoietic protoporphyria (EPP).

Receipts for the 12-month period to 31 December were 36% higher on a year-on-year comparative basis. For the December quarter, customer payments exceeded operating cash outflows by 47%, with a net cash inflow totalling $3.726 million. Since treatment is provided bimonthly, and clinical demand is higher from February to October (in the northern hemisphere), cash receipts follow a similar cyclical pattern.



Decrease in expenditures

In the December quarter, operating expenditures totalled $7.227 million, representing a 12.7% decrease compared to last reported quarter (Q1 FY23).

As stated during previous Strategic Updates, over five financial years (FY21-25) the firm has planned A$175m in expenses to advance the Group organically. CLINUVEL is currently tracking well on this strategic objective.

Commentary

"We stick to a five-year plan to diversify activities, products and markets, leading to a fully independent group of companies," CLINUVEL's Chief Financial Officer, Darren Keamy said. *"This quarter, we managed R&D spending and reinvested proceeds in the business. More specialist staff were introduced to advance the programs and to support the launch of the first specialised dermato-cosmetic products.*

"While we can be encouraged by the current results, there is a collective need to remain driven, and focussed on managing and controlling funds, so that we can navigate the Company through what may transpire to be the next economic downcycle.

"We are currently preparing the 2022-23 half-year financial results, and we will give further context on revenues, expenses and total assets upon their release."

Key activities

Key activities in the December quarter 2022 (Q2 FY23) are summarised below.

Commercial Operations

During the quarter, SCENESSE® treatment of adult EPP patients progressed through direct distribution in Europe, the USA and Israel. Activities also encompassed product re-supply to secure sufficient stock in hospitals, and medical centres.

Melanocortin Drug Portfolio

As part of the melanocortin drug portfolio, manufacturing of NEURACTHEL®, the presentation of adrenocorticotropic hormone (ACTH), and PRÉNUMBRA®, a liquid formulation of afamelanotide, pressed on.

Expanded Clinical Program

During the December quarter, clinical trials (CUV151 - control, CUV156) evaluating afamelanotide as an assisted DNA-repair agent in xeroderma pigmentosum (XP) neared the half-way mark. In the vitiligo trial (CUV104), patients received afamelanotide treatment as monotherapy.

Other Activities and Announcements

On 26 October, a first 'live streamed' AGM was held in Melbourne, whereas a panel discussion was organised, hosted by sell-side analyst Dr David Stanton (Jefferies Australia). All resolutions of the meeting were passed by shareholders, supporting the structure of executive remuneration and the composition of the Board.

The Company's announcements relevant to this Quarterly Update and pertaining to the December 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 its quarterly cash flow results, it elects to continue to do so to keep its long-term global investors updated regularly. A copy of the Appendix 4C – Quarterly Cash Flow Report for the second quarter of FY2023 is attached.

Pursuant to Listing Rule 4.7C $524,000 were recorded in respect to Non-Executive Directors' fees, Managing Director's fees, and payments towards non-monetary benefits.

– END –

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; BÖRSE FRANKFURT: 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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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")** 31 DECEMBER 2022

Consolidated statement of cash flows		**Current quarter** $A'000	**Year to date** (6 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	10,623	36,134
1.2	**Payments for**		
	research and development	(246)	(777)
	product manufacturing and operating costs	(2,520)	(3,755)
	advertising and marketing	(229)	(459)
	leased assets	(71)	(147)
	staff costs	(3,074)	(8,181)
	administration and corporate costs	(1,079)	(2,174)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	252	340
1.5	Interest and other costs of finance paid	(7)	(19)
1.6	Income taxes paid	(1)	(26)
1.7	Government grants and tax incentives	2	11
1.8	Other (provide details if material)	76	76
1.9	**Net cash from / (used in) operating activities**	**3,726**	**21,023**

2.	**Cash flows from investing activities**	-	-
2.1	**Payments to acquire or for:**		
	Entities		
	Businesses	-	-
	property, plant and equipment	(319)	(395)
	Investments	-	-
	intellectual property	-	-
	other non-current assets	-	-
2.2	**Proceeds from disposal of:**	-	
	Entities		
	Businesses	-	-
	property, plant and equipment	-	-
	Investments	-	-
	intellectual property	-	-
	other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
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**	**(319)**	**(395)**

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	(92)	(170)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	(1,976)
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**(92)**	**(2,146)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	137,648	121,509
4.2	Net cash from / (used in) operating activities (item 1.9 above)	3,726	21,023
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(319)	(395)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(92)	(2,146)
4.5	Effect of movement in exchange rates on cash held	(260)	712
4.6	**Cash and cash equivalents at end of period**	**140,703**	**140,703**

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	24,364	34,857
5.2	Call deposits	115,989	102,450
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	350	341
5.5	**Cash and cash equivalents at end of quarter** *(should equal item 4.6 above)*	**140,703**	**137,648**

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	524
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 *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.*	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)	21,047
8.2	Cash and cash equivalents at quarter end (item 4.6)	140,703
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (item 8.2 + item 8.3)	140,703
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.	
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.

Pursuant to Listing Rule 4.7C and as disclosed in Item 6.1 to the attached Appendix 4C, $524,000 were recorded in respect to Non-Executive Directors' fees, Managing Director's fees and payments towards non-monetary benefits.

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: **31 January 2023**

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.