ASX ANNOUNCEMENT **26 October 2023**

September 2023 Quarterly Activity Report

Melbourne, Australia; 26 October 2023: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, has today released its Quarterly Activity Report for the three-month period ended 30 September 2023.

Key highlights:

- **Phase 2 clinical trial in acute graft-versus-host disease (aGvHD) opened for recruitment**
- **Phase 1 clinical trial in patients who have received a kidney transplant obtained regulatory approval**
- **Patient recruitment continuing in Phase 1 Diabetic Foot Ulcer (DFU) and Phase 3 osteoarthritis clinical trials**
- **Strategic review of research and development portfolio completed**
- **Solid cash balance of A$12.1m at end of quarter, with forecast cash runway into H2 2025**

Research and development pipeline update

Phase 2 clinical trial of CYP-001 in aGvHD

On 10 August 2023, the Company announced the opening of recruitment in its Phase 2 clinical trial of CYP-001 in patients with High-Risk acute Graft versus Host Disease (HR-aGvHD). This global trial aims to enrol approximately 60 patients with HR-aGvHD, who will be randomised to receive either steroids plus CYP-001, or steroids plus placebo. CYP-001 is Cynata's Cymerus™ iPSC[1]-derived MSC[2] product candidate for intravenous use. The first clinical centre to open for recruitment was Westmead Hospital, Sydney, Australia.

The opening of recruitment followed ethics approval and regulatory clearance of the trial in Australia and the United States of America (USA), including clearance of the Company's Investigational New Drug (IND) application by the US FDA. Cynata expects to open multiple additional clinical centres by the end of the 2023 calendar year, in both the USA and Australia. The Company is also seeking approval to commence the trial in a number of European countries, and is continuing to progress the regulatory process in those jurisdictions.

The Company's expectation remains that enrolment will be completed by the end of calendar year 2024, with primary results available by H2 2025, as previously communicated. The Company is confident that the trial will build on the success of its Phase 1 trial in GvHD, which found very encouraging safety and efficacy results.[3]

Phase 1 clinical trial of CYP-001 in renal transplantation

On 21 August 2023, the Company announced the approval by the Competent (regulatory) Authority in the Netherlands of the Phase 1 clinical trial of CYP-001 in patients who have received a kidney transplant. This trial is being undertaken in collaboration with Leiden University Medical Centre (LUMC), which will fund and manage the trial, under the leadership of Prof Ton Rabelink. Cynata will provide CYP-001 for use in the trial, while retaining full commercial rights to use the data.

The Primary Objective of the trial is to study the safety and efficacy of CYP-001 in allowing tacrolimus reduction after kidney transplantation. Tacrolimus is a calcineurin inhibitor, which is a type of immunosuppressant drug used to prevent the rejection of transplanted organs. Prof Rabelink and colleagues have previously published encouraging data from a clinical trial in which the patients' own MSCs were used in a similar way. They found that early tacrolimus withdrawal with MSC therapy was safe, without increased rejection, and concluded that this is a potentially useful approach after renal transplantation.[4]

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The trial will seek to recruit a total of up to 16 patients who have undergone a renal transplant. The first six patients will receive either one (n=3) or two (n=3) infusions of CYP-001, in addition to standard treatment. Subject to favourable safety review of the initial cohorts, a further ten patients will receive two infusions of CYP-001, followed by tacrolimus dose reduction.

Phase 3 clinical trial of CYP-004 in osteoarthritis

Recruitment of patients continues in the Phase 3 clinical trial of CYP-004, known as the Stem Cells as a symptom- and strUcture-modifying Treatment for medial tibiofemoral OsteoaRthritis (SCUlpTOR) trial, in collaboration with the University of Sydney.

CYP-004 is Cynata's Cymerus™ iPSC-derived MSC product candidate for intra-articular injection (injection into a joint).

The Company's expectation remains that recruitment will conclude within the coming months, with results expected in H1 2026, following final patient follow-ups and trial data analysis.

Phase 1 clinical trial of CYP-006TK in DFU

Recruitment continues in Cynata's Phase 1 clinical trial of CYP-006TK in patients with DFU. CYP-006TK is Cynata's Cymerus™ iPSC-derived MSC topical wound dressing product candidate, which comprises MSCs seeded onto a novel silicon dressing.

The recruitment rate in this trial accelerated notably during the quarter following steps taken by the Company, including optimising the trial protocol and adding three new clinical sites. The Company continues to anticipate the conclusion of recruitment by the end of 2023, with initial results available mid-2024.

Encouraging initial results from the first six patients enrolled in this trial, which showed a clear reduction in average ulcer size in patients treated with CYP-006TK compared to those who received standard of care treatment, have previously been released.

Corporate update

Strategic review complete

At the start of the quarter, Dr Kilian Kelly was appointed CEO and Managing Director, and immediately initiated a strategic review of the Company's research and development portfolio. The review incorporated assessment of all ongoing and planned clinical programs with input from existing strategic partners, contract research organisations and clinical centres sites to ensure the timely completion of key trials.

Board change

Subsequent to the quarter end, on 9 October 2023, the Company announced that Dr David Atkins informed the Board that he will not be standing for re-election as a Director at the Company's forthcoming Annual General Meeting (AGM). Accordingly, he will cease to be a Director from the conclusion of the AGM.

Financial update

Solid cash position

The Company closed the quarter with A$12.1m in cash. Net operating cash outflows for the quarter totalled A$4.1m. The expenditure incurred in the quarter was significantly higher than the projected average expenditure in the forthcoming two financial years, largely due to payments related to the start-up stage of the Phase 2 aGvHD clinical trial, and other non-recurring costs.

In accordance with ASX rules, the "*Estimated quarters of funding available*" reported in item 8.5 of the Appendix 4C is calculated by dividing the cash at the end of the quarter by the net operating cash outflows in the previous quarter. However, as the net operating cash outflows in the previous quarter were not representative of forecasted expenditure in the forthcoming two financial years, the "*Estimated quarters of funding available*" reported in item 8.5 is not consistent with the Company's expectations. The Company currently expects its cash runway to extend into the 2025-26 financial year.

In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately A$492k comprised of salary and bonus paid to the Managing Director and fees paid to Non-Executive Directors, as well as one-off final payments to the Company's previous CEO and Managing Director, who retired on 30 June 2023, in line with statutory and contractual obligations.

Outlook

Cynata remains committed to the effective execution of its clinical trials and the attainment of its patient recruitment goals. The Company is in a strong position to achieve its operational and growth objectives for FY24 and beyond.

-ENDS-

Authorised for release by Dr Kilian Kelly, Managing Director & CEO

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges of other production methods by using induced pluripotent stem cells (iPSCs) and a precursor cell known as mesenchymoangioblast (MCA) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors.

Cynata's lead product candidate CYP-001 met all clinical endpoints and demonstrated positive safety and efficacy data for the treatment of steroid-resistant acute graft-versus-host disease (GvHD) in a Phase 1 trial. A Phase 2 clinical trial in GvHD under a cleared US FDA IND, as well as trials of Cymerus products in osteoarthritis (Phase 3) and diabetic foot ulcers (DFU) are currently ongoing, while a trial in renal transplant is expected to commence in the near future. In addition, Cynata has also demonstrated utility of its Cymerus technology in preclinical models of numerous diseases, including critical limb ischaemia, idiopathic pulmonary fibrosis, asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.

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[1] iPSC = induced pluripotent stem cell

[2] MSC = mesenchymal stem (or stromal) cell

[3] Bloor AJC, et al. Production, safety and efficacy of iPSC-derived mesenchymal stromal cells in acute steroid-resistant graft versus host disease: a phase I, multicenter, open-label, dose-escalation study. Nat Med. 2020;26(11):1720-1725.

[4] Reinders et al: *Autologous bone marrow-derived mesenchymal stromal cell therapy with early tacrolimus withdrawal: The randomized prospective, single-center, open-label TRITON study*. Am J Transplant. 2021;21:3055–3065

Appendix 4C

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

Name of entity	
CYNATA THERAPEUTICS LIMITED	
ABN	**Quarter ended ("current quarter")**
98 104 037 372	30 SEPTEMBER 2023

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	-	-
1.2	Payments for		
	(a) research and development	(3,140)	(3,140)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(51)	(51)
	(d) leased assets (including premises)	-	-
	(e) staff costs	(672)	(672)
	(f) administration and corporate costs	(409)	(409)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	122	122
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other	22	22
1.9	**Net cash from / (used in) operating activities**	**(4,128)**	**(4,128)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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**	**-**	**-**

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	-	-
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 period	16,167	16,167
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,128)	(4,128)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

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	76	76
4.6	**Cash and cash equivalents at end of period**	**12,115**	**12,115**

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	3,115	7,667
5.2	Call deposits	9,000	8,500
5.3	Bank overdrafts	-	-
5.4	Other	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**12,115**	**16,167**

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	492
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.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(4,128)
8.2	Cash and cash equivalents at quarter end (item 4.6)	12,115
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	12,115
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.9

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?

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?

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?

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: 26 October 2023

Authorised by: The Board of Directors
(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.