ASX ANNOUNCEMENT 26 July 2023

June 2023 Quarterly Activity Report

Melbourne, Australia; 26 July 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 June 2023.

Key highlights:

- **Bolstered leadership team with the appointment of Dr Kilian Kelly as Chief Executive Officer and Managing Director, and the addition of Dr David Atkins to the Board of Directors**
- **Strategic review of clinical development portfolio completed subsequent to the quarter, led by Dr Kelly**
- **Received ethics committee approval for a proposed Phase 2 clinical trial in acute graft-versus-host disease (aGvHD)**
- **Patient recruitment and treatment progressing for Phase 1 DFU (Diabetic Foot Ulcer) and Phase 3 structure-modifying treatment for medial tibiofemoral osteoarthritis (SCUlpTOR) clinical trials**
- **Two-year follow-up data from Phase 1 SR-aGvHD trial selected to be presented at the prestigious International Society for Cell & Gene Therapy (ISCT) Annual Meeting**
- **Successfully completed a A$7.0m capital raising consisting of a A$5.0m placement and A$2.0m SPP which closed oversubscribed**
- **Strong cash balance of A$16.2m as at 30 June 2023**

Corporate update

Dr Kilian Kelly appointed as Chief Executive Officer and Managing Director

Dr Kilian Kelly was appointed to the position of Chief Executive Officer and Managing Director of Cynata during the quarter, following the retirement of Dr Ross Macdonald. Dr Kelly has been with Cynata since 2014 and was originally employed as Vice President of Product Development before moving to Chief Operating Officer in May 2019. During his time with Cynata, Dr Kelly has overseen the development of CYP-001, Cynata's lead product for aGvHD, and directly managed the regulatory and clinical strategy of the successful Phase 1 trial. His comprehensive understanding of the business and knowledge of Cynata's platform technology will be invaluable as the Company advances its clinical pipeline and progresses engagement with potential commercial partners.

Board strengthened

Cynata welcomed Dr David Atkins to the Board of Directors following the departure of non-executive director Dr Stewart Washer. Dr Atkins is the Managing Partner of Bioscience Managers, a major shareholder in Cynata, and has over 25 years of experience as a global leader in a broad range of life science and healthcare businesses, including Johnson & Johnson and Danaher. He has held several senior leadership positions and brings with him extensive product development and commercialisation experience in North American, EMEA, Asian and Latin American markets.

Strategic review complete

Following Dr Kelly's appointment as Managing Director and CEO the Company undertook a strategic review of its clinical development portfolio, which was completed subsequent to the quarter (announced 24 July 2023). 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.

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Investors are invited to join a webcast hosted by Dr Kelly to hear more about the outcomes of the strategic review. The webcast is scheduled for 9:15am (AEST) on Thursday, 27 July 2023. To pre-register for the event, please follow this link: https://ccmediaframe.com/?id=nwqmPZoz. Upon registration, participants will receive a calendar invitation, details and a link to access the webcast.

Clinical update

Proposed Phase 2 clinical trial in aGvHD receives ethics committee approval

During the quarter, Cynata secured approval from the Australian Human Research Ethics Committee (HREC) to initiate its proposed Phase 2 clinical trial of CYP-001 in patients with aGvHD. The approval follows ethics approval from the Institutional Review Board (IRB) in the United States and clearance of the Company's Investigational New Drug (IND) application by the US FDA.

With ethics approvals in Australia and the US secured, Cynata expects to commence recruitment for sites in those regions during the quarter, following the completion of final administrative and contractual steps. The Company is also seeking approval to commence the trial in a number of European countries and is in the process of providing additional information requested by the EU regulatory authorities.

Based on current estimates, Cynata expects that enrolment will be completed in H2 2024 with primary results available by H2 2025 following patient follow-up and data analysis. Cynata aims to recruit approximately 60 patients across multiple clinical sites, and is confident that the trial will build on the success of its Phase 1 trial in GvHD which achieved all safety and efficacy endpoints.

Phase 3 SCUlpTOR clinical trial recruitment accelerating

The University of Sydney continues to progress recruitment of patients in the Phase 3 SCUlpTOR trial of CYP-004, targeting patients suffering from osteoarthritis of the knee. The recruitment rate has accelerated dramatically during 2023 with approximately 300 patients enrolled in the trial. Recruitment is currently estimated to be complete in late 2023 to early 2024, with primary evaluation results available in H1 2026 following final patient follow-ups and trial data analysis.

The trial aims to reduce pain and disease progression in up to 440 patients. The Phase 3 trial marks a significant milestone for the Company and its potential entry into a ~US$11.6bn market.[1]

Recruitment continues in Phase 1 DFU clinical trial

Cynata was pleased to release encouraging initial data from six patients in its Phase 1 clinical trial in DFUs during the quarter, demonstrating a clear reduction in average ulcer size in patients treated with CYP-006TK over the standard of care treatment. The DFU trial aims to enrol 30 patients who are randomised to receive either (i) CYP-006TK treatment for four weeks, followed by standard of care treatment; or (ii) standard of care treatment throughout the study.

Due to a higher-than-expected screening failure rate, recruitment is now estimated to conclude by the end of 2023 with results available mid-2024. Cynata has actively taken steps to improve the enrolment rate including optimising the trial protocol and adding three new clinical sites during the previous quarter.

Renal transplantation clinical trial planning underway

Cynata continues to progress regulatory activities for a Phase 1 clinical trial of CYP-001 in patients who have undergone renal transplantation, with the aim of reducing or withdrawing immunosuppressant (i.e. anti-rejection) drugs. The proposed trial is collaboration between Cynata and Leiden University Medical Centre (LUMC), with LUMC providing funding and Cynata providing Cymerus™ MSCs while retaining full commercial rights.

Discussions are ongoing with LUMC and the Dutch regulatory agency regarding securing regulatory, ethics and administrative approvals. Information is currently being reviewed by regulators and Cynata is expecting to hear the outcome during the current quarter.

Follow-up results of Phase 1 SR-aGvHD trial selected for presentation at ISCT

At the recent ISCT annual meeting in Paris, Cynata presented encouraging outcomes from its Phase 1 clinical trial of CYP-001 for the treatment of steroid-resistant acute GvHD (SR-aGvHD). Distinguished gene and stem cell therapy scientist, Professor John Rasko, AO (Head of Department, Cell & Molecular Therapies, Royal Prince Alfred Hospital, Sydney), presented the findings, including a two-year survival rate of 60% (9/15 patients),, with no treatment-related serious adverse events or safety concerns identified. This survival rate compares very favourably to previously reported outcomes in SR-aGvHD. For example, in the Phase 3 study that supported approval of the drug ruxolitinib, the 18-month overall survival rates were only 38% in the ruxolitinib group and 36% in the "best available treatment" control group (survival at two years was not evaluable).[2] Cynata's selection for oral presentation at the ISCT Annual Meeting validates the significance of the clinical study.

Financial update

Successfully completed capital raising

During the quarter, Cynata raised A$7.0m via a A$5.0m Placement and A$2.0m Share Purchase Plan (SPP) which closed oversubscribed. The Placement was conducted at an offer price of $0.215 and the SPP was conducted at an offer price of $0.155. Both included free attaching listed options on a 1:2 basis, exercisable at $0.30 and expiring on 1 April 2025. The Placement was supported by existing healthcare investor Bioscience Managers, new and existing institutional shareholders, and Cynata's senior management and board members. Proceeds raised will be used to fund Cynata's Phase 2 aGvHD clinical trial and for general working capital.

Strong cash position

Cynata closed the quarter with A$16.2m 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 one-off initial payments totalling $1.7m to the Company's contract research organisation to commence the Phase 2 aGvHD clinical trial, among 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$185k comprised of salary paid to the Managing Director and fees paid to Non-Executive Directors.

Outlook

Cynata continues to focus on the successful execution of its clinical trials and achieving its patient recruitment targets. Under the leadership of the experienced Dr Kelly and with the addition of Dr Atkins to the Board, the Company is well positioned for success and will continue advancing towards its operational and growth targets for FY23 and beyond.

-ENDS-

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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. Planning for a Phase 2 clinical trial in GvHD under a cleared US FDA IND is presently underway. Clinical trials of Cymerus products in osteoarthritis (Phase 3) and diabetic foot ulcers (DFU) are currently ongoing. In addition, Cynata has demonstrated utility of its Cymerus technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as 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] Reflects OA market by 2025; Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025).

[2] Zeiser R, et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. N Engl J Med. 2020;382(19):1800-1810.

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 JUNE 2023

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	-	-
1.2	Payments for		
	(a) research and development *	(3,400)	(13,714)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(83)	(280)
	(d) leased assets	-	-
	(e) staff costs	(261)	(1,043)
	(f) administration and corporate costs	(432)	(1,461)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	109	287
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (2022 R&D Tax Incentive)	-	1,654
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(4,067)**	**(14,557)**

** Includes US$2 million Manufacturing Start-up Fee paid to FUJIFILM Corporation (Fujifilm) in July 2022 under a Strategic Partnership Agreement (as announced to ASX on 30 Sept 2021).*

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
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)	7,042	7,042
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	(344)	(344)
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**	**6,698**	**6,698**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	13,515	23,798
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,067)	(14,557)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,698	6,698
4.5	Effect of movement in exchange rates on cash held	21	228
4.6	**Cash and cash equivalents at end of period**	**16,167**	**16,167**

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	7,667	4,515
5.2	Call deposits	8,500	9,000
5.3	Bank overdrafts		-
5.4	Other (provide details)		-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**16,167**	**13,515**

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	185
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)	(4,067)
8.2	Cash and cash equivalents at quarter end (item 4.6)	16,167
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	16,167
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.98

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 July 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.