

ASX ANNOUNCEMENT 30 July 2025

# **June 2025 Quarterly Activity Report**

# Key highlights:

- Cynata enters a phase of significant momentum, with three clinical trials progressing across high-value therapeutic areas with substantial unmet needs.
- The Phase 2 trial in acute Graft versus Host Disease (aGvHD) is >75% enrolled, with patient recruitment progressing and primary results anticipated during H1 2026.
- The fully enrolled, 321-patient Phase 3 trial in Osteoarthritis is nearing completion in the coming months, with top-line results anticipated between February and April 2026.
- Cohort 1 of the kidney transplant trial has completed treatment, with DSMB review results expected in Q4 2025.
- Cynata remains well-capitalised with \$5 million in cash, with expected R&D tax incentive rebate ~\$1.25m in coming months, providing funding runway through mid-2026, covering all key clinical readouts.
- Positive pre-clinical results in ischaemic heart disease models demonstrated improved cardiac function, supporting potential expansion into large cardiovascular markets.
- Upcoming clinical milestones have the potential to represent inflection points for valuation, partnering, and product approval pathways.

Melbourne, Australia; 30 July 2025: Cynata Therapeutics Limited (ASX: "CYP", "Cynata", or the "Company"), a clinical-stage biotechnology company specialising in cell therapeutics, provides its Ouarterly Activity Report for the three-month period ended 30 June 2025.

# Acute Graft versus Host Disease (aGvHD) - Phase 2 Trial >75% enrolled; Results Expected H1 2026

aGvHD is a serious and often life-threatening complication of bone marrow transplantation, where the donor's immune cells (the graft) attack the recipient's tissues (the host). It affects up to 50% of transplant patients, particularly those with high-risk disease. Standard treatment involves corticosteroids, but these fail in around half of all cases, and the two-year survival rate in steroid-treated patients is less than 20%.

Cynata's Cymerus™ MSC¹ product, CYP-001, is designed to modulate the immune system and improve both response rates and survival outcomes in aGvHD. In a successful Phase 1 trial, 87% of patients improved by at least one grade, 53% showed no signs of aGvHD, and 60% were alive at two years. Importantly, there were no serious adverse events related to treatment, and the results were published in the prestigious journal Nature Medicine.

Cynata is now conducting a global Phase 2 trial, enrolling 60 patients with high-risk aGvHD. Patients are randomised to receive either standard steroid therapy plus CYP-001, or steroids plus placebo. The primary endpoint is overall response at Day 28.

Patient enrolment is now over 75% complete. A fluctuation in enrolment rate, commonly observed in rare disease studies has been experienced, but enrolment continues to progress and recruitment initiatives are being reinforced. The Company anticipates completing enrolment within the coming months and releasing the primary results during H1 2026.



# Osteoarthritis - Phase 3 Trial Completed Recruitment; Results Expected Feb-Apr 2026

Osteoarthritis is a degenerative joint condition affecting over 500 million people globally. Current treatment options are limited to symptom management or invasive surgery, with no therapies available that address cartilage loss and inflammation at the source.

Cynata's Phase 3 trial, known as SCUlpTOR, is being conducted by the University of Sydney and funded through an NHMRC project grant. The trial completed enrolment of 321 patients in November 2023, with all patients now having received their study treatments. Follow-up is ongoing, with final 24-month results anticipated between February and April 2026.

Following a recent advisory meeting with the Australian Therapeutic Goods Administration (TGA), Cynata is optimistic that positive results could support marketing approval of CYP-004 in Australia.

# Kidney Transplantation - First Cohort Complete; DSMB Review Expected Q4 CY 2025

Patients undergoing kidney transplantation typically require lifelong immunosuppressive therapy to prevent organ rejection. These drugs are effective, but they come with serious long-term toxicity and health risks.

This investigator-led 16 patient trial, conducted at Leiden University Medical Centre (LUMC) in the Netherlands, is assessing whether CYP-001 can reduce reliance on calcineurin inhibitors, potentially offering patients safer long-term immune modulation.

The enrolment and treatment of the three patients in Cohort 1 is now complete. Once the third and final patient treated in this cohort is followed up for six weeks, the study's independent Data and Safety Monitoring Board (DSMB) will review the data from this Cohort. The results of this review are anticipated by Q4 2025.

#### Additional Applications: Expanding Therapeutic and Commercial Potential

Beyond the three readouts above, Cynata is also progressing promising clinical and preclinical programs that demonstrate the flexibility and broad utility of its Cymerus™ MSC platform.

Diabetic Foot Ulcers (CYP-006TK) - Phase 1 Trial Completed with Strong Efficacy

Cynata recently completed a successful Phase 1 trial in patients with diabetic foot ulcers (DFU) – chronic, non-healing wounds that can lead to infection, hospitalisation, and amputation.

As <u>announced on 5 December 2024</u>, CYP-006TK, delivered via a novel silicone dressing, showed a mean wound reduction of 83.6% after 24 weeks, compared to 47.8% with standard care. The difference was even greater in patients with larger wounds. The therapy was well tolerated, with no serious adverse events reported.

Given the high unmet need in DFU and the strength of these results, Cynata is actively engaging potential commercial partners and planning further clinical development.

Preclinical Heart Disease Program - Positive Data in Ischaemic Heart Disease

On <u>7 April 2025</u>, <u>Cynata reported positive preclinical results</u> from studies investigating Cymerus™ MSCs in ischaemic heart disease—the leading cause of death globally.

In collaboration with academic partners, Cynata tested a new encapsulation device that delivers MSC-derived factors over time. In rat models of heart attack, treated animals showed significantly improved cardiac function, reduced scar tissue, and lower levels of heart muscle thickening. These findings were supported by in vitro data using 3D human heart tissue ("cardiac spheroids"), which demonstrated enhanced tissue survival and function.



# **Corporate and Strategic Updates**

### **SMART CRC**

On 24 April 2025, the Australian Federal Government announced the funding of the Solutions for Manufacturing Advanced Regenerative Therapies Cooperative Research Centre (the "SMART CRC"). Cynata was a participant in the funding bid and intends to act as a Core Partner in the SMART CRC, subject to agreement on project plans and execution of formal agreements.

The SMART CRC will be a national coordinated effort that harnesses Australia's strengths across the entire value chain with a total budget of \$238M and over 60 partners spanning industry, government, healthcare, universities, and research institutes.

#### New InvestorHub and Website

As <u>announced on 22 May 2025</u>, the Company launched a new InvestorHub portal and website, for dedicated investor engagement.

This enables shareholders, stakeholders, prospective investors and partners to learn more about the Company's activities and key projects. The Company will regularly upload new content to the hub, including videos, key project news and updates.

The refreshed website and associated InvestorHub can be accessed via the same web address as previously: <a href="www.cynata.com">www.cynata.com</a>. Shareholders and interested parties can join InvestorHub via the "sign up" button on the website.

# **Outlook: Momentum Building into a Catalyst-Rich Period**

Cynata is approaching a pivotal period, with three clinical trials progressing towards readouts over the next 9–12 months. These include Phase 2 results in aGvHD, Phase 3 results in osteoarthritis, and a preliminary Phase 1/2 safety readout in kidney transplantation – all targeting large markets with limited treatment options and high unmet need.

Cynata's strategy is to develop multiple candidate products in clinical indications of high unmet need. This includes common diseases affecting millions of patients worldwide. With no internal salesforce or in-house manufacturing, we aim to pursue a partnership-led model, leveraging the strengths of global collaborators to drive execution and market access.

Importantly, we are able to capitalise on years of proof-of-concept research and billions already spent by MSC peers to educate markets and validate clinical use-cases. We plan to introduce more potent, scalable, and consistent iPSC<sup>2</sup>-derived MSC products into markets where demand is proven and competition remains low.

We are also operating in a market environment with accelerating tailwinds, including a global increase in MSC clinical trials now reaching maturity, increasing regulatory support through Fast Track and Orphan Drug pathways, and a rising burden of chronic disease and ageing populations that is driving growing demand for regenerative medicine solutions.

#### **Finance**

The Company closed the quarter with \$5.049m in cash. Net operating cash outflows for the quarter totalled \$3.454m.

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 Company's cash balance at the end of the quarter by the net operating cash outflows in the previous quarter, and the result of this calculation is 1.5 quarters of funding available. However, as the net operating cash outflows in the previous quarter were not representative of forecasted expenditure in the year ahead, this is not consistent with the Company's



expectations. The Company anticipates its cash runway to extend into mid calendar year 2026. The Company notes that payments of approximately \$1.9m were made during the quarter to the contract research organisation managing the Phase 2 GvHD clinical trial. As the payment schedule under this contract is milestone-based, payments per month/quarter vary significantly, and the payments made in the recently completed quarter are expected to far exceed those due in any quarter over the coming year. Notably, the Company is now only funding one ongoing clinical trial (its Phase 2 aGvHD trial). The other ongoing trials (in kidney transplantation and osteoarthritis) are being conducted by partners and funded externally. Furthermore, the Company anticipates receiving a Research and Development Tax Incentive rebate of ~\$1.25m in the coming months.

In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately \$184k consisted of salary paid to the Managing Director and fees paid to Non-Executive Directors

#### **Investor Webinar**

An investor webinar will be held on Tuesday 5<sup>th</sup> August 2025 at 11:00am AEDT, hosted by CEO and Managing Director, Dr Kilian Kelly.

Attendees are required to register in advance for the webinar – using the following link: <a href="https://us02web.zoom.us/webinar/register/WN">https://us02web.zoom.us/webinar/register/WN</a> CeYzDl8ISkWOSzWOvkbCjQ

Upon registration, attendees will receive details to access the webinar.

#### -ENDS-

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

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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 and limitations of conventional MSC production by using induced pluripotent stem cells (iPSCs) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the necessity to obtain tissue from multiple donors on an ongoing basis, and without the complexity and product inconsistency resulting from conventional methods.

Cynata has demonstrated positive safety and efficacy data for its Cymerus™ product candidates CYP-001 and CYP-006TK in Phase 1 clinical trials in steroid-resistant acute graft versus host disease (GvHD) and diabetic foot ulcers (DFU), respectively. Further clinical trials are now ongoing: a Phase 2 trial of CYP-001 in GvHD under a cleared US FDA IND; a Phase 1/2 trial of CYP-001 in patients undergoing kidney transplantation; and a Phase 3 trial of CYP-004 in osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus™ technology in preclinical models of numerous other 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, <u>Automic Group</u>.

<sup>&</sup>lt;sup>1</sup> MSC = mesenchymal stromal (or stem) cell

<sup>&</sup>lt;sup>2</sup> iPSC = induced pluripotent stem cell

# **Appendix 4C**

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

# Name of entity

ABN	Quarter ended ("current quarter")	
CYNATA THERAPEUTICS LIMITED		

98 104 037 372 30 JUNE 2025

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	(2,717)	(7,413)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(118)	(289)
	(d) leased assets (including premises)	-	-
	(e) staff costs	(468)	(2,299)
	(f) administration and corporate costs	(244)	(874)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	93	254
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (2024 R&D Tax Incentive)	-	1,885
1.8	Other	-	-
1.9	Net cash from / (used in) operating activities	(3,454)	(8,736)

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	-

ASX Listing Rules Appendix 4C (17/07/20)

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
	(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)	-	8,116
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	21
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(562)
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	-	7,575

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,503	6,205
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,454)	(8,736)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	7,575
4.5	Effect of movement in exchange rates on cash held	-	5
4.6	Cash and cash equivalents at end of period	5,049	5,049

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	1,049	2,003
5.2	Call deposits	4,000	6,500
5.3	Bank overdrafts		-
5.4	Other		-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	5,049	8,503

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	184
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 qu	ıarter end	-
7.6 Include in the box below a description of each facility above, including the rate, maturity date and whether it is secured or unsecured. If any additional fin have been entered into or are proposed to be entered into after quarter end, providing details of those facilities as well.  N/A		ional financing facilities	

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,454)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,049
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,049
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.5
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

- 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?

No. The Company notes that payments of approximately \$1.9m were made during the quarter to the contract research organisation managing the Company's Phase 2 GvHD clinical trial. As the payment schedule under this contract is milestone-based, payments per month/quarter vary significantly, and the payments made in the recently completed quarter are expected to far exceed those due in any quarter over the coming year. The Company anticipates its cash runway to extend into mid calendar year 2026.

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?

The Company anticipates receiving a Research and Development Tax Incentive rebate of ~\$1.25m in the coming months.

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?

Yes. As noted above, the Company anticipates its cash runway to extend into mid calendar year 2026. Importantly, the Company anticipates reporting results from two major clinical trials during that period.

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: 30 July 2025

Authorised by: By the Board

(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.
- 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.