

## December 2024 Quarterly Activity Report

**Melbourne, Australia; 30 January 2025:** Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, provides its Quarterly Activity Report for the three-month period ended 31 December 2024.

### Key highlights:

- **Phase 1 clinical trial in diabetic foot ulcer (DFU) completed: CYP-006TK demonstrated to be safe and well tolerated, with positive efficacy data indicating substantially improved wound healing for CYP-006TK compared to the standard of care control group**
- **Phase 2 clinical trial in acute graft-versus-host disease (aGvHD): recruitment now >40% complete, with the rate of recruitment substantially accelerating in recent months; primary results still anticipated late 2025**
- **Phase 1 clinical trial in kidney transplantation: first patient treated; completion of first cohort anticipated in Q1 2025**
- **Phase 3 clinical trial in osteoarthritis: all patients have completed study treatment; results expected in 1H 2026**
- **Balance sheet strengthened via \$1.88m R&D Tax Incentive rebate and \$8.10m institutional placement**
- **Strong cash balance of \$10.51m at end of quarter with forecast cash runway into mid 2026**

### Research and Development Pipeline

#### CYP-006TK

CYP-006TK is Cynata’s Cymerus™ iPSC<sup>1</sup>-derived MSC<sup>2</sup> topical wound dressing product candidate, which comprises MSCs seeded onto a novel silicone dressing. This product was used in Cynata’s Phase 1 clinical trial in DFU.

#### ***Phase 1 Clinical Trial in DFU – Trial Complete; CYP-006TK Demonstrates Safety and Efficacy***

Due to reduced blood flow, patients with diabetes are at risk of developing non-healing wounds on the feet/lower limbs, which are also known as diabetic foot ulcers or DFU. In addition to causing severe pain and discomfort, DFU pose a significant risk of infection, and if treatment is unsuccessful, amputation may be necessary. In this trial, CYP-006TK was investigated as a potential treatment to promote wound healing in patients with DFU.

During the quarter, Cynata completed this trial, with results announced in December 2024:<sup>3</sup>

- The trial met its primary objective, with CYP-006TK found to be safe and well-tolerated – no participants withdrew from the trial due to adverse events, and there were no suspected serious adverse reactions reported.
- Importantly, the trial also generated positive efficacy data, indicating improved wound healing for CYP-006TK compared to the standard of care control group.
- The mean change from baseline in wound surface area was:
  - After 12 weeks, a decrease (improvement) of 181 mm<sup>2</sup> in the CYP-006TK group, and an increase (deterioration) of 355 mm<sup>2</sup> in the standard of care control group.

- After 24 weeks (end of study), a decrease (improvement) of 261 mm<sup>2</sup> in the CYP-006TK group, and an increase (deterioration) of 62 mm<sup>2</sup> in the standard of care control group.
- The mean change from baseline in wound surface area expressed as a percentage was:
  - After 12 weeks, a decrease (improvement) of 64.6% in the CYP-006TK group compared to a decrease of 22.0% in the standard of care control group.
  - After 24 weeks, a decrease (improvement) of 83.6% in the CYP-006TK group compared to a decrease of 47.8% in the standard of care control group.
- The study also indicates that larger wounds in particular healed to a greater extent in the CYP-006TK group compared to the standard of care control group.

These results further exemplify the commercial attractiveness of the broader Cymerus™ platform. The Company is now working on the next steps for the DFU program, including strategic planning for further clinical development, engagement with regulatory agencies and engagement with potential commercial partners.

### **CYP-001**

CYP-001 is Cynata's Cymerus™ off-the-shelf iPSC-derived MSC product for intravenous infusion, which is currently in clinical development for two indications (aGvHD and kidney transplantation). The US FDA has granted Orphan Drug Designation<sup>4</sup> to CYP-001 for the treatment of aGvHD.

#### ***Phase 2 Clinical Trial in aGvHD – Recruitment Continues; Results Anticipated by Late 2025***

aGvHD is a potentially life-threatening complication of bone marrow transplants or similar procedures. It arises when immune cells in the transplant (the graft) attack the recipient's tissues (the host) as "foreign". In this trial, CYP-001 is being investigated as a potential immune modulating treatment for aGvHD.

This global Phase 2 trial aims to enrol approximately 60 patients with High-Risk aGvHD (HR-aGvHD), who will be randomised to receive either steroids plus CYP-001, or steroids plus placebo. The Company is confident the trial will build on the success of its Phase 1 trial in GvHD, which generated positive safety and efficacy results and led to two publications in the prestigious peer-reviewed journal Nature Medicine.<sup>5,6</sup>

Patient enrolment is now more than 40% complete, following a substantial increase in the rate of enrolment in recent months. The Company anticipates completing patient enrolment in the first half of 2025 and releasing the primary results in late 2025.

#### ***Phase 1 Clinical Trial in Kidney Transplantation – First Patient Enrolled***

Patients who receive a kidney transplant typically require long-term treatment with immunosuppressant drugs to prevent rejection of the transplanted organ. Immunosuppressants known as calcineurin inhibitors are effective at preventing rejection, but they are associated with very serious toxicities. In this trial, CYP-001 is being investigated as a potential immune modulating treatment in patients who have received a kidney transplant. If successful, this could facilitate dose reduction or withdrawal of calcineurin inhibitors, which would be expected to reduce or avoid toxicity.

This trial is being undertaken in collaboration with Leiden University Medical Centre (LUMC), in the Netherlands, 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 first patient was treated with CYP-001 during the quarter. The Company anticipates that LUMC will complete the enrolment of patients in the first cohort during Q1 calendar year 2025, with results from that cohort expected soon thereafter. The trial aims to recruit a total of up to 16 patients who have undergone a kidney 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.

#### **CYP-004**

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

#### ***Phase 3 Clinical Trial in Osteoarthritis – Recruitment Complete; Patient Follow-up Ongoing***

Osteoarthritis is a chronic inflammatory joint disease that causes pain and disability, which affects over two million people in Australia<sup>7</sup> and over 500 million people worldwide.<sup>8</sup> In this trial, CYP-004 is being investigated as a potential treatment to reduce pain, inflammation and cartilage degeneration in patients with osteoarthritis of the knee.

Known as the SCULpTOR<sup>9</sup> trial, this randomised and placebo-controlled Phase 3 trial is being conducted by the University of Sydney, under the leadership of Professor David Hunter, with funding provided under an Australian Government National Health and Medical Research Council (NHMRC) project grant. The co-primary endpoints of the trial are (i) the proportion of participants achieving patient-acceptable symptom state (PASS) for knee pain at 24 months; and (ii) central medial femorotibial (cMFT) cartilage thickness change from baseline to 24 months, as assessed by magnetic resonance imaging (MRI).

Patient recruitment was completed in November 2023, with a total of 321 participants enrolled. All patients have now completed their study treatment. The follow-up period (two years after the first dose of study treatment) is expected to conclude in November 2025, with results expected in the first half of 2026.

### **Corporate Update**

#### **Intellectual Property Portfolio**

Cynata continues to strengthen its robust intellectual property portfolio, which comprises several different in-licensed and Company-owned patent families.

During the quarter:

- The patent certificate was issued by the European Patent Office, and a notice of eligibility for grant was issued by the Intellectual Property Office of Singapore, for a Cynata-owned patent application entitled “Method for Treating Allergic Airways Disease (AAD/Asthma)”, which describes a method of use of Cymerus™ MSC products in treating diseases of the lungs and airways.
- The patent certificate was issued by the Brazilian Patent and Trademark Office for a patent application entitled “Colony Forming Medium and Use Thereof”, which relates to the optimisation of the Cymerus™ process by Cynata.

#### **Finance**

During the quarter the Company strengthened its balance sheet via receipt of a \$1.88m R&D Tax Incentive rebate in November 2024, followed by an \$8.10m (before costs) institutional placement in December 2024.

The Company closed the quarter with \$10.51m in cash. Net operating cash outflows for the quarter totalled \$1.26m. Notably, as the Phase 1 DFU trial has been completed, 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.

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, and the result of this calculation is 8.3 quarters of funding available. The Company anticipates its cash runway to extend into mid calendar year 2026.

In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately

\$195k consisted of salary paid to the Managing Director and fees paid to Non-Executive Directors.

## Outlook

During the remainder of this financial year, the Company anticipates the following milestones:

- Results of the first patient cohort in the kidney transplantation trial
- Completion of patient enrolment in the GvHD trial

## Investor Webinar

An investor webinar will be held on Thursday 6 February 2025 at 10:30am AEDT, hosted by CEO and Managing Director, Dr Kilian Kelly.

Attendees are required to register in advance for the webinar – using the following link:

[https://us02web.zoom.us/webinar/register/WN\\_X-L7ioGETN6cOcf-D0fQ1Q](https://us02web.zoom.us/webinar/register/WN_X-L7ioGETN6cOcf-D0fQ1Q)

Upon registration, attendees will receive a link 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 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 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 transplant; 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, Automic Group.

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<sup>1</sup> iPSC = induced pluripotent stem cell

<sup>2</sup> MSC = mesenchymal stem (or stromal) cell

<sup>3</sup> Please refer to ASX announcement released on 5 December 2024 for full details.

<sup>4</sup> Orphan Drug Designation qualifies Cynata for incentives including extended marketing exclusivity, tax credits and fee waivers.

<sup>5</sup> Bloor AJC, et al. Nat Med. 2020;26:1720–1725.

<sup>6</sup> Kelly K, et al. Nat Med. 2024;30:1556–1558.

<sup>7</sup> Australian Institute of Health and Welfare. Chronic musculoskeletal conditions: arthritis. 14 December 2023.

<sup>8</sup> World Health Organization. Fact Sheet – Osteoarthritis. 14 July 2023.

<sup>9</sup> SCUptOR = Stem Cells as a symptom- and structure-modifying Treatment for medial tibiofemoral Osteoarthritis

## Appendix 4C

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

**Name of entity**

CYNATA THERAPEUTICS LIMITED

**ABN**

98 104 037 372

**Quarter ended ("current quarter")**

31 DECEMBER 2024

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(2,311)	(3,392)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(52)	(76)
(d) leased assets (including premises)	-	-
(e) staff costs	(716)	(1,326)
(f) administration and corporate costs	(119)	(397)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	51	130
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	1,885
1.8 Other	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,262)</b>	<b>(3,176)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	8,000	8,001
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	(528)	(528)
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>7,472</b>	<b>7,473</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	4,289	6,205
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,262)	(3,176)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,472	7,473
4.5	Effect of movement in exchange rates on cash held	8	5
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>10,507</b>	<b>10,507</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	9,007	1,289
5.2	Call deposits	1,500	3,000
5.3	Bank overdrafts	-	-
5.4	Other	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>10,507</b>	<b>4,289</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	195
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.*

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<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>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</b>		-
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		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,262)
8.2 Cash and cash equivalents at quarter end (item 4.6)	10,507
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	10,507
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	8.3
<i>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.</i>	
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	
<i>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.</i>	



## 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 January 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.
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.