ASX ANNOUNCEMENT 31 January 2023

December 2022 Quarterly Activity Report

Melbourne, Australia; 31 January 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 31 December 2022.

Key highlights:

- **Planning underway for new clinical trial focused on renal transplantation, trial to be funded by Leiden University Medical Center (LUMC) with Cynata retaining full commercial rights**
- **Actively recruiting and treating patients in two ongoing clinical trials:**
  - **The phase 3 SCUlpTOR osteoarthritis clinical trial and,**
  - **The diabetic foot ulcer (DFU) clinical trial**
- **Successful review of Cynata's DFU trial by an independent Data Safety Monitoring Board (DSMB) completed with the recommendation that continue as planned**
- **Finalising start-up activities for a proposed Phase 2 clinical trial in acute graft-versus-host disease (aGvHD), initial sites remain on track to open in early 2023**
- **Intellectual property portfolio continues to expand with the addition of multiple new patents, affording greater protections to Cynata, while enhancing the Company's competitive positioning**
- **Sound financial position with A$16.4m in cash as at 31 December 2022, including ~$1.65m R&D tax incentive received during the quarter**

Clinical update

Planning underway for new clinical trial targeting renal transplantation

Cynata is collaborating with LUMC in the Netherlands for a new phase 1 clinical trial in patients who have received a kidney transplant. There are approximately 130,000 kidney transplantations around the world annually, with patients requiring life-long immune suppressive therapy to reduce the risk of rejection of the transplanted kidney. The use of immune system supressing anti-rejection drugs is associated with significant side effects, with patients having increased risk of infections and cancer as well as being directly toxic to the kidneys. Mesenchymal stem cells (MSCs) have the potential to enhance survival of donor organs and reduce or eliminate the need for anti-rejection therapy and, if successful, would be a substantial breakthrough in transplantation medicine addressing an estimated global market of ~US$5.9 billion[1].

The proposed trial design seeks to recruit 10 renal transplant patients to receive Cymerus™ MSCs post-transplantation followed by withdrawal of anti-rejection medication, with the primary endpoint being the absence of graft loss 6 months post withdrawal. LUMC is fully funding the trial, with Cynata to supply Cymerus MSCs and retaining all commercial rights. The trial is expected to commence in mid-2023, pending receipt of customary and relevant regulatory, ethics and administrative approvals all of which are currently underway.

Phase 3 trial in osteoarthritis underway

The University of Sydney continues to progress the Phase 3 SCUlpTOR (structure-modifying treatment for medial tibiofemoral osteoarthritis) trial of Cynata's Cymerus CYP-003 MSC product in osteoarthritis, with patient recruitment and treatment currently underway. This trial is the largest randomised controlled trial of

[1] Organ Transplant Immunosuppressant Drugs Market in 2026, Grand View Research, Inc.,2019

mesenchymal stem cells (MSC) conducted in patients with osteoarthritis worldwide and is sponsored by the University of Sydney and funded by an Australian Government National Health and Medical Research Council project grant. While results were initially expected to conclude in late-2024, the University of Sydney now expects initial data readout in late 2025, based on the current recruitment rate.

DFU trial continues to progress

Recruitment and treatment are underway for Cynata's DFU phase 1 clinical trial. In accordance with the study protocol, Cynata organised for the trial to be reviewed by an independent DSMB with a primary focus on participant safety, study conduct and progress, and potential modifications to the current trial design. Following its review, the DSMB endorsed Cynata's current trial design and made the recommendation to keep it unchanged, a significant milestone which enables the Company to continue patient enrolment as planned. The trial intends to recruit 30 patients and based on the current recruitment rate and the potential to increase the number of study sites, Cynata aims to complete recruitment mid-way through 2023 with trial results released by the end of 2023.

Development of CYP-004TK, Cynata's MSC product for DFU, seeks to address a significant unmet need in this challenging condition, with 15-25% of the more than 400 million diabetics globally suffering from a DFU during their lifetime, presenting a potential global market of ~US$10 billion[2] for Cynata to target.

Phase 2 trial in aGvHD expected to commence by early 2023

As announced on 26 May 2022, the US FDA has cleared the Company's IND application regarding a phase 2 clinical trial to assess the efficacy of CYP-001 in patients suffering from aGvHD. This trial is on track with expectations to commence in early 2023, with final start-up activities underway in concert with Contract Research Organisation (CRO) IQVIA. The trial is designed to recruit approximately 60 patients across multiple clinical centres in the US, Europe and Australia, who will be randomly allocated to receive either CYP-001 or a placebo, in addition to corticosteroids. Results of the trial are expected in the second half of 2024.

The Company's phase 1 trial in GvHD was a significant success, meeting all the safety and efficacy endpoints while breaking ground as the world's first completed clinical trial of an allogeneic iPSC-derived product.

Commercial update

Intellectual property portfolio strengthened

Cynata continues to enhance its comprehensive intellectual property portfolio having received a Notice of Allowance from the US Patent Office for an application covering its proprietary Cymerus™ MSC platform technology. Entitled "Pluripotent Stem Cell Assay", the patent describes a novel method for ensuring the quality and purity of Cynata's therapeutic MSC products and the unique capability of the Cymerus technology to yield highly consistent MSCs at scale, from a single donation. This patent adds another layer of protection to the Company's proprietary technology, improving the competitive advantage in a crucial commercial jurisdiction. Cynata expects the patent will be granted early 2023, with an expiration date of 15 November 2037.

Further, Cynata received a Notice of Acceptance from IP Australia and a Notice of Allowance from the Canadian Intellectual Property Office for patent application titled "Colony Forming Medium and Use Thereof". The Company received a second Notice of Allowance for a patent application titled "Pluripotent Stem Cell Assay".

Subsequent to the quarter, Cynata also received a Notice of Acceptance from IP Australia for a patent application titled "Method for Treating Allergic Airways Disease (AAD/Asthma)", which is wholly owned by Cynata. The application describes a method of use of Cymerus MSC products in treating diseases of the lungs and airways.

[2] Transparency Market Research, 2020 (Reflects global DFU treatment market by 2027)

Publications

Cymerus™ technology presented at leading stem cell research conference

A study investigating and comparing the consistency of Cymerus MSCs and MSCs derived from various tissue sources was presented at the Biennial Australasian Society for Stem Cell Research (ASSCR) and Australasian Gene and Cell Therapy Society (AGCTS) Scientific Meeting in Melbourne. This investigation was led by Associate Professor Jess Frith and a team of scientists at Monash University with the intention of comparing the consistency of multiple batches of MSCs. The team found that Cymerus™ MSCs exhibit less batch-to-batch heterogeneity (variability) than tissue-derived MSCs and significantly less variability within each batch, with tissue source being a key driver of MSC variability. Product consistency is an essential in regulatory agency requirement for pharmaceutical products, and this new study substantiates the potential of Cymerus MSCs as an off-the-shelf cell therapy.

Corporate update

Strong financial position

Cynata closed the quarter with A$16.4m in cash, as at 31 December. This includes A$1,654,310 R&D Tax Incentive Refund for the 2021/2022 financial year.

Net operating cash outflows for the quarter totalled A$3.3m (excluding the R&D Tax Incentive Refund), primarily relating to the payment of a US$2m manufacturing services fee paid to FUJIFILM Corporation in July 2022 and a reduction in administration and corporate expenses in the September quarter. In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately A$185k compromised of salary paid to the Managing Director and fees paid to Non-Executive Directors.

Outlook

Cynata is well placed to continue driving the development of its proprietary Cymerus platform technology with a rich and diverse clinical product pipeline. The Company has prioritised recruiting and treating patients in its ongoing clinical trials while advancing regulatory and administrative approvals for upcoming trials. Further, Cynata is continuously pursuing commercial partnerships and looks forward to achieving further positive clinical and preclinical results, leading the company closer to product commercialisation.

-ENDS-

Authorised for release by Dr Ross Macdonald, 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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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	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	-	-
1.2	Payments for		
	(a) research and development *	(2,857)	(7,817)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(68)	(132)
	(d) leased assets	-	-
	(e) staff costs	(217)	(548)
	(f) administration and corporate costs	(268)	(807)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	96	126
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	1,654
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,660)**	**(7,524)**

** Year To Date figure 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). Cynata may credit the Manufacturing Start-up Fee paid to Fujifilm against any amount which may become payable to Fujifilm under the Manufacturing Services Agreement (as announced to ASX on 29 Dec 2021).*

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(c) property, plant and equipment	-	-
	(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)	-	-
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**	**-**	**-**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	18,339	23,798
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,660)	(7,524)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	(267)	138
4.6	**Cash and cash equivalents at end of period**	**16,412**	**16,412**

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	6,412	8,339
5.2	Call deposits	10,000	10,000
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)**	**16,412**	**18,339**

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)	(1,660)
8.2	Cash and cash equivalents at quarter end (item 4.6)	16,412
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	16,412
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	9.8

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: 31 January 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.