ASX ANNOUNCEMENT 31 October 2022

September 2022 Quarterly Activity Report

Melbourne, Australia; 31 October 2022: 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 2022.

Key highlights:

- **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**
- **Start-up activities underway for Phase 2 clinical trial in acute graft-versus-host disease (aGvHD) following Investigational New Drug (IND) clearance by the US Food and Drug Administration (FDA)**
  - **On track to open initial study sites in the coming months**
- **Subsequent to the quarter, an independent Data Safety Monitoring Board (DSMB) concluded a successful review of Cynata's DFU trial, recommending the trial continue as planned**
- **Grant awarded to St Vincent's Institute of Medical Research by Medical Research Future Fund (MRFF) for ~$1m to investigate Cynata's MSCs in ischaemic heart disease (IHD) in major preclinical project**
- **Strong financial position with A$18.3m in cash as at 30 September 2022**

Clinical update

Phase 3 osteoarthritis clinical trial underway

Patient recruitment and treatment continues in the Phase 3 SCUlpTOR (structure-modifying treatment for medial tibiofemoral osteoarthritis) osteoarthritis trial, which is the largest randomised controlled trial of MSCs conducted in patients with osteoarthritis worldwide. The trial will assess the efficacy of CYP-004, Cynata's Cymerus™ intra-articular injectable mesenchymal stem cell (MSC) product for osteoarthritis, by recruiting 440 patients with osteoarthritis of the knee and comparing the effects of CYP-004 to a placebo on clinical outcomes over a two-year period. The SCUlpTOR trial is sponsored by the University of Sydney and funded by an Australian Government National Health and Medical Research Council project grant, with Cynata retaining full intellectual property and commercialisation rights. The trial was expected to conclude in late 2024, however the University of Sydney is reviewing this forecast based on the current recruitment rate.

Current management of osteoarthritis focuses primarily on symptom mitigation, with no treatments available to address the underlying disease. Preclinical research suggests that MSCs may have the ability to produce a tissue regenerative response, leading to a potential breakthrough in the US$11.6bn[1] global osteoarthritis market.

DFU trial underway with planned DSMB review completed subsequent to the quarter

Recruitment activities continued during the quarter for Cynata's Phase 1 clinical trial assessing the safety and early efficacy of the Company's topical MSC product CYP-006TK in patients with DFU. Patient enrolment commenced at sites in Adelaide in April 2022 and engagement with additional clinical sites is underway to accelerate completion. The trial aims to recruit 30 patients with DFU with patients undergoing 4 weeks of

[1] Reflects OA market by 2025; Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025).

treatment and being evaluated for a total of 24 weeks. Based on current recruitment estimates results are expected to be announced in the second half of 2023.

Subsequent to the quarter, an independent DSMB undertook a review of the available data for participant safety, study conduct and progress, and to make recommendations regarding potential modifications to the trial (announced 12 October 2022). The DSMB review was planned as part of the study protocol and consistent with good clinical practice. Following the review, the DSMB recommended that the trial continue unchanged. The DSMB's positive endorsement is an important milestone, enabling the Company to continue patient enrolment and complete the trial as soon as possible.

Start-up activities progressing for Phase 2 aGvHD clinical trial

Preparation for Cynata's Phase 2 clinical trial of CYP-001 in patients with aGvHD is progressing following clearance of the Company's IND application by the FDA (announced 26 May 2022). Cynata's IND application leveraged positive data from the Company's Phase 1 GvHD clinical trial, which met all safety and efficacy endpoints and broke ground by being the world's first clinical trial of an allogenic iPSC-derived cell therapy product. The proposed Phase 2 clinical trial will seek to recruit approximately 60 patients with high risk aGvHD at clinical centres in multiple countries including the US and Australia. With a cleared IND in place, Cynata is better positioned to explore further clinical targets and commercial partnering opportunities.

With start-up activities such as negotiations with study centres underway for the Phase 2 clinical trial in aGvHD, the Company expects to open the first clinical trial site in the coming months, subject to timely ethics and administrative approvals. Results are expected in 2024.

Clinical pipeline update following strategic review

During the quarter Cynata conducted a strategic review of its clinical pipeline to ensure that the portfolio was optimised in line with commercial opportunities available to the Company (announced 12 August 2022). Given the success of ongoing clinical activities including the Phase 3 SCUlpTOR trial, Phase 1 DFU trial, and proposed Phase 2 aGvHD trial, the Company prioritised resources towards these initiatives and concluded the MEND respiratory distress clinical trial. While Cynata has not permanently ruled out respiratory distress as an indication, the Company has taken steps to focus resources on the most viable and de-risked opportunities which have the highest probability of delivering shareholder value.

Commercial update

Grant awarded to investigate MSCs in major preclinical project

The National Health and Medical Research Council (NHMRC) awarded a grant of approximately $1 million under the NHMRC 2021 MRFF Cardiovascular Health Mission to St Vincent's Institute of Medical Research (SVIMR), to fund a major preclinical research project investigating Cynata's Cymerus™ MSCs as treatment for ischaemic heart disease (IHD) (announced 26 September 2022). Together with SVIMR, Cynata will partner with multiple leading research institutions to undertake this important project.

The project is expected to run for a period of two years and involves encapsulating Cymerus MSCs in a clinical grade device implanted below the skin to deliver a minimally invasive method of harnessing MSCs and providing long-term cardiac reparative effects. If successful, it is anticipated that these studies would support progression to human trials and address a significant unmet need as IHD is the leading cause of heart failure worldwide.

Intellectual property portfolio strengthened subsequent to the quarter

Cynata's robust intellectual property portfolio was strengthened subsequent to the quarter when the Company received a Notice of Acceptance from IP Australia (the Australian Government's patent agency) and a Notice of

Allowance from the Canadian Intellectual Property Office (CIPO) regarding a patent application entitled "Colony Forming Medium and Use Thereof". The Company received an additional Notice of Allowance from the CIPO for a patent application entitled "Pluripotent Stem Cell Assay". Cynata anticipates that both patents will be granted in the near term.

Publications

A scientific paper describing the optimisation of Cymerus MSCs for the treatment of coronary artery disease (CAD) was published in the highly respected peer-reviewed *Journal of Tissue Engineering and Regenerative Medicine* during the quarter (announced 29 August 2022). These results arise from a collaboration with the University of New South Wales (UNSW) and were led by A/Prof Kristopher Kilian, from the School of Chemistry and the School of Materials Science & Engineering in the UNSW Faculty of Science. The study demonstrated that modification of the cell culture matrix (the material on which the cells are grown) "primes" Cymerus MSCs and enhances their pro-angiogenic and immunomodulatory properties. This paper validates the potential of Cymerus MSCs to treat serious diseases and provides recognition of Cynata's ability to provide a scalable stem cell therapy solution by making it possible to store large batches of primed cells for clinical use.

Corporate update

Ms Janine Rolfe appointed to Cynata Board of Directors

Cynata was very pleased to appoint Ms Janine Rolfe as independent Non-Executive Director (announced 30 August 2022). Ms Rolfe brings over two decades of legal, governance, and management experience across multiple sectors to the Cynata Board. Ms Rolfe's most recent executive position was General Counsel & Company Secretary of Link Group, with a prior diverse and distinguished career including founding Company Matters Pty Ltd and holding senior executive positions at Qantas Airways, and King & Wood Mallesons.

Strong financial position

Cynata closed the quarter with A$18.3m in cash, as at 30 September 2022.

Net operating cash outflows for the quarter totalled A$5.86m, primarily relating to the payment of a US$2million manufacturing services fee paid to FUJIFILM Corporation in July 2022 and increased costs related to the manufacture of clinical trial product. In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately A$230k compromised of remuneration paid to the Managing Director and fees paid to Non-Executive Directors.

Outlook

Cynata is in a strong position to advance the development of its proprietary Cymerus™ platform technology. The Company remains focused on completing recruitment in its active clinical trials and navigating the beginning of its Phase 2 clinical trial in aGvHD. In tandem, the Company continues to engage in commercial discussions with multiple potential partners and add to its robust pipeline with an extensive database of preclinical data. Cynata looks forward to continuing to build a firm foundation of positive clinical and preclinical results to prepare for product commercialisation.

-ENDS-

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

Cynata Therapeutics Limited
Level 3, 100 Cubitt Street, Cremorne, Victoria, 3121, Australia
PO Box 7165, Hawthorn North, Victoria 3122
T: +613 7067 6940 E: info@cynata.com
ABN – 98 104 037 372

CONTACTS: Dr Ross Macdonald, CEO, Cynata Therapeutics, +61 (0)412 119343, ross.macdonald@cynata.com
Lauren Nowak, Media Contact, +61 (0)400 434 299, laurenmaree@live.com.au

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), respiratory failure 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.

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 2022

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 *	(4,960)	(4,960)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(64)	(64)
	(d) leased assets	-	-
	(e) staff costs	(331)	(331)
	(f) administration and corporate costs	(539)	(539)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	30	30
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(5,864)**	**(5,864)**

** Includes US$2 million Manufacturing Services 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 Services 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	-	-
	(c) property, plant and equipment	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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)	-	-
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	Interest on Director's Loan received	-	-
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	23,798	23,798
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,864)	(5,864)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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)	-	-
4.5	Effect of movement in exchange rates on cash held	405	405
4.6	**Cash and cash equivalents at end of period**	**18,339**	**18,339**

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	8,339	13,798
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)**	**18,339**	**23,798**

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	230
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)	(5,864)
8.2	Cash and cash equivalents at quarter end (item 4.6)	18,339
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	18,339
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.1

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 October 2022

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.