ASX ANNOUNCEMENT 28 July 2021

June 2021 Quarterly Activity Report

Melbourne, Australia; 28 July 2021: 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 2021.

Key highlights

- **Actively recruiting patients in the Phase 3 osteoarthritis clinical trial**
- **Actively recruiting patients with respiratory failure in the MEND trial**
- **Received ethics approval and engaged leading Contract Research Organisation (CRO) for a clinical trial in patients with diabetic foot ulcers (DFU)**
- **Signed a worldwide exclusive licence agreement with TekCyte Pty Ltd ('TekCyte') to utilise advanced wound dressing technology for the proposed DFU trial**
- **Strong financial position with A$26.7m in cash as at 30 June 2021**

Dr. Ross Macdonald, Cynata's CEO and MD, said:

"I am extremely pleased with the progress Cynata has made this quarter in its rich clinical development pipeline. The company is leveraging the breadth of applicability of Cymerus™ MSCs with several clinical trials underway including the landmark SCUlpTOR Phase 3 osteoarthritis trial, and the MEND respiratory distress trial. We have also made good progress on our other candidate clinical programs, allowing us to increase the shots on goal in a range of indications with significant unmet medical needs. Notably, we expect to commence recruitment activities for the DFU trial in 2H CY21, after signing a licence agreement with TekCyte, receiving ethics approval for the proposed trial and engaging Datapharm as CRO. Cynata is well placed to fund all planned trials with its current cash reserves, and I look forward to working with the rest of the team to execute our strategic priorities and build shareholder value through the generation of robust clinical data."

Clinical update

Multiple clinical trials currently underway

The Phase 3 SCUlpTOR osteoarthritis trial is now well underway, with recruitment progressing. The trial is designed to assess the effect of CYP-004, Cynata's Cymerus mesenchymal stem cell (MSC) product for osteoarthritis, compared to placebo on clinical outcomes and knee joint structure over a two-year period, in 440 patients with osteoarthritis of the knee. The trial is sponsored by the University of Sydney and funded by an Australian Government National Health and Medical Research Council project grant, with study centres located in Sydney and Tasmania. The trial is supported by preclinical research which suggests that MSCs can exert several important effects relevant to osteoarthritis. There is no current cure for osteoarthritis and available treatment options only focus on improving symptoms. Any product that might result in a durable and tissue regenerative response will be a major breakthrough in this highly prevalent disease.

During the quarter, Cynata achieved a significant trial milestone by enrolling the first patient in its active MEND clinical trial in respiratory distress. The open-label randomised controlled clinical trial aims to investigate the safety and early efficacy of Cymerus MSCs in 24 adult patients with respiratory failure. Having successfully sought to expand recruitment to include patients admitted to an ICU with respiratory failure of any cause, COVID-19 is no longer a limiting requirement for eligibility. Acute respiratory distress syndrome (ARDS), sepsis and cytokine release syndrome (CRS) are related complications representing significant unmet medical needs and are manifestations of the excessive inflammatory responses typically seen in acutely unwell patients. Cynata's pre-

clinical studies have shown that these conditions can potentially be improved with Cymerus MSCs which modulate the inflammatory reaction associated with these diseases. The combined market opportunity of ARDS, CRS and sepsis is estimated to be over US$8bn.[1]

Expanding clinical development pipeline

Significant progress has been made towards the proposed clinical trial in DFU. During the quarter, Cynata received approval from the Central Adelaide Local Health Network Human Research Ethics Committee to commence a clinical trial of Cymerus MSCs in patients with DFU. Cynata also signed a worldwide exclusive licence agreement with a leading manufacturer of innovative biomedical coatings, TekCyte Pty Ltd, to utilise its wound dressing technology which can be used to apply Cynata's MSCs directly to wounds. DFU represents a significant unmet medical need, with an estimated market value approaching US$10b[2]. Cymerus MSCs have demonstrated efficacy in a preclinical model of DFU conducted independently by the Cooperative Research Centre for Cell Therapy Manufacturing, establishing a solid preclinical foundation for the proposed DFU trial. During the quarter, Cynata also engaged leading Australian full-service CRO Datapharm Australia to assist in the conduct and management of the DFU trial. Patient enrolment for the DFU trial is expected to commence in 2H CY21, subject to regulatory and administrative approvals, and completion of trial start up activities, which are presently underway. The planned DFU trial is fully funded from Cynata's available cash reserves.

Corporate update

Cynata closed the quarter with A$26.7m in cash, as at 30 June 2021.

Cynata is well placed to fund its expanding clinical development pipeline, with ~A$3.3m raised in the previous quarter via an entitlement offer and shortfall placement, in addition to A$15m raised as part of the institutional placement in Q2 FY21.

Net operating cash outflows for the quarter totalled A$1.6m, primarily relating to normalisation of R&D expenditure over the previous quarter during which a $408k refund was received following the cancellation of a contract and an increase in administration and corporate costs over the previous quarter due to corporate insurance renewals, grant lodgement costs and office deposit and rent. In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately A$165k compromised of salary paid to the Managing Director and fees paid to Non-Executive Directors.

The Company's registered office telephone number has changed and is now +61 (03) 7067 6940.

Outlook

Current clinical trials and results

The osteoarthritis (SCUlpTOR) and respiratory failure (MEND) clinical trials are underway, with active enrolment and treatment of patients ongoing.

The Phase 3 trial in osteoarthritis seeks to enrol a total of 440 patients, randomised to receive either Cymerus MSC treatment or placebo. Following enrolment, each participant will receive injections of Cymerus MSCs (or placebo) on three occasions over a one-year period, and will then continue follow up for an additional year, with final results expected in 2024.

[1] Vasomune Therapeutics company announcement, 2018 (Reflects ARDS global market opportunity of US$2.5bn); GlobeNewswire, 2020 (Represents CRS global market opportunity of US$0.16m in 2017); GlobalData 2017 (Reflects Sepsis global market opportunity of US$5.9bn in 2026).

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

The MEND trial seeks to enrol a total of 24 adult patients admitted to ICU with respiratory distress, randomised to receive either Cymerus MSC infusions, in addition to standard of care therapy, or standard of care therapy only. Given the seasonal nature of the incidence of respiratory distress and the highly uncertain situation around COVID-19 outbreaks in Australia at present, the Company is currently unable to provide guidance on when trial results might be expected.

The Phase I DFU trial is expected to commence recruitment of 30 adult patients with non-healing ulcers in 2H CY21. Patients will be randomly assigned to receive CYP-006TK (a polymer-coated silicon dressing seeded with Cymerus MSCs) or standard care of treatment. The treatment period will be 4 weeks, and each patient will be evaluated for a total of 24 weeks.

The approved Phase 2 clinical trial in critical limb ischemia (CLI) remains on hold and opportunities to initiate this trial and/or to partner the indication will be assessed as the COVID-19 pandemic situation, particularly in the UK and Australia, stabilises.

Commercial opportunities

Through its global license, FUJIFILM remains responsible for all further development and commercialisation of CYP-001, the Cymerus MSC product for GvHD. The Company is in active discussions with FUJIFILM, noting that activities towards a further clinical trial continue, with details to be announced at the appropriate time. The Company maintains an active engagement with strategic parties and potential partners and will assess opportunities as they arise.

Additional indications

Cynata is also exploring additional indications. During the quarter, clinical trial planning for IPF continued, supported by positive preclinical results which demonstrate the efficacy of Cymerus MSCs in rodent models of IPF. The disease is incurable and causes extensive scarring of the lungs, often progressing to respiratory failure. The Company also advanced planning activities for a potential clinical trial in renal transplantation. Donor kidney transplantation is a high-risk procedure that is associated with significant morbidity. Cymerus MSC treatment in a preclinical transplant model demonstrated immunoregulatory effects expected to prevent or reduce kidney transplant rejection, providing a promising outlook for future clinical trials. Existing treatment options for both indications have limited effects on disease progression and survival rates, representing significant unmet medical needs.

Strategic pathway

Cynata is also focused on optimising and expanding manufacturing capabilities and progressing its US regulatory strategy, to place the Company in a strong position for commercialisation. Cynata's Cymerus manufacturing process addresses the challenges identified by the FDA in their review of other MSC products, by providing a consistent cell therapy product with effectively limitless expansion, that can be derived from one cell donor in a single donation.

-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. Cynata has active clinical trials underway using its Cymerus MSCs in patients admitted to intensive care with respiratory failure and a in major Phase 3 trial in osteoarthritis. A clinical trial in patients with diabetic foot ulcers has received ethics committee approval and is expected to commence later in 2021. Cynata plans to advance into trials for GvHD (through licensee Fujifilm) and critical limb ischemia and is investigating opportunities for additional clinical programs in further indications including idiopathic pulmonary fibrosis and renal transplantation, following encouraging pre-clinical data. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of asthma, organ transplantation, diabetic wounds, 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	30 JUNE 2021

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	(785)	(3,484)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(138)	(575)
	(d) leased assets	-	-
	(e) staff costs	(308)	(1,200)
	(f) administration and corporate costs	(509)	(1,107)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	24	82
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives		
	- Export Market Development Grant	100	100
	- 2020 R&D Tax Incentive	-	1,391
	- Innovation Connections Grant	-	56
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,616)**	**(4,737)**

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)	-	18,307
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	-	(660)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	400
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – Interest on Directors' Loan received	-	62
3.10	**Net cash from / (used in) financing activities**	**-**	**18,109**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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	28,230	13,650
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,616)	(4,737)
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)	-	18,109
4.5	Effect of movement in exchange rates on cash held	103	(305)
4.6	**Cash and cash equivalents at end of period**	**26,717**	**26,717**

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	16,717	18,230
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)**	**26,717**	**28,230**

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	165
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)	(1,616)
8.2	Cash and cash equivalents at quarter end (item 4.6)	26,717
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	26,717
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	16.5

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: 28 July 2021

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.