ASX ANNOUNCEMENT 30 October 2020

September 2020 Quarterly Activity Report

Melbourne, Australia; 30 October 2020: Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, has today released its Quarterly Activity Report for the quarter ended 30 September 2020.

Key highlights

- **Significant progress towards multiple clinical trials using Cynata's Cymerus™ mesenchymal stem cell (MSC) products**
  - COVID-19 clinical trial now open for patient enrolment
  - Osteoarthritis phase 3 clinical trial approved and expected to commence in Q4 2020
  - Completed phase 1 graft-versus-host disease (GvHD) two-year follow-up with positive efficacy results comparing very favourably to published outcomes for other GvHD products
  - Planning continues for a phase 2 GvHD clinical trial via global licensee FUJIFILM
- **Results of the Phase 1 clinical trial in GvHD published in the highly prestigious journal *Nature Medicine* underscoring the significance of this world-first clinical trial of an allogeneic induced pluripotent stem cell (iPSC)-derived product**
- **Positive pre-clinical results from studies in idiopathic pulmonary fibrosis (IPF) and heart attack**
- **The unique nature of Cynata's manufacturing technology ensures consistency and quality of MSC product, the importance of which was recently highlighted by FDA commentary in relation to conventional MSC manufacturing approaches**
- **Cynata Board strengthened with appointment of Dr. Geoff Brooke as Chairman**
- **Cynata remains in a strong financial position with A$12.3m in cash as at 30 September 2020**

Dr. Ross Macdonald, Cynata's CEO and MD, said:
"Cynata is in a strong position, with great progress being made towards commencing several new clinical trials. This strategy for building further shareholder value is supported by the strength of the results from the phase 1 GvHD two-year follow-up, which indicates a potential for longer-term benefit from treatment with our MSCs.

"The progress we are making is underpinned by our Cymerus technology - which is a commercially viable MSC manufacturing platform. Cymerus consistently produces high-quality and potent MSCs from a single donation, which sets us apart from other conventional stem cell companies. In recent months the FDA has confirmed that manufacturing is a critical component assessed in the path toward approval, and we are pleased that our technology has clear advantages in areas the FDA has focused on. We look forward to further developing our MSC products in the upcoming trials to continue advancing towards commercialisation."

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Clinical update

Further positive outcomes from GvHD phase 1 trial underpin further development

A paper describing the positive results from the phase 1 GvHD clinical trial of CYP-001, Cynata's lead induced pluripotent stem cell (iPSC)-derived MSC product was published in the prestigious *Nature Medicine* on 14 September. Publication in this journal highlights the importance of the findings from the study, which achieved outstanding safety and efficacy results. This publication is also a major endorsement of the unique nature of Cynata's proprietary Cymerus technology.

In July, Cynata announced positive results from the two-year follow-up of patients enrolled in the phase 1 clinical trial of CYP-001. The overall survival after two years was 60% (9/15 patients) and there were no treatment-related serious adverse events or safety concerns. These results compare very favourably to previously published outcomes in this patient population, and suggest potential longer-term benefits following treatment with Cymerus MSCs.

Progress in clinical trials, with Covid-19 trial patient enrolment open

Patient enrolment has opened for the MEND (MEseNchymal coviD-19) trial. This is a key milestone and represents formal commencement of the trial which will investigate early efficacy of Cynata's proprietary Cymerus MSCs in adults admitted to intensive care with COVID-19. This will build on the pre-clinical foundations developed for Cymerus MSCs in respiratory diseases, including acute respiratory distress syndrome (ARDS), cytokine release syndrome and sepsis, all of which are common hallmarks of critically ill COVID-19 patients. Cynata looks forward to advancing the MEND trial to investigate the potential benefits the MSCs could have to treat patients in critical need.

Preparations have progressed significantly toward the Phase 3 clinical trial in osteoarthritis patients, and the trial is expected to commence in Q4 2020.

Pre-clinical update

In September, Cynata announced positive efficacy data from a study of its Cymerus MSCs in a preclinical rodent model of idiopathic pulmonary fibrosis (IPF). IPF causes extensive scarring or fibrosis of the lungs and can lead to respiratory failure. The study saw significant improvements in multiple harmful effects of IPF, including interstitial fibrosis, dynamic lung compliance and airway resistance. This exciting news adds to the large body of evidence on the potency of Cynata's MSCs and their potential utility in treating a wide range of devastating diseases. The study was led by Professor Chrishan Samuel at the Department of Pharmacology at Monash University, and Cynata will continue to work with Professor Samuel to determine the next steps for this program.

In addition, Cynata received further positive efficacy data from a study of its Cymerus MSCs in a preclinical heart attack model. These results enhanced the Company's understanding of the superior therapeutic effects that were demonstrated by Cymerus MSC treatment compared to conventional bone marrow-derived MSC treatment, and placebo. More specifically, the new data demonstrated that Cymerus MSCs enhance the recovery of the blood supply to the damaged heart through the generation of new blood vessels. New blood vessel formation is acknowledged as an essential element of repair after the damage caused by a heart attack. The study was led by Associate Professor James Chong, Westmead Institute for Medical Research, Sydney.

Cymerus manufacturing process addresses key areas the FDA has focused on

The advancement of Cynata's development pipeline and significant clinical interest provides validation of the Company's proprietary Cymerus technology. From a single blood donation from a single donor, the Cymerus technology ensures the manufacture of highly consistent and potent MSC products. This directly addresses key manufacturing aspects the FDA has indicated have been of concern in recent reviews for conventional mesenchymal stem cell products, which typically require multiple donations from multiple donors and extensive MSC culture expansion. Cynata is confident that the unique nature of its manufacturing process ensures product homogeneity and quality, supporting the ongoing clinical development of its MSC products across multiple indications.

Corporate update

New Chairman appointed and strengthened patent portfolio

During the quarter, Dr. Geoff Brooke was appointed Chairman of Cynata. Dr. Brooke has over 30 years of experience in the healthcare, life sciences and venture capital sectors and, together with his substantial local and international network, is expected to be invaluable in leading the Cynata Board. Dr. Paul Wotton, who has been a Non-Executive Director of Cynata since June 2016 and Chairman since February 2017, will continue as a Non-Executive Director. Cynata sincerely thanks Dr. Wotton for his invaluable contributions to the Company.

Progress has also been made to further strengthen Cynata's growing patent portfolio, with a Notice of Allowance from the Korean Intellectual Property Office received. Korea is an important market for regenerative medicine, as an early adopter of stem cell-based therapeutics. The patent builds on the existing strong IP protection of the Cymerus platform and supports commercialisation activities.

Strong financial position

Cynata closed the quarter with A$12.3m in cash and remains in a strong financial position, while continuing to prudently manage cash flows. Net operating cash outflows for the quarter totalled A$1.56m, the increase in staff costs and R&D primarily relating to hiring of additional personnel in manufacturing and clinical areas and an increase in clinical trial activity, respectively. Administration and corporate costs decreased following one-off insurance-related and other costs in the previous quarter. In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately A$235k comprised of salary paid to the Managing Director and fees paid to Non-Executive Directors.

Outlook

Cynata is focused on building shareholder value by advancing clinical trials to provide treatments globally for patients with serious and life-threatening diseases, with multiple clinical trials expected to commence towards the end of the year. The world continues to feel the effects of COVID-19, and Cynata has now formally commenced its phase 2 trial as part of the COVID-19 Program. This trial is open for patient enrolment, targeting recruitment of 24 adults with COVID-19 admitted to intensive care. The trial is taking place at study centres in New South Wales, Australia. In parallel, Cynata is assessing opportunities to expand this program to other jurisdictions.

While the COVID-19 situation in Australia appears to be improving, there remains uncertainty around easing of restrictions. The phase 3 clinical trial is osteoarthritis is ready to commence, with recruitment dependent on the lifting of COVID-19 related restrictions currently in place. Cynata continues to

monitor the situation closely and will provide further details around upcoming clinical trial timelines in due course. The trial is planned to take place at study centres in Sydney and Tasmania.

A phase 2 study in critical limb ischaemia (CLI) was initially planned to take place at study centres in the UK and Australia, with ethics approval received in January of this year. Given the current pandemic environment, and potential adverse impact on CLI recruitment due to the age and underlying conditions of the typical patient, this trial remains on hold with Cynata focusing on progressing other opportunities. The situation will be continually assessed as the restrictions evolve.

The board and management look forward to commencing additional clinical trials and pursuing further corporate partnering and commercialisation opportunities as they arise. The recently released final positive outcomes from Cynata's phase 1 GvHD trial supports plans for further clinical development and has generated further interest in our technology from potential partners. The Company continues to collaborate with its global GvHD licensee, FUJIFILM, on the planning and start-up activities towards a phase 2 trial.

With the clinical pipeline progressing well, Cynata continues to assess further opportunities, leveraging its significant dataset generated in other indications through preclinical studies. The Company is considering next steps for the most attractive opportunities, in line with its broader clinical development program. Cynata continues to engage with strategic parties and potential partners, with interest received in several indications. In parallel, the significant data from the pre-clinical studies is being submitted for publication to peer-reviewed medical journals, which will further validate and promote the Company's findings.

-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 plans to advance its Cymerus™ MSCs into Phase 2 trials for severe complications arising from COVID-19, GvHD, critical limb ischemia and into a Phase 3 trial for osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus™ MSC technology in preclinical models of asthma, diabetic wounds, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

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 2020

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	(898)	(898)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(155)	(155)
	(d) leased assets	-	-
	(e) staff costs	(283)	(283)
	(f) administration and corporate costs	(268)	(268)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	20	20
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	28	28
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,556)**	**(1,556)**

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	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
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	(53)	(53)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	400	400
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – Interest on Directors' Loan received	62	62
3.10	**Net cash from / (used in) financing activities**	**409**	**409**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	13,650	13,650
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,556)	(1,556)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	409	409
4.5	Effect of movement in exchange rates on cash held	(160)	(160)
4.6	**Cash and cash equivalents at end of period**	**12,343**	**12,343**

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	5,343	6,650
5.2	Call deposits	7,000	7,000
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)**	**12,343**	**13,650**

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	235
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)	(1,517)
8.2	Cash and cash equivalents at quarter end (item 4.6)	12,343
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	12,343
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	8.14

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: 30 October 2020

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.