

## December 2020 Quarterly Activity Report

**Melbourne, Australia; 29 January 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 31 December 2020.

### Key highlights

- **Phase 3 Osteoarthritis trial commenced**
- **Cynata’s proprietary Cymerus™ mesenchymal stem cell (MSC) technology featured on the front cover of *Nature Medicine*, a prestigious medical journal**
- **Expanding clinical pipeline, with high priority targets including idiopathic pulmonary fibrosis (IPF), renal transplantation and diabetic foot ulcers (DFU)**
- **Strong financial position with A\$24.9m in cash as at 31 December 2020, including ~A\$15.0m capital raised via an institutional placement in December 2020**
  - **Significant endorsement of pipeline and platform technology through the A\$10 million cornerstone investment from BioScience Managers**
  - **Subsequent to the quarter, Cynata successfully completed a non-renounceable entitlement offer and shortfall placement in January 2021, raising an additional ~A\$3.3m**

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

*“We are very pleased with the progress made in the December quarter. Cynata’s advanced MSC manufacturing platform, multiple active clinical trials, progress towards expanding the clinical pipeline and strengthened balance sheet puts us in a strong position.*

*The recent investment by experienced healthcare investor BioScience Managers provides significant endorsement of our platform technology, clinical trial plans and investment opportunity. The Cynata board and management look forward to advancing our product development to further demonstrate the broad clinical applicability and commercial viability of the Cymerus technology.”*

### Clinical update

#### Multiple clinical trials currently underway

In November, Cynata announced the commencement of the Phase 3 SCULpTOR (“Stem Cells as a symptom-and strUcture-modifying Treatment for medical tibiofemoral OsteoaRthritis”) Trial of CYP-004, Cynata’s Cymerus MSC product for osteoarthritis. The trial is sponsored by the University of Sydney and funded by an Australian Government National Health and Medical Research Council competitive project grant. Study centres are located in Sydney and Tasmania, with initial subjects treated from the University of Sydney’s volunteers’ database. The aim of the trial is to assess the effect of Cymerus MSCs compared to placebo on clinical outcomes and knee joint structure over a two-year period, in 440 patients with osteoarthritis of the knee. There is no cure for osteoarthritis and current treatment options focus on alleviating symptoms, rather than addressing the underlying cause of the disease. Consequently, this trial is anticipated to be influential in informing clinical practice globally.

The MEND (MEseNchymal coviD-19) clinical trial in COVID-19 patients remains open for recruitment in Australia. This will investigate early efficacy of Cynata’s proprietary Cymerus MSCs in 24 adult

patients admitted to intensive care with COVID-19 and with compromised lung function, such as respiratory distress. This severe complication represents a significant unmet need in patients with COVID-19 as well as in patients infected with other respiratory pathogens. Cynata is actively progressing a strategy to accelerate recruitment.

### Expanding clinical development pipeline

Cynata is planning for the expansion of its clinical development pipeline into additional conditions with vast unmet medical needs. High priority indications, including IPF, renal transplantation and DFU, have been carefully selected based on promising results and solid foundations from studies in relevant pre-clinical disease models as well as significant commercial opportunity. Preclinical studies demonstrated the substantial potential for Cymerus MSCs to improve patient outcomes and to provide new standards of care.

### Cynata technology featured on front cover of *Nature Medicine*

In November, Cynata's ground-breaking Cymerus MSC technology was featured on the front cover of the esteemed medical journal *Nature Medicine*, with a supplementary feature on the journal's website. The cover illustration depicts an induced pluripotent stem cell (iPSC)-derived mesenchymoangioblast colony, a crucial intermediate step in the Cymerus process. This issue also includes a paper describing the Phase 1 clinical trial of CYP-001 in patients with graft-versus-host disease (GvHD), the world's first clinical trial of an allogeneic iPSC-derived product. This recognition elevates Cynata's product development, and the importance of the Cymerus MSC technology to the wider field of regenerative medicine. The global distribution and impact value of this journal has generated substantial interest in Cynata, expanding the Company's commercial opportunities.

### Corporate update

Cynata closed the quarter with A\$24.9m in cash, as at 31 December 2020. This includes A\$15.0m raised during the quarter by an institutional placement to existing and new investors at \$0.70 per new share, cornerstoned with a A\$10m investment by Phillip Asset Management Limited as a trustee for BioScience Managers Translation Fund 1. This investment endorses Cynata's platform technology and clinical development pipeline.

Subsequent to the quarter, Cynata completed a 1 for 15 non-renounceable pro-rata entitlement offer to eligible shareholders on the same terms as the Placement, which raised gross proceeds of ~A\$2.5m. Additionally, Cynata successfully placed ~A\$0.8m of shortfall shares.

These proceeds will be primarily used to expand Cynata's clinical development pipeline, enhance process development and progress regulatory strategy for commercialisation and general working capital purposes.

Net operating cash outflows for the quarter totalled A\$2.0m (A\$1.56m for the previous quarter), primarily relating to an increase in research and development expenditure from \$0.9m in the previous quarter to \$1.4m and a reduction in administration and corporate costs from \$283k in the previous quarter to \$161k. In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately A\$165k comprised of salary paid to the Managing Director, fees paid to Non-Executive Directors and Company Secretarial Fees.

### Outlook

The osteoarthritis (OA) Phase 3 SCULpTOR trial is underway following successful completion of a four-week follow-up of the initial patients treated in November 2020. Following enrolment, each

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participant will receive injections of Cymerus MSCs (or placebo in the case of the control group) on three occasions over a one-year period and will be followed up for a total of two years from enrolment. Co-primary endpoints at 24 months include: the proportion of participants achieving patient-acceptable symptom state (PASS), and central medial femorotibial (cMFT) cartilage loss from baseline. This will be one of the largest MSC clinical trials world-wide, showcasing Cynata's ability to manufacture MSCs at scale. Osteoarthritis represents a very large unmet medical need with the global OA treatment market forecast to reach in excess of US\$11b by 2025<sup>1</sup>.

The COVID-19 Phase 2 MEND trial in severe complications arising from COVID-19 is currently open for enrolment, with Cynata progressing a strategy to accelerate this process. The trial will involve 12 critically infected patients randomised to receive Cymerus MSC infusions, in addition to standard of care, while 12 patients will be randomised to the control group and will receive current standard of care. The two endpoints in the trial include an improvement in PaO<sub>2</sub>/FiO<sub>2</sub> ratio, and safety and tolerability.

The Critical Limb Ischaemia (CLI) trial is Phase 2 ready with regulatory and ethics approval received, in the UK and Australia. Trial timing remains uncertain due to the continued impact of COVID-19 on recruitment.

Cynata continues to collaborate with its global GvHD licensee, FUJIFILM, on the planning and start-up activities towards a further clinical trial. All further development and commercialisation costs will be met by FUJIFILM. There are multiple potential cash flow events in relation to upcoming milestones, including A\$2.86m on completion of the GvHD Phase 2 trial, and A\$100m+ in potential future milestone payments and royalties. The FUJIFILM transaction provides validation of Cymerus and supports the licensing of additional target areas.

Preparations are currently underway for the Company's pipeline expansion, including clinical development programs for high priority indications including IPF, renal transplantation and DFU. Key activities include final trial design, regulatory consultation, endpoint selection, key opinion leader engagements and clinical site selection. Good progress is being made and it is expected further information about clinical programs, trial schedule, endpoints, study centres and other important details will be announced as soon as these have been ratified following completion of consultations with relevant stakeholders and agencies.

The board and management look forward to further advancing clinical development and transacting additional corporate partnering and commercialisation opportunities as they arise. Cynata continues to vigorously engage with strategic parties and potential partners, with interest received in several indications. In parallel, positive data from multiple pre-clinical studies are being submitted for publication to peer-reviewed medical journals, which will further validate and promote the Company's findings.

Cynata is also focused on enhancing process development. This involves optimising and expanding manufacturing capabilities to enhance scale-up efficiencies and progressing Cynata's US regulatory strategy, to place the Company in a strong position to commercialise its proprietary therapeutic MSC products.

-ENDS-

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

<sup>1</sup> Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025).

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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, using its Cymerus™ MSCs for a Phase 3 trial in osteoarthritis and a Phase 2 trial in severe complications arising from COVID-19. Cynata plans to advance into trials for GvHD (through licensee Fujifilm) and critical limb ischemia. Cynata is planning for additional clinical programs in further indications (including idiopathic pulmonary fibrosis, renal transplantation, and diabetic foot ulcers), following encouraging pre-clinical data. 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**

98 104 037 372

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

31 DECEMBER 2020

<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	(1,418)	(2,316)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(150)	(305)
(d) leased assets	-	-
(e) staff costs	(305)	(588)
(f) administration and corporate costs	(161)	(429)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	9	29
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	28
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,025)</b>	<b>(3,581)</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	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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)	-	-
<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)	15,008	15,008
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	(69)	(122)
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
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>14,939</b>	<b>15,348</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	12,343	13,650
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,025)	(3,581)
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 (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	14,939	15,348
4.5	Effect of movement in exchange rates on cash held	(337)	(497)
4.6	<b>Cash and cash equivalents at end of period</b>	<b>24,920</b>	<b>24,920</b>

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	17,920	5,343
5.2	Call deposits	7,000	7,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>24,920</b>	<b>12,343</b>

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	-
<i>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.</i>		

<b>7. Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>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)	(2,025)
8.2 Cash and cash equivalents at quarter end (item 4.6)	24,920
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	24,920
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	12.3
<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: 29 January 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.