

June 2020 Quarterly Activity Report & Appendix 4C

Melbourne, Australia; 28 July 2020: Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, has today released its Quarterly Activity Report and Appendix 4C Report for the quarter ended 30 June 2020.

Key highlights

- **Significant clinical development advancement, with multiple trials expected to commence in CY20**
 - Received ethics approval and expedited regulatory pathway for Phase 3 osteoarthritis clinical trial, with patient recruitment to commence once COVID-19 restrictions are lifted
 - Received ethics approval for a clinical trial in COVID-19 patients admitted to intensive care, following compelling pre-clinical results
 - Phase 2 graft-versus-host disease (GvHD) clinical trial logistics and planning continues in association with global licensee, FUJIFILM
- **Cynata Board strengthened with the appointment of former R&D Executive at CSL, Dr. Darryl Maher, as a Non-Executive Director**
- **Cynata is in a strengthened financial position following successful completion of a capital raising, with A\$13.65m in cash as at 30 June 2020**

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

"Cynata is in a strengthened position to drive shareholder value going forward, with multiple clinical trials expected to commence in the near-to-medium term. The recent capital raising provides the funds needed to advance our clinical development plans in these uncertain times, and we thank our shareholders for their encouraging level of participation in the SPP and their continued support of Cynata."

"Our unique and commercially viable therapeutic mesenchymal stem cell (MSC) platform technology, Cymerus™, sets the company apart from other stem cell approaches with its ability to consistently manufacture high quality and potent MSCs at scale. Cymerus™ products show very exciting clinical potential as treatments for numerous indications and we look forward to further breakthrough results from our upcoming clinical trials."

Operational update

Upcoming Phase 3 clinical trial for osteoarthritis

In June, the Phase 3 clinical trial of CYP-004 for osteoarthritis was formally approved by the University of Sydney Human Research Ethics Committee, representing a key milestone towards commencing the recruitment of the trial.

Furthermore, an agreement was reached on an expedited regulatory pathway for this trial. Following extensive discussions, the Therapeutic Goods Administration (TGA) advised that the trial can be



conducted under the Clinical Trial Notification (CTN) scheme, which requires only submitting a notification to the TGA, as opposed to undergoing a formal review and approval process.

The 440-patient Phase 3 clinical trial is sponsored by the University of Sydney and funded by an Australian Government National Health and Medical Research Council (NHMRC) competitive project grant. The trial is one of the largest ever conducted using MSCs and is designed to assess the effect of Cymerus MSCs compared to placebo on clinical outcomes and knee joint structure in patients with osteoarthritis of the knee. A successful outcome will drive the development of a Cymerus product which has the potential to favourably modify the progressively degenerative nature of osteoarthritis, giving Cynata an attractive competitive advantage in a very large market opportunity.

Focus on the COVID-19 clinical trial, following positive pre-clinical ARDS results

In April, Cynata announced compelling results demonstrating the beneficial effects of Cymerus MSCs in a pre-clinical model of acute respiratory distress syndrome (ARDS). The study was conducted independently of Cynata and led by Professor John Fraser of the Critical Care Research Group, The Prince Charles Hospital, Brisbane. A scientific paper describing the findings was accepted for publication in the *American Journal of Respiratory and Critical Care Medicine (AJRCCM)*, which is widely regarded as the foremost peer-reviewed journal in the field of respiratory and critical care medicine. ARDS is an inflammatory process that leads to the build-up of fluid in the lungs and is one of the most serious complications experienced by patients suffering from COVID-19.

Following these exciting findings, in May, Cynata received approval to conduct a clinical trial to investigate the efficacy of Cynata's MSCs in adults admitted into intensive care with COVID-19. The trial will build on Cynata's strong pre-clinical study results not only in ARDS, but also in sepsis and cytokine release syndrome (CRS), which together are the leading causes of death in COVID-19 patients. This trial forms part of a broader strategy for Cynata to leverage increased interest to accelerate its development program and validate its technology. ARDS, sepsis and CRS each represent significant unmet needs with broader applications beyond COVID-19 and Cynata's existing strong pre-clinical database across these targets positions the Company well in these large areas of unmet medical need.

Other clinical development programs

Cynata's GvHD license partner, FUJIFILM, is responsible for the further development of CYP-001, the Cymerus MSC product for the treatment of GvHD. Cynata continues to work collaboratively with FUJIFILM on the planning and start-up activities toward the proposed Phase 2 clinical trial in GvHD, expected to commence in Japan toward the end of 2020.

Cynata and its clinical advisors expect the COVID-19 pandemic to have a continued impact on potential recruitment due to the age and underlying conditions of the typical CLI patient, and believe it would be imprudent to commence recruitment in this trial under current global circumstances. As such, Cynata has decided to re-direct its financial and operational resources to progress other opportunities. This situation will be continually assessed as the restrictions caused by the pandemic evolve.

Further, Cynata's broad pre-clinical study database provides multiple opportunities for additional clinical trials, either through the Company's own activities or in partnership with other parties.

As part of our activities to keep shareholders informed we have released an interview conducted by William Canty, CEO of Boardroom.Media providing further background on Cynata's market position, research and clinical trials. This can be found on the Cynata website under the "News" section.

Corporate update

Strengthened Board positions Cynata to drive shareholder value

During the quarter, Dr. Darryl Maher joined the Cynata Board as an independent Non-Executive Director, bringing over 23 years of global biopharmaceutical development experience and commercialisation capability to the Cynata Board. Dr Maher was most recently Vice President of R&D and Medical Affairs at CSL Behring Australia, where he was responsible for the development of multiple successful drug products from initiation through clinical development and ultimately to commercialisation. In addition, Mr Peter Webse, Non-Executive Director, stepped down from the Cynata Board effective 30 June 2020 and remains as Company Secretary.

Strong financial position

Cynata remains in a strong financial position with A\$13.65m in cash as at 30 June 2020, and continues to invest in value accretive R&D, minimise corporate expenses and prudently manage cash flow.

Net operating cash outflows for the quarter totalled A\$1.752m, in line with the previous quarter after adjusting for the R&D tax incentive refund received in that quarter, with a reduction in R&D expenditure primarily relating to the cyclic nature of our external R&D contractor activities and an increase in administration and corporate costs primarily due to renewal of the Company's insurance policies. In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately A\$185k comprised of salary paid to the Managing Director, fees paid to Non-Executive Directors and Company Secretarial Fees.

During the quarter, Cynata raised ~A\$8.3m via a successful institutional placement of ~A\$3.55m, followed by a share purchase plan (SPP) of ~A\$4.8m. In light of receiving valid applications for ~A\$10.6m worth of shares under the SPP, the Company resolved to increase the size of the SPP to A\$4.8m, from an initial cap of A\$2.0m. The funds raised strengthens Cynata's balance sheet and will be used to drive Cynata's clinical development and provide flexibility to assess and potentially advance new opportunities. The Board thanks all shareholders for their ongoing support.

Outlook

Cynata is focused on advancing clinical development to provide clinical trial data in support of potential treatments for patients with serious and debilitating diseases, with multiple clinical trials expected to commence this year. Cynata continues to engage strategic and commercial parties, and considers collaboration and partnering opportunities as they arise.

The Phase 3 clinical trial in osteoarthritis, funded by the NHMRC, is expected to commence patient recruitment in CY2020, following the lifting of COVID-19 related restrictions. The trial will take place at study centres in Sydney and Tasmania, and patients will be followed up for a total of two years from enrolment. Cynata is currently completing the final procedural and administrative arrangements required to commence recruitment. Once enrolled, participants will receive injections of Cymerus MSCs (or placebo) on three occasions over 1 year, and outcomes will be compared to baseline at 24 months. This 440-patient study will showcase Cynata's ability to consistently manufacture high quality MSCs at scale, and represents a significant opportunity with the osteoarthritis market estimated to be worth ~US\$11.6bn.

The Phase 2 clinical trial in COVID-19 patients admitted to ICUs with respiratory distress is expected to commence recruitment in the near term, subject to finalisation of relevant agreements with study centres and related practical matters. ARDS represents a significant unmet medical need beyond COVID-19 patients, and also provides a valuable opportunity with the treatment market estimated at ~US\$2.5bn. Given the uncertainties surrounding the pandemic it is premature to provide a reliable



estimate of recruitment rate and trial duration. However, it is the current expectation that the trial will complete within 6-12 months of commencement. To ensure timely completion of this clinical trial the Company is considering multiple strategies, including the potential to expand the trial to other jurisdictions.

The planned Phase 2 clinical trial in GvHD continues to progress via license partner FUJIFILM. The partnership offers Cynata a potentially lucrative future revenue stream from milestone payments and royalties, potentially worth more than A\$100m. The next key milestone is trial commencement expected this calendar year. Upon completion a milestone payment of US\$2m will be due to Cynata.

-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

98 104 037 372

Quarter ended ("current quarter")

30 JUNE 2020

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	(823)	(6,637)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(157)	(944)
(d) leased assets	-	-
(e) staff costs	(193)	(770)
(f) administration and corporate costs	(622)	(1,580)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	14	85
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	29	2,539
1.8 Other – Fujifilm Option License Fee *	-	4,227
1.9 Net cash from / (used in) operating activities	(1,752)	(3,080)

* US\$3million (net of applicable Japanese withholding taxes) paid by FUJIFILM Corporation under the graft-versus-host-disease (GvHD) license agreement in Sept 2019 quarter.

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
(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)	8,329	8,329
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	1,053
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(369)	(384)
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	900	1,000
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other – Interest on Directors' Loan received	-	85
3.10 Net cash from / (used in) financing activities	8,860	10,083

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	6,926	6,977
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,752)	(3,080)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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)	8,860	10,083
4.5	Effect of movement in exchange rates on cash held	(384)	(330)
4.6	Cash and cash equivalents at end of period	13,650	13,650

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	6,650	3,926
5.2	Call deposits	7,000	3,000
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)	13,650	6,926

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	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<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>		
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.	<div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>N/A</p> </div>	

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,752)
8.2 Cash and cash equivalents at quarter end (item 4.6)	13,650
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	13,650
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.8
<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?	<div style="border: 1px solid black; padding: 5px; min-height: 40px;"> <p>N/A</p> </div>
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?	<div style="border: 1px solid black; padding: 5px; min-height: 40px;"> <p>N/A</p> </div>
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?	<div style="border: 1px solid black; padding: 5px; min-height: 40px;"> <p>N/A</p> </div>
<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: 28 July 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.