ASX ANNOUNCEMENT 29 April 2022

March 2022 Quarterly Activity Report

Melbourne, Australia; 29 April 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 31 March 2022.

Key highlights

- **Actively recruiting and treating patients in three ongoing clinical trials:**
  - **the Phase 3 SCUlpTOR osteoarthritis clinical trial,**
  - **the MEND respiratory distress clinical trial and,**
  - **subsequent to the quarter, enrolled initial patients in the diabetic foot ulcer (DFU) clinical trial**
- **Substantial progress on executing the strategy for commencing a Phase 2 clinical trial in acute graft-versus-host disease (aGvHD) in the USA**
- **Enhanced intellectual property portfolio with patents granted in China and Japan, which are core markets for the development of cutting-edge regenerative medicine technologies**
- **Completed all remaining details of the Strategic Partnership Agreement (SPA) with FUJIFILM and the Manufacturing Services Agreement (MSA) with Fujifilm Cellular Dynamics, Inc (FCDI)**
- **Received a ~A$833k R&D Tax Incentive Refund for the 2020/2021 financial year**
- **Strong financial position with A$25.28m in cash as at 31 March 2021**

Clinical update

Phase 3 osteoarthritis clinical trial underway

Cynata's Phase 3 SCUlpTOR (structure-modifying treatment for medial tibiofemoral osteoarthritis) osteoarthritis trial is currently recruiting 440 patients with osteoarthritis of the knee and 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. The co-primary endpoints are pain alleviation and improvement in the underlying disease measured by cartilage loss, which provides a more objective performance assessment of the efficacy of MSCs. The trial is sponsored by the University of Sydney and fully funded by an Australian Government National Health and Medical Research Council (NHMRC) project grant, with full intellectual property and commercialisation rights held by Cynata. Currently, there is no cure for osteoarthritis and available treatment options only focus on managing symptoms. Preclinical research suggests that MSCs have the potential to evoke a regenerative response in the underlying disease, which is currently a significant unmet need with a market size of approximately US$11.6bn.[1]

MEND respiratory distress clinical trial underway

Patient recruitment and treatment in the MEND (MEseNchymal coviD-19) trial has passed the half-way mark and is expected to complete this year. The Omicron outbreak created considerable pressure on the hospitals involved in the study, causing unexpected delays as routine patient care was prioritised for patients with COVID-19. The Company has worked to implement mitigation strategies to ensure that the trial is completed by the end of the year. The randomised controlled clinical trial aims to recruit a total of 24 adult patients with respiratory failure

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

who meet the established criteria for acute respiratory distress syndrome (ARDS). Beyond ARDS, sepsis and cytokine release syndrome (CRS) have been identified as potential further therapeutic targets, as they are manifestations of the excessive inflammatory responses typically seen in patients experiencing respiratory distress and present significant unmet medical needs. Pre-clinical studies have shown that these conditions can potentially be improved with Cymerus MSCs through modulation of the associated inflammatory reaction.

Diabetic Foot Ulcers clinical trial underway

Cynata has progressed recruitment activities for the clinical trial in DFU after initiating the trial late last quarter and enrolled the initial patients in April 2022. Subjects are being followed as planned for a treatment period of 4 weeks, and each patient will be evaluated for a total of 24 weeks. The trial aims to recruit 30 patients with DFU by the end of the calendar year, who will be randomly assigned to receive CYP-006TK or standard care of treatment. CYP-006TK is a novel polymer-coated silicon wound dressing seeded with Cymerus™ mesenchymal stem cells (MSCs) to facilitate topical application to the wound. This unique dressing technology has been exclusively licensed from leading manufacturer of innovative biomedical coatings, TekCyte Limited.

Commercial update

Completion of operational details under the SPA with FUJIFILM and MSA with FCDI

This quarter, Cynata completed all the remaining operational details of the SPA with FUJIFILM and the associated MSA with FCDI and activities associated with establishing the Cymerus manufacturing process at FCDI have commenced. This process will include technology transfer, process validation and manufacturing under stage-by-stage, commercial, arms-length statements-of-work, the first of which has been executed. FCDI is a global leader in the manufacturing of cell therapy products and developed the original iPSC line used in Cynata's Cymerus™ manufacturing process. FCDI's scale and networks will be of significant value to Cynata's commercialisation strategy.

Corporate update

Strong financial position

Cynata closed the quarter with A$25.28m in cash, as at 31 March. The R&D Tax Incentive is an initiative by the Australian Government to support companies engaging in research and development benefitting Australia, reflective of the potential that Cymerus MSCs have on improving the lives of patients suffering from a range of devastating diseases.

Net operating cash outflows for the quarter totalled A$1.23m, primarily relating to the receipt an A$833k R&D Tax Incentive Rebate and a reduction in research and development expenses (as a consequence of the cyclic nature of R&D expenditure) of $1.83m. 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.

Outlook

Current clinical trials and results

Cynata expects to complete recruitment of 24 patients in the MEND respiratory distress trial and 30 patients in the DFU trial by the end of the calendar year.

The Phase 3 osteoarthritis trial is the largest randomised controlled trail of MSCs conducted in patients with osteoarthritis worldwide, and so the results have the potential to have a major impact on clinical management of OA patients, globally. The sponsor of the study, the University of Sydney, expects the trial to conclude in 2024, as planned.

Cynata regained commercialisation rights to CYP-001, its lead MSC product candidate, following the Strategic Partnership Agreement with Fujifilm and plans to conduct a Phase 2 clinical trial in acute graft-versus-host disease (aGvHD) in the US. Trial planning activities for a Phase 2 aGvHD trial are currently underway and the Company will seek FDA approval this year. CYP-001 has previously met all clinical endpoints and demonstrated ground-breaking positive safety and efficacy data for the treatment of aGvHD in a Phase 1 trial, providing important validation of Cymerus MSCs.

Cynata's core focus is to complete recruitment in its active clinical trials, initiate a Phase 2 clinical trial in aGvHD, and to engage in commercial discussions with multiple potential partners. Cynata's pipeline is robust and diverse, with positive preclinical data demonstrated in a host of disease models including idiopathic pulmonary fibrosis (IPF), renal transplantation and myocardial infarction (heart attacks). The versatility of MSCs make it a powerful clinical asset and Cynata's history of positive preclinical and clinical results are a promising indication that MSCs can be leveraged across a range of target indications.

-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. Planning for a Phase 2 clinical trial in GvHD 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	31 MARCH 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,562)	(7,489)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(62)	(220)
	(d) leased assets	-	-
	(e) staff costs	(317)	(1,067)
	(f) administration and corporate costs	(131)	(575)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	9	40
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (2021 R&D Tax Incentive)	833	833
1.8	Other (FUJIFILM Fee*)	-	6,732
1.9	**Net cash from / (used in) operating activities**	**(1,230)**	**(1,746)**

** US$5 million paid by FUJIFILM Corporation in October 2021 under the Strategic Partnership Agreement (as announced to ASX on 30 September 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 (9 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	-	200
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Interest on Director's Loan received	-	10
3.10	**Net cash from / (used in) financing activities**	**-**	**210**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	26,787	26,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,230)	(1,746)

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 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)	-	210
4.5	Effect of movement in exchange rates on cash held	(280)	96
4.6	**Cash and cash equivalents at end of period**	**25,277**	**25,277**

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	15,277	16,787
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)**	**25,277**	**26,787**

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)	(1,230)
8.2	Cash and cash equivalents at quarter end (item 4.6)	25,277
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	25,277
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	20.55

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: 29 April 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.