

## March 2020 Quarterly Activity Report & Appendix 4C

**Melbourne, Australia; 24 April 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 for the quarter ended 31 March 2020.

### Key highlights

- **Further progress on three planned Phase 2 clinical trial programs**
  - Osteoarthritis (OA) trial progressing towards commencement
  - Critical limb ischaemia (CLI) trial application approved by UK regulatory authority in January 2020 and engagement with study centres making good progress
  - Graft-versus-host disease (GvHD) trial logistics and regulatory activity continuing at FUJIFILM
- **Broad preclinical pipeline, with further data generated**
  - Acute respiratory distress syndrome (ARDS) pre-clinical study in final stages of completion (favourable results announced after close of the quarter); given ARDS is a major cause of mortality in COVID-19 patients, investigations are underway in opportunities in this area
- **Canadian Patent granted and Notices of Allowance received from Japan and Israel to strengthen the patent protection of Cynata's Cymerus™ mesenchymal stem cell (MSC) technology**
- **Receipt of a ~A\$2.51m R&D Tax Incentive Refund for the 2018/2019 financial year**
- **Cynata remains in a strong financial position with A\$6.9m in cash as at 31 March 2020, with an additional ~A\$3.55m raised via an institutional Placement subsequent to the quarter, and an SPP to raise up to A\$2m**

Dr. Paul Wotton, Cynata's Chairman, said:

*"Under the present circumstances Cynata continues to make good progress. The current climate is inevitably causing an industry wide slow-down of clinical trial enrolment, including our planned Phase 2 trials. We are advancing critical activities to the final stages before recruitment and are in continued discussions with hospitals and strategic partners, as well as our other collaborators, to ensure that we are positioned to commence the trials effectively after the crisis resolves. Our recent capital raising places us in an enhanced financial position to continue development of our Cymerus™ technology without unnecessary delay during this period of adjustment."*

### Operational update

#### Phase 2 clinical trial plans progress in CLI, OA and GvHD

In January 2020, the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved Cynata's application for the proposed Phase 2 clinical trial of the Cymerus MSC product, CYP-002, in patients with CLI. The Company anticipates conducting trials at multiple centres in the UK and Australia, with the timing of trial commencement currently uncertain as Cynata expects that patient recruitment will be delayed due to COVID-19 associated restrictions outside of the Company's control.

Cynata is also planning for a Phase 2 clinical trial of Cymerus MSCs as a potential treatment of OA. The sponsor of this trial, the University of Sydney, in response to the coronavirus pandemic, recently advised that newly approved trials should not commence trial participant involvement (first visits) until further notice. This advice is expected to remain in place until the pandemic situation resolves.

Although the timing of actual commencement of the OA trial remains uncertain, other planning and protocol development activities continue to progress towards that point. The 448-patient trial is led by the University of Sydney and is funded by the National Health and Medical Research Council. This will be one of the largest MSC trials to be conducted, showcasing Cynata's MSC manufacturing capability.

Meanwhile, FUJIFILM, Cynata's license partner, continues to progress further development of CYP-001, the Cymerus MSC product for the treatment of GvHD. Cynata continues to work collaboratively on the trial planning and start-up activities.

### **Broad preclinical pipeline**

The preclinical study in Acute Respiratory Distress Syndrome (ARDS) has been completed, with favourable results announced subsequent to the end of the quarter. Cynata has received increased market interest in the ARDS study recently, as ARDS can result from a severe COVID-19 infection and is one of the leading causes of death in the current health crises. Accordingly, Cynata is exploring relevant opportunities for its Cymerus MSCs to be a potential treatment in ARDS, including in ARDS resulting from serious complications of a COVID-19 infection.

### **Strengthened Patent portfolio**

During the quarter, the Canadian Intellectual Property office granted a Patent covering its proprietary MSC technology, with an expiration date of 16 March 2031.

Further, the Israel Patent Office and the Japan Patent Office both issued Notices of Allowance for patent applications covering Cynata's unique Cymerus MSC technology. Cynata anticipates that both patents will have an expiration date of 12 March 2034.

These patents expand the already strong IP protection of the Cymerus platform and its unique ability to manufacture MSCs at scale, from a single donation, to create therapeutic stem cell products.

### **Strong financial position**

During the quarter Cynata received ~A\$2.5m in R&D tax incentive refunds, with A\$1.89m received in January 2020 and an additional A\$618k in March 2020. Net operating cash outflows for the quarter after adjusting for the R&D tax incentive refunds amounted to approximately A\$1.7m, primarily relating to R&D expenditure of \$1.1m, investor relations and marketing expenditure of \$247k and administration and staff costs of \$356k. In item 6 of the Appendix 4C cash flow report for the quarter, payments to Related Parties of ~A\$183k comprised of salary paid to the Managing Director, fees paid to Non-Executive Directors and Company Secretarial Fees.

Cynata remains in a strong financial position with A\$6.9m in cash as at 31 March 2020, and continues to invest in value accretive R&D, minimise corporate expenses and prudently manage cash flow.

Subsequent to the quarter, on 22 April 2020, Cynata announced a ~A\$5.55m capital raising, via a successful institutional Placement of ~A\$3.55m, followed by a share purchase plan of up to A\$2m, which currently remains open to eligible shareholders. This was a prudent decision by the Cynata Board to ensure operational certainty for Cynata, given the volatile and uncertain economic outlook due to the COVID-19 pandemic. Funds raised will be used to progress clinical development, strengthen



Cynata's balance sheet, and provide flexibility to assess and potentially advance new opportunities as they arise.

## Outlook

Cynata is focused on advancing Phase 2 clinical trials to provide potential treatments for patients with serious and debilitating diseases. While the scheduling remains uncertain due to the unprecedented impacts of COVID-19, there are numerous workstreams which are being progressed in the meantime to ensure we are ready for patient recruitment once this crisis resolves. Cynata is vigilantly monitoring the evolving situation and will continue to provide further updates as necessary to keep shareholders informed.

The planned target indications of OA and CLI present significant opportunities, with the global CLI treatment market forecasted to reach US\$5.4 billion by 2025 and the osteoarthritis market forecast to grow to US\$11.6bn by 2025. In parallel, Cynata continues to work closely with FUJIFILM on progressing the next GvHD trial, with the FUJIFILM agreement offering a potentially lucrative future revenue stream from milestone payments and royalties.

Cynata's broad pre-clinical pipeline continues to expand, with further positive results from the ARDS study. Given the potential of MSCs to treat a number of severe complications (including ARDS and sepsis) arising from infection with COVID-19 and the increased interest as a result, Cynata is exploring further opportunities for its Cymerus MSCs in this area.

-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 GvHD, critical limb ischemia and osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of asthma, diabetic wounds, heart attack and cytokine release syndrome, a life-threatening condition stemming from cancer immunotherapy.

## 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 March 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 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	(1,125)	(5,814)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(247)	(787)
(d) leased assets	-	-
(e) staff costs	(180)	(577)
(f) administration and corporate costs	(176)	(958)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	21	71
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,510	2,510
1.8 Other – (Fujifilm option license fee*)	-	4,227
<b>1.9 Net cash from / (used in) operating activities</b>	<b>803</b>	<b>(1,328)</b>

\* 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.

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

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	1,053
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	-	(15)
3.5 Proceeds from borrowings	-	-
3.6 Repayment of by related parties	-	100
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (interest on directors' loan received)	-	85
<b>3.10 Net cash from / (used in) financing activities</b>	<b>-</b>	<b>1,223</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	5,918	6,977
4.2 Net cash from / (used in) operating activities (item 1.9 above)	803	(1,328)

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)	-	1,223
4.5	Effect of movement in exchange rates on cash held	205	54
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>6,926</b>	<b>6,926</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	3,926	2,918
5.2	Call deposits	3,000	3,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,926</b>	<b>5,918</b>

**6. Payments to related parties of the entity and their associates**

6.1	Aggregate amount of payments to related parties and their associates included in item 1	183
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

**Current quarter  
\$A'000**

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

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

**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 <b>Total financing facilities</b>	-	-

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

<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)	803
8.2 Cash and cash equivalents at quarter end (Item 4.6)	6,926
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	6,926
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	N/A – positive cashflow for the quarter

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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?

Answer: N/A

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?

Answer: N/A

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

## 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: 24 April 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.