

## March 2017 Quarterly Report

- License option agreement signed with leading global technology and healthcare company FUJIFILM to further develop and commercialise the Cymerus™ technology
- \$10 million in funding received from successful share placement and equity investment from FUJIFILM, making the Company well-funded to progress its development initiatives
- Strong preclinical data achieved in cardiovascular study and asthma study, advancing the product pipeline and path to clinical trials
- Preclinical study to commenced in acute respiratory distress syndrome (ARDS) in partnership with prestigious research team, *Critical Care Research Group*
- Appointment of Dr Paul Wotton to Chairman of the Board of Directors, strengthening the board and management team

**Melbourne, Australia; 26 April 2017:** Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has today released its Appendix 4C Report for the three-month period to 31 March 2017 and is pleased to provide a review of the progress during the period.

### Operational

#### GvHD – Phase I Clinical Trial Commencing

During the quarter, the Company received the final report of its proof of concept study of its Cymerus™ therapeutic mesenchymal stem cell (MSC) product CYP-001 for acute graft versus host disease (GvHD), in a humanised mouse model. The report confirmed the initial study findings which showed a clear therapeutic effect with prolonged survival. Following the September 2016 clinical trial approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA), the Company has also received Ethics Approval from an Australian *Human Research Ethics Committee (HREC)* and the *National Health Service (NHS) Health Research Authority (HRA)* in the UK. The Phase 1 clinical trial of CYP-001 is now recruiting patients and the Company expects the first patient to be dosed imminently.

Under the license option agreement with FUJIFILM, FUJIFILM can exercise its option to the license at any time up until 90 days after the completion of the aforementioned Phase I clinical trial. Upon signing of the license agreement, Cynata will receive an upfront US\$3 million fee along with future milestone payments that potentially total in excess of AUD\$60 million, together with royalties on product sales. Future development costs of CYP-001 will be borne by FUJIFILM.



### **Respiratory – Positive Preliminary Data and New Study Added**

The final report of the initial preclinical study with *Monash University* confirmed Cymerus MSCs have a significant and beneficial impact on all three components of asthma: hyper-responsiveness, inflammation and airway remodelling. The findings from the report led to Cynata signing an agreement in March 2017 with the *Monash Lung Biology Network* (part of a consortia that includes Monash University) to conduct a further preclinical study for the use of Cymerus MSCs in the treatment of asthma with and in comparison to corticosteroids, which are the most widely used treatment to control asthma exacerbations. The study will pave the way for a clinical trial in asthma patients.

Post the quarter, the Company also announced it is commencing an investigation into the use of its Cymerus MSCs as a treatment for acute respiratory distress syndrome (ARDS) with the *Critical Care Research Group* in association with the *Prince Charles Hospital*. The study will evaluate the effectiveness of Cymerus MSCs in sheep with ARDS who are currently being supported by a treatment called extracorporeal membrane oxygenation (ECMO), which acts as an artificial lung to oxygenate the blood. A successful evaluation would lead to a potential clinical study in this serious condition.

### **Cardiovascular – Positive Preliminary Data**

Cynata received positive preliminary data from its preclinical heart attack study conducted at the *Westmead Institute for Medical Research*, Sydney. The results have indicated that Cynata's Cymerus™ therapeutic MSCs have the potential to restore cardiac function and reduce scar size after a heart attack. The study will continue to add to the data already generated with a final report due later this year.

### **Oncology – Licensing Rights Retained and IP Strengthened with Additional Patents**

The Company also announced that its Cymerus technology successfully integrated with apceth GmbH & Co. KG's (apceth) in-house cell culture and genetic modification system aimed at developing new therapeutics for MSCs in cancer and other diseases. This has provided strong validation that the Cymerus technology can integrate with other technologies. Whilst apceth has reviewed its internal strategy and will no longer be focusing on oncology as a core disease area, the license option agreement remains in place for the parties to investigate other disease areas. Meanwhile, Cynata regains the rights to its platform in the oncology field and have also filed for patent protection in relation to the use of its platform in this disease area to further strengthen its intellectual property.

As part of its agreement with Massachusetts General Hospital (MGH), the largest teaching hospital of Harvard Medical School, Cynata is also investigating the use of its Cymerus MSCs, engineered to enhance their properties in killing cancer cells.



## Financial and Corporate Update

### Funding Position Bolstered

In January, Cynata signed a strategic partnership with FUJIFILM, a leading global technology and healthcare company focused on innovative technologies, to collaborate on the further development and commercialisation of the Cymerus therapeutic MSC product CYP-001 for acute graft-versus-host disease (GvHD).

As part of the partnership, FUJIFILM also took a \$3.97 million equity stake in Cynata making them the largest shareholder of the Company with a ~9% holding. The equity investment signified FUJIFILM's commitment to Cynata and its strong belief in the significant potential of the Cymerus technology. Notably, the clinical-grade induced pluripotent stem cells (iPSCs) used in the Cymerus manufacturing process have been sourced from Cellular Dynamics International, Inc, a leading manufacturer of human cell products, which is 100% owned by FUJIFILM following its US\$307 million acquisition.

Furthermore, in January, Cynata secured \$6 million in a Placement of 9.23 million shares at \$0.65c to sophisticated and institutional investors. The funds raised during the quarter have resulted in the Company closing the quarter with \$11.6 million cash at bank. The funds will be used to continue to develop its the Cymerus therapeutic MSC products in its key target areas of GvHD, cardiovascular disease, oncology (glioblastoma) and respiratory disease. Based on current plans this cash position should provide the Company with a runway beyond 2018.

### New Chairman Appointed

The Company strengthened its board and management team with the appointment of Dr Paul Wotton to Chairman of the Board of Directors. Dr Wotton brings a wealth of biotechnology expertise and the necessary skills required to drive the Company to its next phase of growth. Dr Stewart Washer remains on the Board as a Non-Executive Director.

## Outlook

With its unique and proprietary therapeutic stem cell platform technology Cymerus, Cynata is well positioned in the regenerative medicine space and is focused on a number of key target disease areas to generate data to support clinical utility. Strong progress has been delivered for its lead target, GvHD, which has progressed to patient recruitment for a Phase 1 trial.



The Company is on the cusp of delivering another important milestone with the first GvHD patient expected to be dosed imminently, under the Phase 1 trial. The trial is expected to report results in H1 2018 based on historic rates of diagnosis at the relevant study centres.

Cynata continues to work closely with its strategic partner FUJIFILM. The Company has an active business development program to build additional relationships with parties that have the interest and resources to further develop the Company's technologies.

"This quarter has seen Cynata make significant progress in a number our key focus areas. We're particularly excited to be recruiting for the graft versus host disease (GvHD) trial and with the positive preliminary results in our preclinical studies in heart attacks and asthma. This next quarter will see us commence dosing the first patients in the GvHD clinical trial and further progress our preclinical studies as we advance towards clinical studies in other target diseases," said Dr Ross Macdonald, Cynata's Managing Director and Chief Executive Officer.

**Ends**

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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 that is developing a therapeutic stem cell platform technology, Cymerus™, originating from the University of Wisconsin-Madison, a world leader in stem cell research. The proprietary Cymerus™ technology addresses a critical shortcoming in existing methods of production of mesenchymal stem cells (MSCs) for therapeutic use, which is the ability to achieve economic manufacture at commercial scale. Cymerus™ utilises induced pluripotent stem cells (iPSCs) to produce a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ platform provides a source of MSCs that is independent of donor limitations and provides an "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical product business model and economies of scale. This has the potential to create a new standard in the emergent arena of stem cell therapeutics and provides both a unique differentiator and an important competitive position.

## Appendix 4C

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

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

**Name of entity**

Cynata Therapeutics Limited

**ABN**

98 104 037 372

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

31 March 2017

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date</b>
	<b>\$A'000</b>	<b>(9 months)</b>
		<b>\$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,162)	(3,007)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(173)	(322)
(d) leased assets	-	-
(e) staff costs	(181)	(466)
(f) administration and corporate costs	(101)	(666)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	22	57
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	1,749
1.8 Other (fees pursuant to license agreement)	(309)	(309)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,904)</b>	<b>(2,964)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date (9 months)</b>
	<b>\$A'000</b>	<b>\$A'000</b>
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.2 Proceeds from disposal of:</b>		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.3 Cash flows from loans to other entities</b>	-	-
<b>2.4 Dividends received (see note 3)</b>	-	-
<b>2.5 Other (provide details if material)</b>	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	-	-

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares	9,972	9,972
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	20	30
3.4 Transaction costs related to issues of shares, convertible notes or options	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other		
- Share issue costs	(386)	(386)
- Refund of option exercise monies	(30)	(30)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>9,576</b>	<b>9,586</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	3,914	4,866
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,904)	(2,964)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter</b>	<b>Year to date (9 months)</b>
		<b>\$A'000</b>	<b>\$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	9,576	9,586
4.5	Effect of movement in exchange rates on cash held	-	98
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>11,586</b>	<b>11,586</b>

<b>5. Reconciliation of cash and cash equivalents</b>	<b>Current quarter</b>	<b>Previous quarter</b>
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>\$A'000</b>	<b>\$A'000</b>
5.1	Bank balances	3,914
5.2	Call deposits	-
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>11,586</b>

**6. Payments to directors of the entity and their associates**

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

<b>Current quarter</b>
<b>\$A'000</b>
342
-

Directors' fees, salaries including superannuation benefits, annual leave payout and professional consultancy fees. All payments are on normal commercial terms.

**7. Payments to related entities of the entity and their associates**

- 7.1 Aggregate amount of payments to these parties included in item 1.2
- 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

<b>Current quarter</b>
<b>\$A'000</b>
-
-

-

8. <b>Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities	-	-
8.2 Credit standby arrangements	-	-
8.3 Other (please specify)	-	-
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

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9. <b>Estimated cash outflows for next quarter</b>	\$A'000
9.1 Research and development	1,040
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	59
9.4 Leased assets	-
9.5 Staff costs	68
9.6 Administration and corporate costs	181
9.7 Other (provide details if material)	-
<b>9.8 Total estimated cash outflows</b>	<b>1,348</b>

10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	Acquisitions	Disposals
10.1 Name of entity	-	-
10.2 Place of incorporation or registration	-	-
10.3 Consideration for acquisition or disposal	-	-
10.4 Total net assets	-	-
10.5 Nature of business	-	-

### **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.

Sign here: .....  
**Managing Director**

Date: 26 April 2017

Print name: Dr Ross Macdonald

### **Notes**

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.