



ASX ANNOUNCEMENT

31 October 2016

## ACTIVITY REPORT & APPENDIX 4C

**Melbourne, Australia; 31 October 2016:** Regenerative medicine company Cynata Therapeutics Limited's Quarterly Cash Flow Report for the quarter ended 30 September 2016 is attached.

### Operational Highlights:

- Execution of a non-binding development and commercialisation term sheet with FUJIFILM Corporation of Japan
- Regulatory approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) to commence a Phase 1 clinical trial in steroid-resistant graft-versus-host disease (GvHD); a world first for an allogeneic, iPSC-derived cell therapy product
- Generation of compelling data from a proof of concept study in an experimental model of asthma

In the field of stem cells and regenerative medicine, mesenchymal stem cells (MSCs) have emerged as one of the most promising candidates for mainstream medical use in a wide variety of economically important diseases and as such have very exciting commercial potential. Cynata's business focus is the development and commercialisation of a novel, proprietary technology that addresses a critical shortcoming in existing methods of production of MSCs for therapeutic use, which is the ability to achieve economic manufacture at commercial scale. With its Cymerus™ process, which involves the use of induced pluripotent stem cells (iPSC's) as starting material, Cynata is the only company in the world with technology for the manufacture of therapeutic allogeneic MSCs without reliance upon multiple stem cell donors.

A major highlight for the quarter was the execution of a non-binding term sheet with FUJIFILM Corporation of Japan. The term sheet anticipates a definitive agreement, presently being reviewed by the parties, under which Cynata will grant FUJIFILM an option to an exclusive, worldwide licence to market and sell Cynata's lead MSC product, CYP-001, for prevention and treatment of graft-versus-host disease (GvHD). The definitive agreement also describes an option to negotiate a licence to manufacture CYP-001, and certain other rights to Cynata's proprietary Cymerus™ technology. FUJIFILM proposes to make a direct investment in Cynata by way of the acquisition of Cynata shares to the value of US\$3 million, such shares to be priced at, in consideration for the rights granted under the agreement, a 35% premium to the 6 month VWAP as at 2 September 2016. The draft definitive agreement also contemplates Cynata receiving certain upfront and milestone payments, together with a royalty on end-product sales. Entry into a definitive agreement remains subject to satisfactory completion of negotiations. FUJIFILM has emerged as a major participant in the growing regenerative medicine industry. Founded in 1934, FUJIFILM has expanded the use of its core fundamental technologies allowing it to transform into a major healthcare company with total sales in 2015-16 of \$US22b. Notably FUJIFILM acquired Cellular Dynamics International, Inc (CDI) in 2015 for \$US307m; CDI is a regenerative medicine company, which like Cynata, was also spun out from the University of Wisconsin-Madison.

Meanwhile the Company's existing commercial relationship with apceth GmbH & Co continues on plan with that company making good progress in its evaluation of Cynata's Cymerus MSCs.

The Company achieved a major product development milestone during the quarter with the approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) to proceed with the Phase 1 clinical trial of CYP-001 in patients with steroid-resistant graft-versus-host disease (GvHD). Activities are now underway to commence enrolment of patients in the study and to begin treatment; the first patient is expected to be treated before the end of calendar 2016. The trial aims to recruit a total of approximately 16 participants who have undergone a bone marrow transplant or similar procedure, and were subsequently diagnosed with steroid-resistant Grade II-IV acute GvHD. This achievement represents a major milestone in the field of regenerative medicine as it is believed to be the world's first clinical trial involving a therapeutic product



derived from allogeneic induced pluripotent stem cells (iPSCs). The approval has received considerable global attention and the Company expects the treatment of the first patient to be extensively covered in the media.

In addition to demonstrating efficacy in pre-clinical models of GvHD and critical limb ischaemia, the Company now has compelling data for its Cymerus™ MSCs in an animal model of asthma. In a study conducted under the supervision of Associate Professor Chrishan Samuel and Dr Simon Royce at Monash University, intravenous administration of Cynata's MSCs in animals in which a chronic allergic airways disease had been induced caused a statistically significant improvement in their symptoms. Moreover, intranasal administration of Cynata's MSCs completely normalised the symptoms in the experimental animals. Given that the features of this model closely resemble the clinical manifestations of asthma in humans the findings in this study suggest that Cymerus™ MSCs could have a profound effect in the treatment of asthma.

The significant achievements made by the Company during the quarter provide a sound foundation for the next phase in the Company's growth, setting Cynata on a path to sustainable success and cementing the Company's commercial and technical leadership in second generation MSC technologies.

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#### **About Cynata Therapeutics (ASX: CYP)**

Cynata Therapeutics Limited (ASX: CYP) is an Australian 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™ does so through the production of a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ MCA platform provides a source of MSCs that is independent of donor limitations and provides a potential "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical 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")**

30 September 2016

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date</b>
	<b>\$A'000</b>	<b>(3 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	(705)	(705)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(67)	(67)
(d) leased assets	-	-
(e) staff costs	(118)	(118)
(f) administration and corporate costs	(316)	(316)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	27	27
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,179)</b>	<b>(1,179)</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	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter</b>	<b>Year to date (3 months)</b>
		<b>\$A'000</b>	<b>\$A'000</b>
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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 shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
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 (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>-</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 quarter/year to date	4,866	4,866
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,179)	(1,179)
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)	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter</b>	<b>Year to date (3 months)</b>
		<b>\$A'000</b>	<b>\$A'000</b>
4.5	Effect of movement in exchange rates on cash held	19	19
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>3,706</b>	<b>3,706</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	900
5.2	Call deposits	3,966
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>4,866</b>

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

- |  | <b>Current quarter</b> |
|--|------------------------|
|  | <b>\$A'000</b>         |
| 6.1  | 245                    |
| 6.2  | -                      |
| 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2 |                        |

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

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

- |  | <b>Current quarter</b> |
|--|------------------------|
|  | <b>\$A'000</b>         |
| 7.1  | -                      |
| 7.2  | -                      |
| 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2 |                        |

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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	2,468
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	32
9.4 Leased assets	-
9.5 Staff costs	123
9.6 Administration and corporate costs	205
9.7 Other (provide details if material)	-
<b>9.8 Total estimated cash outflows</b>	<b>2,828</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:

  
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**Managing Director**

Date: 31 October 2016

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.