

## December 2019 Quarterly Report

**Melbourne, Australia; 30 January 2020:** Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, has today released its Appendix 4C Report for the three-month period to 31 December 2019 and is pleased to provide a review of operational progress during the period.

### Highlights

- **Planning for three Phase 2 clinical trial programs progressing**
  - Osteoarthritis Research Support Agreement signed, accelerating trial planning and start-up activities, with trial design nearing completion and protocol development advancing
  - Critical limb Ischaemia (CLI) trial application lodged and subsequently approved by UK healthcare regulatory authorities
  - FUJIFILM planning underway for Phase 2 graft-versus-host disease (GvHD) clinical trial
- **Broad and robust preclinical pipeline, with further validating data generated**
  - Grant received for Coronary Artery Disease (CAD) of A\$50k to support continued research at the University of Sydney
  - Achieved positive efficacy data in a preclinical model of sepsis
- **Notice of Allowance received from the Canadian Intellectual Property Office (CIPO) for a patent application further strengthening the protection of Cynata's Cymerus™ MSC technology**

Dr. Paul Wotton, Cynata's Chairman:

*"Cynata continues to expand the utility of its Cymerus MSCs as a treatment for a broad range of indications. Further positive efficacy data was generated during the quarter, including in a preclinical model of sepsis, which makes us optimistic that our product can provide a new treatment option for patients in need. We look forward to initiating our planned Phase 2 studies and to making further advances towards commercialising our MSC platform."*

### Operational update

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

In November 2019, Cynata lodged an application with the UK Medicines Healthcare Products Regulatory Agency (MHRA) for the proposed Phase 2 clinical trial of Cynata's Cymerus mesenchymal stem cells (MSC) product, CYP-002, treating patients with CLI. Subsequent to the quarter, the MHRA completed its review and granted approval to Cynata to proceed with the trial. The Company anticipates conducting trials at multiple centres in the UK and Australia with detailed logistic planning toward commencing the trial now underway.

Significant progress was made for the Phase 2 clinical trial of Cynata's Cymerus MSCs as a treatment of osteoarthritis, following the signing of a Research Support Agreement with the University of Sydney. The 448-patient Phase 2 clinical trial is expected to commence in the near-term, led by Professor David Hunter at the University of Sydney, who has been a Chief Investigator of numerous clinical trials in



osteoarthritis. This will also be one of the largest MSC trials to ever be conducted, showcasing Cynata's MSC manufacturing capability.

The Company's licensee for CYP-001 for the treatment of GvHD, FUJIFILM, is progressing further development of the product, following the exercise of its license option in GvHD in September 2019. Cynata continues to work collaboratively on the trial planning and start-up activities with the first GvHD Phase 2 trial expected to commence this calendar year.

#### **Broad preclinical pipeline generates further compelling data**

During the quarter, Cynata received an Innovation Connections grant of A\$50k to advance the development of therapies for CAD. The grant was received from the Australian Government's Department of Industry Innovation and Science to support continued research at UNSW Sydney, under the leadership of Associate Professor Kristopher Killian.

In December 2019, Cynata received positive efficacy data from preclinical studies for the treatment of sepsis. Sepsis is a serious disease, and sometimes referred to as blood poisoning. In the model, Cymerus MSC treatment was successful in increasing blood oxygen levels, lung compliance and decreasing inflammation, all markers of the degree of severity of the condition. Studies were performed under Cynata's development partnership with the Royal College of Surgeons in Ireland, under the leadership of Professor Gerard Curley.

#### **Strengthened patent portfolio**

During the quarter, Cynata announced that a Notice of Allowance was received from CIPO for a patent application covering its Cymerus MSC technology. Cynata anticipates that the patent will be granted before 11 April 2020, with an expiration date of 16 March 2031. The patent will 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.

#### **Focus on ongoing commercial activities**

Cynata continues a vigorous and active partnering strategy with discussions underway with multiple potential partners in multiple indications. This strategy was validated by FUJIFILM's execution of the GvHD license agreement, which can be leveraged to support ongoing commercial discussions.

As previously announced on 19 July 2019, Cynata received an indicative, non-binding and conditional proposal from Sumitomo regarding the possible acquisition of all shares in Cynata at \$2.00 per share in cash by way of a scheme of arrangement. After engaging in discussions on a non-exclusive basis, Cynata was unable to reach agreement on terms to its satisfaction and accordingly withdrew from those discussions in October 2019.

## **Outlook**

The progression into multiple Phase 2 clinical trials presents an exciting opportunity to provide treatment for patients with serious and debilitating diseases and represent significant milestones and value catalysts for the Company, progressing Cynata closer towards commercialisation.

The approval of the CLI trial allows the Company to move forward and expects to commence the recruitment process in the near-term. This is a significant opportunity, with the global CLI treatment market forecasted to reach US\$5.4 billion by 2025. In parallel, Cynata continues to work closely with



the University of Sydney on trial planning in osteoarthritis and with FUJIFILM on progressing the GvHD trial, with both Phase 2 trials expected to commence this year. Osteoarthritis is a significant opportunity with the market forecast to grow to US\$11.6bn by 2025, and the FUJIFILM license agreement in GvHD offering a potentially lucrative future revenue stream from milestone payments and royalties.

Cynata's broad pre-clinical pipeline continues to expand, with work continuing on various studies and potential collaborations in several indications.

The Company holds A\$5.92m in cash at the end of December 2019 and received a further A\$1.9m in cash by way of the R&D tax rebate received in January 2020.

**-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 report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/169

**Name of entity**

Cynata Therapeutics Limited

**ABN**

98 104 037 372

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

31 December 2019

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date</b>
	<b>\$A'000</b>	<b>(6 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	(2,723)	(4,689)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(233)	(540)
(d) leased assets	-	-
(e) staff costs	(176)	(397)
(f) administration and corporate costs	(174)	(782)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	19	50
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (Fujifilm option license fee*)	-	4,227
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,287)</b>	<b>(2,131)</b>

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

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

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
(c) investments	-	-
(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	-	-
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	102	1,053
3.4 Transaction costs related to issues of shares, convertible notes or options	(2)	(15)
3.5 Proceeds from borrowings	-	-
3.6 Repayment by related parties	-	100
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (interest on directors' loans received)	-	85
<b>3.10 Net cash from / (used in) financing activities</b>	<b>100</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 quarter/year to date	9,202	6,977
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(3,287)	(2,131)
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 (6 months)</b>
		<b>\$A'000</b>	<b>\$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	100	1,223
4.5	Effect of movement in exchange rates on cash held	(97)	(151)
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>5,918</b>	<b>5,918</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	2,918	5,702
5.2	Call deposits	3,000	3,500
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>5,918</b>	<b>9,202</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

**Current quarter  
\$A'000**

183

-

Directors' fees, salaries including superannuation benefits and company secretarial fees.

**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

**Current quarter  
\$A'000**

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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	1,438
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	182
9.4 Leased assets	-
9.5 Staff costs	194
9.6 Administration and corporate costs	88
9.7 Other (provide details if material)	-
<b>9.8 Total estimated cash outflows</b>	<b>1,902</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/CEO**

Date: 30 January 2020

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.