

## June 2019 Quarterly Report

**Melbourne, Australia; 4 July 2019:** Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP or “the Company”), has today released its Appendix 4C Report for the three-month period to 30 June 2019 and is pleased to provide a review of operational progress during the period.

### Highlights

- **Commercialisation of the Company’s proprietary Cymerus™ stem-cell technology is a major area of focus**
  - Cynata and Fujifilm continue to work towards the exercise of Fujifilm’s licence option for CYP-001 in graft-versus-host disease (GvHD) following an extension of the agreement in March
  - Ongoing commercial interactions with potential strategic partners in multiple indications and geographies
- **Three Phase 2 trials on-track to commence in late 2019**
  - Graft-versus-host disease: Planning discussions ongoing with Fujifilm; Fujifilm to commence clinical trial pending exercise of its licence option
  - Critical Limb Ischemia: Clinical trial protocol at final draft stage; contract research organisation (CRO) engaged; trial expected to commence in Q4-2019
  - Osteoarthritis: Activities progressing for the 448-patient trial; trial to be run by the University of Sydney, substantially funded by NHMRC
- **Strengthened Board and Executive Management Team to support Cynata’s growing commercial activities**
  - Dr Geoff Brooke appointed as director to the Board
  - Dr Suzanne Lipe appointed as Vice President, Alliance Management
  - Dr Kilian Kelly promoted to Chief Operating Officer

### Operational update

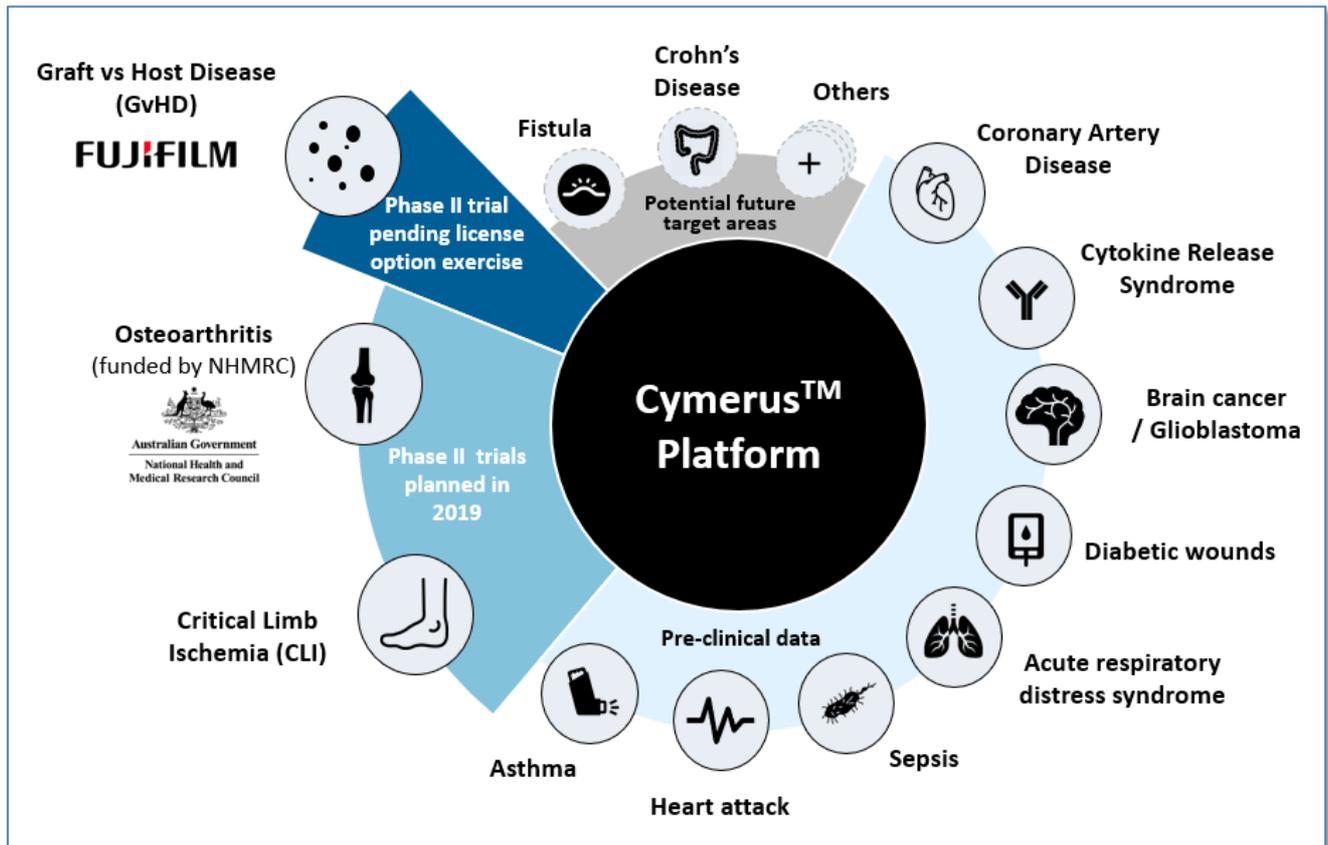
#### Fujifilm license option update

Cynata announced on 21 March 2019 that the license option had been extended to 5:00pm Melbourne time on 19 September 2019. The extension was granted to accommodate certain requests made by Fujifilm to include in the GvHD license agreement certain rights that were not structurally consistent with rights in-licensed by Cynata in 2013 from Wisconsin Alumni Research Foundation (**WARF**).

Since granting the extension, Cynata has been working, and continues to work, intensively and co-operatively with Fujifilm and WARF on finalising the outstanding matters. Substantial progress has been made following numerous bi-lateral discussions and a recent tri-lateral face-to-face meeting at WARF. This progress underscores the extent to which all the relevant parties involved have the same primary interest, which is to ensure the Cymerus technology is developed in an efficient manner and made available to improve outcomes in patients with GvHD.

Cynata is committed to delivering a positive outcome for all stakeholders. In addition to the numerous teleconferences and international meetings with Fujifilm and WARF, Cynata continues to make steady progress in planning the GvHD Phase 2 clinical trial.

**Cymerus platform overview – broad applicability across a range of target areas**



**Presentations at meetings/conferences; validation that Cynata is at the forefront of regenerative medicine**

Towards the end of May the Company announced that the Cymerus technology was to be featured in several presentations at the Annual Meeting of the International Society of Cell and Gene Therapy (ISCT). Invitations to present at meetings and conferences around the world like this provide tremendous validation that Cynata is at the forefront of regenerative medicine and cell therapy. The ISCT Annual Meeting attracts over one thousand delegates from around 50 countries and represents the peak international meeting of scientists, thought leaders, companies and investors in cell therapy. Cynata was featured in several presentations at this Annual Meeting highlighting the growing global interest in the Cymerus technology.

**Phase 2 Clinical Trial of CYP-002 in critical limb ischemia (CLI) update**

The Company was pleased to announce during the quarter further progress has been made in relation to the start-up activities for the planned Phase 2 clinical trial of its Cymerus MSC product, CYP-002, for patients with CLI. The clinical trial protocol is now at final draft stage and has been reviewed and commented on by key clinical opinion leaders with expertise in CLI.

Cynata also engaged a leading contract research organisation (CRO) to help prepare and advance the final clinical trial protocols. The Company expects to commence this trial by the fourth quarter of this calendar year.



### **Strengthened Board & Executive Management Team**

Cynata continues to make good progress on the path to commercialising its proprietary Cymerus technology. As the point of commercialisation approaches, there is a growing need to employ the people best placed to not only continue the product development activities, but also execute on the commercial partnering plans as we now have multiple planned Phase 2 clinical trials.

During the quarter, we significantly strengthened the Board and Executive Management team of Cynata with the appointment of Dr Geoff Brooke as Director to the Board, Dr Suzanne Lipe as Vice President, Alliance Management and Dr Kilian Kelly has been promoted to Chief Operating Officer.

Dr Brooke brings 30 years of international experience in the healthcare sector and has outstanding connections in capital markets developed through his positions as founder and former Managing Director of two leading life sciences venture capital firms. Dr Lipe enters a newly created role within the Company and possesses highly relevant experience in stem cell therapeutics and regenerative medicine as former Vice President Operations at Mesoblast. Finally, Dr Kelly's outstanding achievements in the continued development of Cynata have been recognised with the promotion to the new role of Chief Operating Officer.

### **Strengthened IP through grant of new Patent**

Early in the quarter the Company announced the European Patent Office granted a patent covering its proprietary Cymerus mesenchymal stem cell (MSC) technology. The patent has an expiry date of 12 March 2034. This patent provides further IP protection for the Cymerus technology, including CYP-001, which is being developed as a treatment for GvHD.

### **Outlook**

Cynata is encouraged by the progress made over the last quarter during the many discussions held with Fujifilm and WARF. All parties recognise the importance of finalising Fujifilm's option agreement in GvHD and continue to work together towards finalising the agreement during the upcoming quarter.

The company will continue to progress other commercial interactions with potential strategic partners in multiple indications and geographies.

There are currently three Phase 2 clinical trials expected to commence in calendar 2019, all of which represent significant milestones, taking Cynata closer to the point of commercialisation. The Company continues to work closely with the University of Sydney regarding the Phase 2 clinical trial in osteoarthritis, which will be one of the largest MSC trials ever undertaken.

Cynata will also continue to seek new patent opportunities to strengthen the intellectual property portfolio on The Company closed the June quarter with \$7 million in cash to continue to support its product development activities. Significantly, two of the three Phase 2 clinical trials to commence in 2019 are expected to be substantially funded by external collaboration/strategic partners.

The Board and Management of Cynata look forward to further demonstrating the broad applicability of our Cymerus platform and MSC based therapeutic products.

**-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 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")**

30 June 2019

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date</b>
	<b>\$A'000</b>	<b>(12 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	(1,335)	(5,597)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(280)	(751)
(d) leased assets	-	-
(e) staff costs	(183)	(705)
(f) administration and corporate costs	(579)	(1,218)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	38	189
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	1,309
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,339)</b>	<b>(6,773)</b>

*Note: 1.2(f) includes an increase in costs primarily legal and insurance consistent with an increase in the Company's activities.*

<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	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
(d) intellectual property	-	-
(e) other non-current assets	-	-
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 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 shares	-	-
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	51	1,406
3.4 Transaction costs related to issues of shares, convertible notes or options	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment by related parties	-	200
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	(2)	(76)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>49</b>	<b>1,530</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	9,275	12,206
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,339)	(6,773)
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)	49	1,530

<b>Consolidated statement of cash flows</b>		<b>Current quarter</b>	<b>Year to date (12 months)</b>
		<b>\$A'000</b>	<b>\$A'000</b>
4.5	Effect of movement in exchange rates on cash held	(8)	14
4.6	<b>Cash and cash equivalents at end of quarter</b>	<b>6,977</b>	<b>6,977</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	977	3,275
5.2	Call deposits	6,000	6,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,977</b>	<b>9,275</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>
155
-

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

<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	1,723
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	153
9.4 Leased assets	-
9.5 Staff costs	291
9.6 Administration and corporate costs	267
9.7 Other (provide details if material)	-
<b>9.8 Total estimated cash outflows</b>	<b>2,434</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: 4 July 2019

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.