

September 2019 Quarterly Report

Melbourne, Australia; 24 October 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 September 2019 and is pleased to provide a review of operational progress during the period.

Highlights

- **Fujifilm exercised the license option for CYP-001 in graft-versus-host disease (GvHD)**
 - Fujifilm endorsement via exercising license option in GvHD validates Cynata’s Cymerus™ platform
 - Future development of CYP-001 being funded by Fujifilm
 - Preparation for Phase 2 clinical development program underway
 - Lucrative potential future revenue stream from milestone payments and royalties
 - Supports continued focus on commercialisation of Cynata’s proprietary Cymerus stem-cell technology in other therapeutic targets
- **Planning for three Phase 2 clinical trial programs underway**
 - GvHD: Under the license agreement, Fujifilm is responsible for development and commercialisation of CYP-001 with a Phase 2 clinical trial expected to commence in 2020
 - Osteoarthritis: advancing towards 448 patient Phase 2 clinical trial expected to commence Q1 CY20
 - Critical Limb Ischemia (CLI): planning activities continued with expected filing of a Clinical Trial Authorisation application with regulatory authorities imminently and trial planned to commence in early 2020
- **Cynata’s Cymerus™ platform has therapeutic potential in numerous additional target areas, with preclinical studies and commercial discussions ongoing to enhance the potential value of the technology**
- **Withdrawal from acquisition discussions with Sumitomo, following the non-binding indicative offer of \$2 per share, as Cynata was unable to reach agreement on terms to its satisfaction**

Dr. Paul Wotton, Cynata’s Chairman:

“Cynata is on the verge of entering the next stage of clinical trials, with three Phase 2 trials expected to commence in the near term. The endorsement from strategic partner Fujifilm validates the platform technology and supports our active commercial partnering discussions. We look forward to advancing to Phase 2 trials and continuing discussions with potential partners.”

Operational update

Phase 2 Clinical Trial of CYP-001 in GvHD / Fujifilm update

On 17 September 2019, Fujifilm was granted an exclusive, worldwide license to develop and commercialise Cynata’s lead mesenchymal stem cell (MSC) product, CYP-001, in GvHD. Fujifilm is to bear responsibility for all further costs of product development activities in relation to GvHD, regulatory submissions and commercialisation and activities are now underway to accelerate further development of CYP-001 for GvHD with a Phase 2 clinical

trial expected to commence in 2020. This follows the success of Cynata's world-first Phase 1 induced pluripotent stem cell (iPSC)-derived MSC trial, which demonstrated no safety issues and achieved all efficacy endpoints.

In addition to the A\$3.97m equity stake at a 35% premium in 2017, Cynata has received US\$3m up-front license fee (less applicable Japanese withholding taxes) from Fujifilm, with potential future milestone payments totalling up to US\$43m, as well as 10% royalty on all future product sales.

Fujifilm's endorsement validates Cynata's Cymerus platform and strongly supports commercialisation of the Company's unique and proprietary stem-cell technology in other therapeutic targets.

Phase 2 Clinical Trials in Osteoarthritis and Critical Limb Ischemia

Planning for the Phase 2 trial in Osteoarthritis is progressing well with the 448 patient Phase 2 clinical trial expected to commence in Q1 CY20. Key developments include execution of the Research Support Agreement and finalising of trial design and protocol developments. This will be one of the largest MSC trials to be conducted and showcases Cynata's therapeutic MSC technology. The conduct of the trial will be led by the University of Sydney and is substantially funded by a project grant awarded by the Australian National Health and Medical Research Council (NHMRC). Under the agreement, Cynata retains full commercial rights to the use of Cymerus MSCs in Osteoarthritis. This represents an exceptional commercial opportunity for Cynata with the global osteoarthritis treatment market being estimated to be in excess of US\$11 billion by 2025¹.

Planning for the conduct of the CLI Phase 2 clinical trial is at an advanced stage. The Company expects to submit the application for regulatory approval of the trial (the Clinical Trial Authorisation application) to the UK Medicines and Healthcare Products Regulatory Authority (MHRA) during Q4 CY2019, with recruitment expected to commence early in 2020.

Cymerus MSC's have potential in a broad range of target areas

Pre-clinical research is ongoing in several target areas in which Cynata's MSC's have potential, expanding the data set to support the overall demonstration of utility of the Cymerus technology and potential further clinical trials.

Further, a scientific paper demonstrating the efficacy of Cynata's Cymerus MSC's to prevent organ transplant rejection in a preclinical study has been published in leading peer-reviewed Journal, *Stem Cell Research & Therapy*, on 23 September 2019. The study results build on the body of data demonstrating the profound immunomodulatory properties of Cymerus MSC's.

Withdrawal from acquisition discussions

As previously announced on 19 July 2019, Cynata received an indicative, non-binding and conditional proposal from Sumitomo Dainippon Pharma Co., Ltd for the possible acquisition of all shares in Cynata at \$2.00 per share in cash by way of a scheme of arrangement. The parties then engaged in discussions on a non-exclusive basis before withdrawing from discussions on 17 October 2019 as Cynata was unable to reach agreement on terms to its satisfaction.

¹ Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025)"

Outlook

The Board and Management now look forward to commencing the Phase 2 clinical studies and pursuing further commercialisation opportunities to capture the true value of the Cymerus platform. Cynata's three upcoming Phase 2 trials highlight the growing therapeutic potential for the Company's Cymerus MSC's and positions the company for an exciting and productive CY20. In addition, the Company remains actively engaged in commercial discussions with parties interested in partnering with Cynata for other opportunities. This is supported by the growing and compelling pre-clinical dataset in multiple other high-value target areas.

The Company closed the September quarter with A\$9.2m in cash, with two of the three Phase 2 trials substantially funded by strategic partners or external collaborations (Fujifilm for GvHD; NHMRC for osteoarthritis).

The AGM is scheduled for Wednesday, 27 November 2019 at 11:00 am (AEDT), as announced to the market on 27 September 2019.

-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 September 2019

Consolidated statement of cash flows	Current quarter	Year to date
	\$A'000	(3 months)
		\$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,966)	(1,966)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(307)	(307)
(d) leased assets	-	-
(e) staff costs	(221)	(221)
(f) administration and corporate costs	(608)	(608)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	31	31
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 license fee*)	4,227	4,227
1.9 Net cash from / (used in) operating activities	1,156	1,156

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

2. Cash flows from investing activities		
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 (3 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)	-	-
2.6 Net cash from / (used in) investing activities	-	-

3. Cash flows from financing activities		
3.1 Proceeds from issues of shares	-	-
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	951	951
3.4 Transaction costs related to issues of shares, convertible notes or options	(13)	(13)
3.5 Proceeds from borrowings	-	-
3.6 Repayment by related parties	100	100
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (interest on directors' loans received)	85	85
3.10 Net cash from / (used in) financing activities	1,123	1,123

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of quarter/year to date	6,977	6,977
4.2 Net cash from / (used in) operating activities (item 1.9 above)	1,156	1,156
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)	1,123	1,123

Consolidated statement of cash flows		Current quarter	Year to date (3 months)
		\$A'000	\$A'000
4.5	Effect of movement in exchange rates on cash held	(54)	(54)
4.6	Cash and cash equivalents at end of quarter	9,202	9,202

5. Reconciliation of cash and cash equivalents	Current quarter	Previous quarter	
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	\$A'000	\$A'000	
5.1	Bank balances	5,702	977
5.2	Call deposits	3,500	6,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	9,202	6,977

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
250
-

Directors' fees, salaries including performance bonus, 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
-
-

-

8. Financing facilities available <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.		
-		

9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	2,651
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	155
9.4 Leased assets	-
9.5 Staff costs	194
9.6 Administration and corporate costs	315
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	3,315

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	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/CEO

Date: 24 October 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.