

December 2018 Quarterly Report

Melbourne, Australia; 29 January 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 31 December 2018 and is pleased to provide a review of operational progress during the period.

Highlights

- Completion of the Clinical Study Report (CSR) for Phase 1 Trial of CYP-001 in GvHD and submission of the CSR to Fujifilm, thereby triggering a 90 day deadline for Fujifilm to exercise its licence option
- National Health and Medical Research Council (NHMRC) approved a grant to fund a major Phase 2 trial of Cynata’s Cymerus™ mesenchymal stem cells (MSCs) in patients with osteoarthritis
- Notice of Allowance issued by the European Patent Office for Cymerus Patent Application
- Further positive results in pre-clinical studies support the use of engineered MSCs produced using the Cymerus platform to target various cancers
- Well-funded to support ongoing product development activities, including initiating three Phase 2 clinical trial programs in 2019 for the treatment of graft-versus-host-disease (GvHD), critical limb ischemia (CLI) and osteoarthritis

Operational update

Phase I Clinical Trial of CYP-001 in GvHD complete

Towards the end of the December quarter the Company announced that it had completed the CSR describing full details of the results from the Phase 1 clinical trial of CYP-001 for the treatment of steroid-resistant acute graft versus host disease (GvHD). Significantly, a copy of the CSR has now been provided to Fujifilm in accordance with the terms of the licence option between Cynata and Fujifilm. This triggered a 90 day period for Fujifilm to exercise the licence option. A decision to do so would see Fujifilm pay an initial US\$3m upfront licence fee to Cynata for the exclusive worldwide licence for the product for GvHD and a potential further ~A\$60m in milestone payments, plus double-digit royalties on product sales. Fujifilm would also take on all development and commercialisation costs associated with progressing CYP-001 to market for GvHD.

It remains our view that the actions of Fujifilm indicate an intention to exercise the licence option for GvHD. Cynata has commenced planning for a Phase 2 trial in GvHD with Fujifilm, including conducting a joint meeting with Japanese regulator (PMDA) and joint media briefings.

Phase 2 Clinical Trial in Osteoarthritis announced

Mid way through December, the Company was very pleased to announce that the Australian National Health and Medical Research Council (NHMRC) approved a grant to fund a Phase 2 clinical trial to evaluate Cynata’s Cymerus mesenchymal stem cells (MSCs) as a treatment for osteoarthritis. The 448-patient Phase 2 clinical trial will be one of the largest MSC trials ever run, providing a breakthrough opportunity for Cynata to showcase its ability to produce MSCs at scale.



Cynata retains full commercial rights to the use of Cymerus MSCs in osteoarthritis, a major disease with a market opportunity that, based on published market research, will be approximately US\$11.6 billion globally by 2025.

Strengthened IP through new Patent Application

During the quarter Cynata announced further progress in strengthening and protecting its proprietary Cymerus MSC technology with the European Patent Office (EPO). Cynata received a Notice of Allowance from the EPO for a key Cymerus patent application. The Notice of Allowance is sent to the applicant when the EPO intends to issue a patent. Cynata anticipates that the patent will be granted by late February 2019, with an expiration date of 12 March 2034, further protecting Cynata's intellectual property portfolio in overseas jurisdictions.

Preclinical Progress and Development

During the quarter, Cynata continued to expand its portfolio of target indications and potential commercial opportunities through further preclinical studies. Positive preclinical research continues to strengthen and expand its data set to support further clinical trials. Consistent with its business model, the Company is actively seeking partners to assist in accelerating its pre-clinical programs into clinical trials.

- *Preclinical Studies Demonstrate MSCs Anti-Cancer Effects*

Cynata was pleased to announce during the quarter results from its preclinical program using the Cymerus platform technology to develop genetically engineered cells, derived from MSCs, to treat cancer. This study showed that genetically engineered cells were successfully produced using the Cymerus platform to express diagnostic and therapeutic anti-cancer agents. The engineered Cymerus cells could be effectively tracked by real time imaging and they showed highly promising therapeutic benefits.

Following the positive outcomes from this preclinical study, Cynata intends to continue to investigate this promising new approach to cancer treatment as part of its pipeline strategy.

Corporate Update

The Company received a \$1,308,551.78 R&D Tax Incentive Refund for the 2017/2018 financial year from the Australian Government as part of the program that refunds up to 43.5% of eligible expenditure on research and development.

Outlook

We started calendar 2018 with a single Phase 1 trial in progress. Much was achieved during the year and we now enter calendar 2019 with **three Phase 2 clinical trials** expected to commence in the coming year. Through our preclinical work we will continue to evaluate other high-potential target areas, dramatically expanding the commercial opportunities which Cynata is actively pursuing.

The clinically and commercially significant outcomes generated by our Phase 1 trial in GvHD provide clear validation of Cynata's MSCs and the Cymerus platform. We believe this will support the continued evaluation of Cynata's MSCs in a Phase 2 trial in GvHD in partnership with Fujifilm (assuming exercise of the licence option).

Our engagement during 2018 with Boston-based consultancy, Clearview Healthcare Partners, has helped prioritise and identify our next target indication. We have selected critical limb ischemia (CLI) as our next indication and have announced our intention to commence a Phase 2 trial for CLI in 2019.



The other Phase 2 clinical trial which has been announced for 2019 is in osteoarthritis. This trial will be largely funded by the NHMRC and will be one of the largest MSC trials ever conducted which provides Cynata with the opportunity to showcase our capacity to produce MSCs at scale.

These three Phase 2 clinical trials represent significant milestone opportunities for Cynata in 2019 as we move closer to commercialising our Cymerus MSC technology. We will also continue to advance our preclinical studies using Cymerus MSCs to identify new indications to add to our target portfolio.

While several patents have already been granted on core aspects of the Cymerus technology in major commercial jurisdictions, we continue to file new patent applications in order to strengthen and broaden the protection of our intellectual property portfolio.

The Company closed the December quarter with \$10.64 million in cash to continue to support its product development activities. Significantly, two of the three Phase 2 trials expected to commence in 2019 are being 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 its proprietary MSC-based therapeutic products in 2019. The company will continue to progress commercial interactions with potential strategic partners in multiple indications and geographies.

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CONTACTS:

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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 and 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 2018

Consolidated statement of cash flows	Current quarter	Year to date
	\$A'000	(6 months)
		\$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,420)	(2,564)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(43)	(187)
(d) leased assets	-	-
(e) staff costs	(158)	(347)
(f) administration and corporate costs	(234)	(523)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	67	101
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,309	1,309
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(479)	(2,211)
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	Year to date (6 months)
	\$A'000	\$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	-	417
3.4 Transaction costs related to issues of shares, convertible notes or options	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment by related parties (<i>part repayment of Director Loan by Ross Macdonald</i>)	200	200
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	(17)
3.10 Net cash from / (used in) financing activities	200	600

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	10,907	12,206
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(479)	(2,211)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter	Year to date (6 months)
		\$A'000	\$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	200	600
4.5	Effect of movement in exchange rates on cash held	12	45
4.6	Cash and cash equivalents at end of quarter	10,640	10,640

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	3,640	3,907
5.2	Call deposits	7,000	7,000
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)	10,640	10,907

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**

209

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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. 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.		

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9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	1,452
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	123
9.4 Leased assets	-
9.5 Staff costs	152
9.6 Administration and corporate costs	116
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	1,843

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: 29 January 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.