

December 2017 Quarterly Report

- Enrolment and dosing of first patient cohort (Cohort A) completed in Cynata's world first clinical trial of CYP-001 for the treatment of GvHD
- Dosing of Cohort A represents the mid-way point in the trial and triggered the independent Data Safety Monitoring Board (DSMB) review
- Completion of a second preclinical asthma study confirmed efficacy of Cymerus™ MSCs when used independently or in conjunction with corticosteroid treatment
- Well-funded to progress GvHD clinical trial with cash runway into 2019 based on current projections
- Interaction with Fujifilm progressing well as part of and the licencing option agreement in place to generate a potential USD\$3m upfront licencing fee and A\$60m+ in milestone payments plus royalties

Melbourne, Australia; 30 January 2018: Australian clinical stage stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has today released its Appendix 4C Report for the three-month period to 31 December 2017 and is pleased to provide a review of operational progress during the period.

Operational

First Patient Cohort Dosing Completed in World First Clinical Trial

In November 2017, Cynata completed a key milestone with the enrolment and dosing of the eighth patient in its world first clinical trial of its CYP-001 product for the treatment of graft-versus-host-disease (GvHD). The enrolment of the eighth patient represents the mid-way point in the trial and the independent Data Safety Monitoring Board (DSMB) review was triggered 28 days after the first CYP-001 infusion of the eighth patient.

Patent Portfolio Strengthened

The Company received a Notice of Allowance from the US Patent and Trademark Office (USPTO) for a further patent tied to its proprietary Cymerus mesenchymal stem cell technology. The patent, which is expected to be granted within the next few months, covers a key aspect of the platform and is in addition to existing patents granted by the USPTO and IP Australia.



Completion of Preclinical Asthma Study with Strong Efficacy Data Confirmed

In December 2017, the Company completed a further preclinical asthma study. The preclinical study was the second in asthma, with the first study confirming that Cymerus MSCs had significant beneficial effects on all three key components of asthma: airway hyper-responsiveness, inflammation and airway remodeling.

The second study focused on the effects of Cymerus MSCs in combination with or in comparison to the corticosteroid, dexamethasone, which is commonly used to treat exacerbations of asthma in human patients.

The study confirmed that treatment with Cymerus MSCs in a clinically-relevant model caused significantly greater reduction of airway hyperresponsiveness, airway remodeling and fibrosis compared to corticosteroid treatment and that when used in combination with corticosteroids there was a pronounced effect producing substantial anti-inflammatory effects in addition to the benefits seen with Cymerus treatment alone.

Asthma impacts over 300 million people globally and can be a life threatening and debilitating disease for many. This strong efficacy data and body of evidence advances the path towards clinical trials in asthma and could potentially bring a life changing treatment to millions of asthma patients. Furthermore, the evidence indicates that Cymerus MSCs could be used as a standalone treatment for asthma for those patients unable to tolerate corticosteroids.

Pulmonary Disease—Study Continues

The Company continues its investigation into the use of its Cymerus MSCs as a treatment for **acute respiratory distress syndrome (ARDS)** with the *Critical Care Research Group* in association with the *Prince Charles Hospital*. A successful study could likely result in progression to a clinical trial in this very challenging condition, which results in approximately 10% of all ICU admissions.

Outlook

The Company achieved a number of very important milestones in the 2017 calendar year and the outlook for the coming quarters is positive. The completion of the first patient cohort in the Phase I GvHD clinical trial, representing the half-way point in the overall trial, was a key achievement.

Pre-clinical results are expected from studies in heart attack and ARDS and the results from the second preclinical trial in asthma provides the Company with a solid base from which to seek and secure additional partnerships and licencing agreements and advances the path towards further clinical trials.



There are multiple commercialisation paths available to Cynata and the existing licence option agreements with FUJIFILM and apceth are evidence of its ability to secure these agreements. The agreement with FUJIFILM is potentially worth an upfront licencing fee of USD\$3 million with over A\$60 million in milestone payments, plus royalties on eventual product sales.

Cynata received a A\$1.3 million Tax Incentive Refund for the 2016/2017 financial year. The refund has further bolstered the Company's funding position. As at 31 December 2017, the Company had \$8.8 million cash and is well funded to complete the clinical trial in GvHD and has an operating runway into 2019, based on current projections.

Subsequent Events

Subsequent to the completion of the reporting period the Company announced that the DSMB had recommended that the clinical trial of CYP-001 should progress to the next stage as planned and further announced that the first patient in the second patient cohort (Cohort B) had been treated. The Company also announced encouraging early safety and efficacy data. Finally, Cynata also announced the execution of a memorandum of understanding with Celularity Inc., for the commercial evaluation of Cynata's Cymerus production technology for use with Celularity's therapeutic stem cell technologies.

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 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™ utilises induced pluripotent stem cells (iPSCs) to produce a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ platform provides a source of MSCs that is independent of donor limitations and provides an "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical product 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")

31 December 2017

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	(852)	(1,929)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(64)	(270)
(d) leased assets	-	-
(e) staff costs	(109)	(255)
(f) administration and corporate costs	(195)	(641)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	36	85
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives		
- Export Market Development Grant	-	46
- 2017 R&D Tax Incentive	1,329	1,329
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	145	(1,635)

2. Cash flows from investing activities		
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	-	-
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	-	-
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)	-	-
3.10 Net cash from / (used in) financing activities	-	-

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	8,696	10,350
4.2 Net cash from / (used in) operating activities (item 1.9 above)	145	(1,635)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	(2)	124
4.6	Cash and cash equivalents at end of quarter	8,839	8,839

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	3,339	3,196
5.2	Call deposits	5,500	5,500
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)	8,839	8,696

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**

239

-

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

- 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	1,375
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	149
9.4 Leased assets	-
9.5 Staff costs	96
9.6 Administration and corporate costs	133
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	1,753

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:

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Managing Director/CEO

Date: 30 January 2017

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.