



ASX ANNOUNCEMENT

26 April 2019

March 2019 Quarterly Report

Melbourne, Australia; 26 April 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 March 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 a major area of focus**
 - Fujifilm maintains the right to exercise its licence option in GvHD following an extension of the agreement
 - Ongoing engagement with multiple potential partners for multiple therapeutic targets
- **Preparation underway for three Phase 2 clinical trial programs in 2019 for the treatment of graft-versus-host-disease (GvHD), critical limb ischemia (CLI) and osteoarthritis**
 - Ongoing planning discussions with Fujifilm for a Phase II trial in GvHD, pending exercise of a licence option agreement
 - Favourable advice received from UK Regulatory Agency (MHRA) for planned Phase 2 trial of CYP-002 in patients with critical limb ischemia (CLI)
 - Start-up activities commenced for the 448 patient Phase II clinical trial in osteoarthritis – a trial that is substantially funded by NHMRC and will be one of the largest MSC trials ever run
- **Ongoing pre-clinical research efforts to further enhance the potential value of the Cymerus technology**
 - Positive preclinical results support the use of Cynata’s Cymerus™ platform to develop stem cell therapies for coronary artery disease (CAD)
 - Joint Cynata-University of Melbourne study receives funding to investigate the manufacture and delivery of highly potent MSCs
- **Received Notice of Acceptance from IP Australia for a patent covering proprietary Cymerus technology – an important development in the goal to strengthen the robust intellectual property assets around Cymerus**

Dr. Paul Wotton, Cynata’s Chairman:

“Cynata has continued to make great progress. The management team has done an excellent job building pre-clinical and clinical validation with our platform across various therapeutic target areas, and preparation is now underway for three Phase 2 clinical trials. Our commercialisation efforts are gaining traction and we are in conversations with multiple potential partners.”

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ABN - 98 104 037 372



Operational update

Fujifilm update

Towards the end of the March quarter the Company announced an extension of the Fujifilm Licence Option in GvHD to 5:00pm Melbourne time on 19 September 2019. This licence option was due to expire 90 days after Cynata submitted the clinical study report to Fujifilm, as announced on 18 December 2018. However, an extension has been granted to enable the parties to seek to accommodate certain requests made by Fujifilm in relation to structural aspects of the GvHD license agreement. Should Fujifilm exercise the licence option on or before 19 September 2019, the parties will execute the GvHD Licence Agreement, the material terms of which were set out in Cynata's ASX announcement of 19 January 2017. Cynata has confirmed that it is not negotiating any changes to those material terms and no changes have been agreed.

It remains our view that the actions of Fujifilm indicate an intention to exercise the licence option for GvHD. Moreover, Mr. Junji Okada, Fujifilm's Director Corporate Vice President, has said recently that Fujifilm continues to "...look forward to working with Cynata to finalise the license agreement". Cynata continues to plan for a Phase 2 program in GvHD with Fujifilm.

Phase 2 Clinical Trial of CYP-002 in CLI update

Cynata was pleased to announce that it had received favourable advice from the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, regarding its planned Phase 2 clinical trial of CYP-002 in patients with CLI. Cynata now anticipates conducting the clinical trial at a number of centres in the UK and Australia. Planning continues to advance towards an expected commencement during the second half of calendar 2019.

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 results continue 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 preclinical programs into clinical trials.

- ***Positive Preclinical results support MSCs in treatment of coronary artery disease (CAD)***

Cynata was pleased to announce during the quarter initial results from its collaboration with the University of New South Wales (UNSW) with positive preclinical data for the development of MSC therapies based on its Cymerus technology platform for the treatment of CAD. The findings mean that Cymerus MSCs could potentially be used therapeutically to encourage new blood vessel growth in the heart of patients in whom the existing blood supply has been compromised as a result of CAD.

Following the initial positive outcomes from this preclinical collaboration, Cynata looks forward to working with UNSW to determine next steps for the development of these customised MSCs for the treatment of CAD.

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- ***Joint Cynata-University of Melbourne Study receives Funding***

The Company was pleased to announce the successful outcome of a grant application submitted by the University of Melbourne for a study investigating advanced materials for the delivery of highly potent mesenchymal stem cells (MSCs). The study is focusing on industrially scalable biomaterials that facilitate the expansion and delivery of MSCs and will use Cynata's proprietary Cymerus MSCs as the source cell therapeutic product. The cash award to Melbourne University is being provided by the Victorian Medical Research Accelerator Fund and Cynata will provide Cymerus MSCs for the study.

Strengthened IP through new Patent Acceptance

During the quarter Cynata announced further measures to strengthen and protect its technology with the Notice of Acceptance received from IP Australia for a patent covering its proprietary Cymerus mesenchymal stem cell (MSC) technology. The Notice of Acceptance is sent when IP Australia intends to issue a patent. Cynata anticipates that the patent will be granted by late April 2019, with an expiration date of 12 March 2034.

This announcement comes on the back of the Notice of Allowance from the European Patent Office last quarter. Cynata continues to build a robust intellectual property portfolio around the Cymerus therapeutic stem cell platform technology in both Australia and overseas jurisdictions as the Company advances multiple Phase 2 clinical programs in multiple therapeutic areas.

Outlook

The progress achieved in calendar 2018 has set an important platform for the Company in calendar 2019 with three Phase 2 clinical trials expected to commence. Through our preclinical work we will continue to evaluate other high-potential target areas and indications, significantly expanding the commercial opportunities which Cynata is actively pursuing.

The clinically and commercially significant outcomes generated by our Phase 1 trial in GvHD provides clear validation of Cynata's MSCs and more broadly for the Cymerus platform. We believe this supports the continued clinical and eventual commercial development of Cynata's MSCs in this challenging disease. The endpoints achieved in our Phase 1 trial in GvHD trial were the same as those that would be required in a Phase 3 (market authorisation) trial, so this, together with fast track approval provisions in Japan, provide a clear and relatively short path to market.

The favourable safety profile observed in that trial will allow Cynata to progress directly to Phase 2 in other indications. We continue to demonstrate the broad applicability of our Cymerus platform to treat a wide variety of diseases.

As mentioned, there are currently three Phase 2 clinical trials expected to commence for Cynata in 2019, all of which represent significant milestone opportunities for the Company as we move closer to commercialising our Cymerus MSC technology. However, we will also continue to advance our preclinical studies using Cymerus MSCs to identify new indications to add to our target portfolio and to expand the demonstration of utility of our platform.

We continue to file new patent applications to strengthen the intellectual property portfolio on core aspects of the Cymerus technology both in Australia and in major overseas commercial jurisdictions.



The Company closed the December quarter with \$9.275 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; this is through the NHMRC grant for the osteoarthritis trial and with funding from Fujifilm (assuming exercise of the license option) for GvHD.

The Board and Management of Cynata look forward to further demonstrating the broad applicability and commercial relevance of our Cymerus platform and its MSC based therapeutic products in 2019. The Company will continue to progress commercial interactions with potential strategic partners in multiple indications and geographies.

-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 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.

+Rule 4.7B

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 March 2019

Consolidated statement of cash flows	Current quarter	Year to date (9 months)
	\$A'000	\$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,698)	(4,262)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(284)	(471)
(d) leased assets	-	-
(e) staff costs	(175)	(522)
(f) administration and corporate costs	(116)	(639)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	50	151
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)	-	-
1.9 Net cash from / (used in) operating activities	(2,223)	(4,434)

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 (9 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	938	1,355
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)	(57)	(74)
3.10 Net cash from / (used in) financing activities	881	1,481
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	10,640	12,206
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,223)	(4,434)
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)	881	1,481

Consolidated statement of cash flows	Current quarter	Year to date (9 months)
	\$A'000	\$A'000
4.5 Effect of movement in exchange rates on cash held	(23)	22
4.6 Cash and cash equivalents at end of quarter	9,275	9,275

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter	Previous quarter
	\$A'000	\$A'000
5.1 Bank balances	3,275	3,640
5.2 Call deposits	6,000	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)	9,275	10,640

6. Payments to directors of the entity and their associates	Current quarter
	\$A'000
6.1 Aggregate amount of payments to these parties included in item 1.2	171
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	

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

7. Payments to related entities of the entity and their associates	Current quarter
	\$A'000
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	

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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	1,338
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	163
9.4	Leased assets	-
9.5	Staff costs	174
9.6	Administration and corporate costs	457
9.7	Other (provide details if material)	-
9.8	Total estimated cash outflows	2,132

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: 26 April 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.