

## Peter Webse

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## ACTIVITY REPORT & APPENDIX 4C

**Melbourne, Australia; 29 April 2016:** Regenerative medicine company Cynata Therapeutics Limited's Quarterly Cash Flow Report for the quarter ended 31 March 2016 is attached.

### Operational Highlights:

- Favourable advice from the UK Medicines and Healthcare product Regulatory Agency (MHRA)
- Compelling results from pre-clinical study in Graft-versus-Host Disease (GvHD)
- Preliminary agreement for a strategic alliance with Regience for Japan and certain other Asian countries
- Receipt of \$930k through the R&D Tax Incentive programme

In the field of stem cells and regenerative medicine, mesenchymal stem cells (MSCs) have emerged as one of the most promising candidates for mainstream medical use in a wide variety of economically important diseases and as such have very exciting commercial potential. Cynata's business focus is the development and commercialisation of a novel, proprietary technology that addresses a critical shortcoming in existing methods of production of MSCs for therapeutic use, which is the ability to achieve economic manufacture at commercial scale. With its Cymerus™ process Cynata is the only company in the world with technology for the manufacture of therapeutic allogeneic MSCs without reliance upon multiple stem cell donors.

The completion of a very active quarter saw Cynata reach several very important milestones in its product development and commercial activities. In particular, the very convincing data from the GvHD proof-of-concept study, together with the favourable advice from the MHRA, are clear demonstrations that Cynata is on the right track with its proprietary Cymerus™ MSC technology.

The advice from the MHRA has provided a clear path to commence a Phase 1 clinical trial in patients with graft versus host disease at study centres in the UK and potentially also in Australia. It has also allowed the Company to begin scheduling the many activities toward commencing the trial, presently targeted for late in the second quarter. Of particular note, this proposed study will be the first time ever that an allogeneic iPSC-derived mesenchymal stem cell product will be used in humans, a very exciting outcome for Cynata. The MHRA advice confirms that a globally recognised regulatory body is comfortable with the proposal to use an allogeneic, iPSC-derived cell product in a human trial, dispelling suggestions that this might be a "bridge too far" for regulators.

The data from the proof-of-concept study in GvHD provided a very important demonstration of the activity of Cynata's Cymerus MSC product, CYP-001. Interim data from the study demonstrated that CYP-001 treatment substantially prolonged survival in the mouse model of GvHD, with at least a doubling of median survival time of CYP-001 treated mice compared with the control animals. The study, being undertaken at the University of Massachusetts Amherst (UMass) in the USA, adds further weight to the substantial body of evidence from *in vitro* laboratory testing of CYP-001. Cynata has previously reported and published favourable results of its Cymerus MSCs in another proof-of-concept study, in this case in an animal model of critical limb ischemia (CLI). CLI is a disease characterised by obstruction of the arteries particularly in the arms and legs and produces severe pain, skin ulcers, or gangrene in patients with this condition. Cynata's Cymerus MSCs have shown to have a significant and protective effect against the effects of CLI in the proof-of-concept model of this disease.

The Company's commercial activities progressed with the execution of a preliminary agreement as the first step in a potential future strategic alliance with Regience K.K., a Japanese regenerative medicine company. The agreement provides a 60-day entitlement for Regience to make an initial investment of A\$250,000 in new ordinary shares issued by Cynata, based on a 10-day Volume Weighted Average Price (VWAP) plus 25%. Any shares issued under this agreement will be subject to a 12-month escrow period from the date of issue. Under the proposed strategic alliance, the parties will co-operate to develop and commercialise Cynata's Cymerus™

technology in Japan and certain other Asian countries. Negotiations toward a potential option and license agreement with apceth GmbH & Co. KG continue and whilst it is regrettable that it has been a lengthy process, substantial progress has been made.

The Company's balance sheet was strengthened by the receipt of an R&D Tax Incentive refund of \$932,580.65 for the 2014/2015 financial year. This non-dilutive revenue provides a useful extension to our operating runway.

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### **About Cynata Therapeutics (ASX: CYP)**

Cynata Therapeutics Limited (ASX: CYP) is an Australian 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™ does so through the production of a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ MCA platform provides a source of MSCs that is independent of donor limitations and provides a potential “off-the-shelf” stem cell platform for therapeutic product use, with a pharmaceutical 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 admitted on the basis of commitments

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10

Name of entity

**Cynata Therapeutics Limited**

ABN

**98 104 037 372**

Quarter ended ("current quarter")

**31 March 2016**

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (9 months) \$A'000
1.1 Receipts from customers	-	-
1.2 Payments for:		
(a) staff costs	(109)	(369)
(b) advertising and marketing	(66)	(286)
(c) research and development	(896)	(3,048)
(d) leased assets	-	-
(e) other working capital	(211)	(617)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	42	103
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Other		
- TRIP rebate received	-	2
- R&D rebate received	933	933
<b>Net operating cash flows</b>	<b>(307)</b>	<b>(3,282)</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	Current quarter \$A'000	Year to date (9 months) \$A'000
1.8 Net operating cash flows (carried forward)	(307)	(3,282)
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	-	-
(e) other non-current assets	-	-
1.10 Proceeds from disposal of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	-	-
(e) other non-current assets	-	-
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities	-	-
1.13 Other (provide details if material)	-	-
<b>Net investing cash flows</b>	-	-
<b>1.14 Total operating and investing cash flows</b>	<b>(307)</b>	<b>(3,282)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	-	5,000
1.16 Proceeds from sale of forfeited shares	-	-
1.17 Proceeds from borrowings	-	-
1.18 Repayment of borrowings	-	-
1.19 Dividends paid	-	-
1.20 Other (share issue costs)	-	(465)
<b>Net financing cash flows</b>	-	4,535
<b>Net increase (decrease) in cash held</b>	<b>(307)</b>	<b>1,253</b>
1.21 Cash at beginning of quarter/year to date	6,367	4,671
1.22 Exchange rate adjustments to item 1.21	(29)	107
<b>1.23 Cash at end of quarter</b>	<b>6,031</b>	<b>6,031</b>

+ See chapter 19 for defined terms.

**Payments to directors of the entity and associates of the directors**

**Payments to related entities of the entity and associates of the related entities**

		Current quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	232
1.25	Aggregate amount of loans to the parties included in item 1.11	-

1.26 Explanation necessary for an understanding of the transactions

Directors' fees, salaries including superannuation benefits and professional consultancy fees. All payments are on normal commercial terms.
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**Non-cash financing and investing activities**

2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

N/A
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2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

N/A
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**Financing facilities available**

*Add notes as necessary for an understanding of the position.*

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities	N/A	N/A
3.2	Credit standby arrangements	N/A	N/A

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

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**Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	Current quarter \$A'000	Previous quarter \$A'000
4.1 Cash on hand and at bank	678	35
4.2 Deposits at call	5,353	6,332
4.3 Bank overdraft	-	-
4.4 Other (provide details)	-	-
<b>Total: cash at end of quarter</b> (item 1.23)	<b>6,031</b>	<b>6,367</b>

**Acquisitions and disposals of business entities**

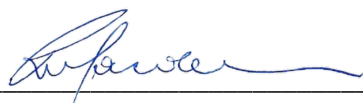
	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity	N/A	N/A
5.2 Place of incorporation or registration	N/A	N/A
5.3 Consideration for acquisition or disposal	N/A	N/A
5.4 Total net assets	N/A	N/A
5.5 Nature of business	N/A	N/A

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+ See chapter 19 for defined terms.

**Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Sign here:  Date: 29 April 2016

Print name: Dr Ross Macdonald  
*(Managing Director)*

**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 wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report except for any additional disclosure requirements requested by AASB 107 that are not already itemised in this report.
3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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