

#### **ASX Announcement**

### **December 2021 Quarterly Activity Report and Appendix 4C**

- Breakthrough preclinical cardio-protection discovery that Zantrene® protects heart muscle cells from anthracycline-induced cell death while improving the killing of cancer cells
- Related discovery that Zantrene® protects the heart from carfilzomib-induced cell death, while synergising to better kill cancer cells
- Race raised \$29.7 million in an oversubscribed SPP to fund an expanded Three Pillar strategy, with new clinical programs announced for FTO-directed solid tumours, cardio-protection trial in breast cancer, an expansion of the EMD AML into Europe, and enhanced Zantrene® formulations
- Post quarter, new independent study identifies activity of Zantrene<sup>®</sup> in FTO.

#### Race expands Three Pillar Strategy to capitalise on RNA therapeutics opportunity

**28 January 2022** - The December 2021 quarter (Q2 FY 2022) was highlighted by new pre-clinical findings that Zantrene® reduces anthracycline and carfilzomib-induced heart damage, while also improving the cancer cell killing effects of both drugs (ASX announcements: 22 November 2021 & 8 December 2021).

A second highlight was the strong support of our shareholders in funding the new and expanded Three Pillar strategy shared at Race's Annual General Meeting (ASX announcement: 23 November 2021). This support enables the Company to progress the following clinical programs: Phase 1b/2 FTO solid tumour clinical trial (\$8.0 million); cardio-protection Phase 2b clinical trial in breast cancer patients (\$7.5m); Phase 2 Extramedullary Acute Myeloid Leukaemia (AML) / Myelodysplastic syndrome (MDS) clinical trial in Europe (\$9.2 million); enhanced formulations of Zantrene® (\$3.2 million); preclinical cardio-protection studies (\$1.0 million) and the development of new molecules (\$0.8 million). Shareholder subscriptions of \$44 million were received with \$29.7 million accepted (ASX announcement: 21 December 2021) in line with the full case funding proposal.

More broadly the team made continued progress in its Australian EMD AML program announcing the ethics documentation submission (ASX announcement: 1 November 2021), the securing of two additional USA patents (ASX announcements: 6 October 2021 & 19 October 2021) and adding new R&D development capability via a collaboration with the University of Wollongong (ASX announcement: 9 November 2021) to further support formulation and new drug developments.

In sum, the quarter saw considerable progress and the Race team is now appropriately funded to progress and accelerate the expanded clinical and preclinical program.



#### Key events of the quarter

- On 6 & 19 October 2021, Race announced that it had been granted its fifth and sixth USA patents, providing additional protection around the use, formulation, and compositions of Zantrene for improving the efficacy of related treatments.
- On 27 October 2021, Race announced a FTO biomarker research collaboration with Chaim Sheba Hospital, Israel. This research program will see analysis of clinical patient samples by Dr Dom Dominissini, to assess FTO biomarker and m6A RNA methylation status in patients treated with Zantrene<sup>®</sup>.
- On 1 November 2021, Race announced submission of its human ethics application to commence a Phase 1b/2 extramedullary AML & MDS trial. This clinical program underpins future registration trials in the EU and US for Zantrene<sup>®</sup>. The study is led by Associate Professor Anoop Enjeti (Calvary Mater Hospital Newcastle) with the support of the Contract Research Organisation, Parexel.
- On 3 November 2021, Race initiated a collaboration study to develop a genomics-based companion diagnostic for Zantrene® to support its use as a precision oncology drug. This study will be led by the experienced genomics researcher Professor Murray Cairns at the University of Newcastle. The study will utilise the latest RNA genomics tools to identify genetic biomarkers associated with a cancer's sensitivity to Zantrene® at the patient specific level.
- On 9 November 2021, Race announced initiation of a strategic collaboration with The University of Wollongong, focused on the optimisation of new formulations to support long-acting peripheral intravenous delivery (IV) delivery of Zantrene<sup>®</sup>. This collaboration will also pursue the development of an oral formulation of Zantrene<sup>®</sup>. The collaboration will be led by experienced oncology formulator, Professor Marie Ranson in collaboration with Race's Principal Scientist, Professor Michael Kelso, and is supported with the appointment of Race's Senior Scientist, Dr Ben Buckley.
- On 22 November 2021, Race announced a preclinical breakthrough heart protection discovery for Zantrene®. While anthracyclines are effective anti-cancer drugs they carry a serious risk of causing permanent heart damage. Zantrene® was shown to protect heart muscle from anthracycline-induced cell death when used in combination. Furthermore, a Zantrene®/doxorubicin combination was also found to better kill cancer cells. This effect was independent of Zantrene® FTO inhibiting activity, and provides Race with an entirely novel commercial opportunity.
- On 23 November 2021, Race announced an update to its "Three Pillar" Strategy at the Company's AGM, along with a Share Purchase Plan (SPP) designed to fund plans enabling execution of the new strategy and capitalising on Zantrene's expanded commercial potential, by pursuing the following activities:



**Pillar 1 – Current Zantrene**, by expanding the EMD AML & FTO clinical programs, initiating a US IND, and progressing the cardio-protective opportunity.

**Pillar 2 – Optimises Zantrene**, with formulation development to improve utility via an improved IV formulation, oral formulation, and associated IP.

**Pillar 3 – Beyond Zantrene**, utilises team capabilities to pursue new RNA targeting molecules, via internal development, partnership, or acquisition.

The SPP was announced with three levels of potential funding to support an expanded FTO-targeted clinical program in solid tumours, improved formulations, a cardio-protection clinical program, new drug development, and expansion of the Phase 1b/2 EMD AML program into Europe.

The SPP was launched at \$3.00 per share to shareholders of record on 22 November 2021, closing 17 December 2021, with the maximum raise capped at \$29.7 million.

- On 8 December, Race announced an additional heart protection preclinical discovery. Zantrene was found to protect heart muscle cells from damage caused by the Multiple Myeloma drug, carfilzomib (Kyprolis®) while synergising to improve anticancer effects. This cardio-protective observation broadens the formulation and potential commercial opportunities for Zantrene® via the potential development of new Zantrene®/carfilzomib formulations.
- On 10 December 2021, Race announced an extension to its heart protection collaboration with the University of Newcastle. This program plans to assess Zantrene's cardio-protective potential with additional anti-cancer drugs, where heart damage is a known treatment risk.
- On 21 December 2021, Race announced raising the full \$29.7 million target in a heavily oversubscribed SPP. This allows progression of the FTO solid tumour Phase 1b/2 clinical trial, cardio protective pre-clinical and clinical Phase 2b trial, expansion of the EMD AML Phase 2 trial into Europe, improved Zantrene® formulations, and new molecule development.

#### Summary of cash flow and quarterly activity

As of 30 December 2021, Race held cash and equivalents of \$37.10 million, compared with \$8.94 million on 30 September 2021. The expansion in cash reserves reflects receipts from the SPP, exercise of options and an acceleration in research spending concurrent with expanded programs (\$1.79m vs \$0.93m in the prior quarter).

#### Listing rule 4.7C.3

Payments during the quarter to Related Parties amounted to \$313k, comprising payments of salaries, bonuses, and superannuation to executive directors of \$270k and board fees to non-executive directors of \$43k.



#### Shareholders by holding range

Race is pleased to share that shareholder numbers had increased to 9,420 on December 31, 2021, up from 9,198 on September 30, 2021, confirming continued new shareholder interest in Race's progress.

Holding Ranges	Holders	Total Units	% Issued Share Capital
Above 0 up to and including 1,000	4,062	1,786,623	1.12%
Above 1,000 up to and including 5,000	2,784	6,814,115	4.27%
Above 5,000 up to and including 10,000	879	6,560,721	4.11%
Above 10,000 up to and including 100,000	1,461	43,879,588	27.52%
Above 100,000	234	100,403,735	62.97%
	9,420	159,444,782	100.00%

#### Post quarter news

- On 18 January 2022, Race announced receiving its FY2021 R&D Tax refund of \$708k, reflecting additional investment by Race in Australian R&D activities. This support is an important source of non-dilutive capital and encouragement to maximise the use of Australia as a hub for research.
- Post quarter, a new independent scientific publication was released in the journal *Cells*<sup>1</sup>, further confirming that Zantrene (bisantrene dihydrochloride) is a highly effective inhibitor of the Fat Mass and Obesity associated protein (FTO). The investigators at the University of Lille assessed the utility of Zantrene in Type 2 diabetes (T2D), a disease that is characterized by chronic high blood sugar and impaired pancreatic insulin secretion.

The University of Lille team demonstrated that FTO plays a critical role in driving T2D and that inhibition of FTO by Zantrene at low concentration (100 nM); i.e. well below the level observed to cause toxicity in previous studies, increases the production of insulin by more than 20-fold from human and mouse diabetic pancreatic tissues.

This third independent confirmation that Zantrene is able to target FTO<sup>2,3</sup>, this time in the pancreas, and reverse the impaired insulin secretion seen in Type 2 diabetes, is of major significance. While further study is needed, it does emphasise the importance of FTO and m<sup>6</sup>A dysregulation in human metabolic diseases beyond cancer.



#### **Expected news**

In the current quarter, shareholders can expect updates on the following activities:

- **Pre-clinical** *in vitro* updates on the progress of FTO-directed preclinical programs underway in melanoma, clear cell renal cell carcinoma and extramedullary AML.
- **Pre-clinical** *in vivo* mouse model studies are underway exploring the use of Zantrene<sup>®</sup> in combination with anti-PD-1 in melanoma and in combination with decitabine for EMD AML, with results to be announced.
- **Clinical** Human ethics approval for EMD AML Phase 1b/2 trial. Subject to patient recruitment, an update on the AML R/R Israel trial progress, once the dose escalation phase (6-12 patients) is complete.

#### **Management commentary**

Race CEO Phillip Lynch said: "The most recent quarter has been significant. We now have an entirely novel and large opportunity in cardio-protection, an evolved and strategic "Three Pillar" program and importantly the required capital and human resources to deliver against these opportunities. Thanks go to our shareholders, for their support and belief in our plans as reflected through their SPP participation"

Race CSO Daniel Tillett said: "I would like to thank all the shareholders who participated in the SPP for their continued support of Race. We have been given an amazing opportunity with Zantrene®, but it is one that can only be taken into the clinic with the support of our shareholders. We are looking forward to updating our investors on the rapid progress we are making over 2022 and beyond.

We are further encouraged by the newly released independent study showing Zantrene's potential to inhibit FTO in Type 2 Diabetes. While this is not our primary area of focus, it is important in that it builds upon the original identification of Zantrene as a potent FTO inhibitor by Professor Chen and his team at the City of Hope Hospital (2020), which was later confirmed by Professor He's team at the University of Chicago (2021)."

Race Chairman John Cullity said: "The exceptional work of our team and collaborators continues to unlock Zantrene's potential. I'm particularly impressed by candidate clinical applications in the cardio-protection setting, which might recalibrate anthracycline therapeutics. On behalf of the Board, my particular thanks to our shareholders for supporting the recent SPP, and to Phil and Daniel for driving that process."

1. Bornaque, F. et al. (2022) Glucose Regulates m6A Methylation of RNA in Pancreatic Islets. Cells 11, 291.



- 2. Cui, YH., Yang, S., Wei, J. *et al.* (2021) Autophagy of the m<sup>6</sup>A mRNA demethylase FTO is impaired by low-level arsenic exposure to promote tumorigenesis. *Nat Communications* **12**, 2183
- 3. Su, R., Dong, L., Li, Y., Gao, M., Han, L., Wunderlich, M., et al. (2020) Targeting FTO Suppresses Cancer Stem Cell Maintenance and Immune Evasion. *Cancer Cell*, *38*(1), 79–96.e11.

-ENDS-

#### **About Race Oncology (ASX: RAC)**

Race Oncology is an ASX listed precision oncology company with a Phase 2/3 cancer drug called Zantrene<sup>®</sup>.

Zantrene is a potent inhibitor of the Fatso/Fat mass and obesity associated (FTO) protein. Overexpression of FTO has been shown to be the genetic driver of a diverse range of cancers. Race is exploring the use of Zantrene as a new therapy for melanoma and clear cell renal cell carcinoma, which are both frequent FTO over-expressing cancers.

In breakthrough preclinical research, Race has also discovered that Zantrene protects from anthracycline-induced heart damage, while in tandem acting with anthracyclines and proteasome inhibitors to improve their ability to target breast cancer. Race is evaluating this discovery.

The Company also has compelling clinical data for Zantrene as a chemotherapeutic agent and is in clinical trial in Acute Myeloid Leukaemia (AML).

Race is pursuing outsized commercial returns for shareholders via its 'Three Pillar' strategy for the clinical development of Zantrene. Learn more at www.raceoncology.com

#### Release authorised by:

Phil Lynch, CEO/MD on behalf of the Race Board of Directors phillip.lynch@raceoncology.com

#### **Media contact:**

Jane Lowe +61 411 117 774

jane.lowe@irdepartment.com.au

## RACE ONCOLOGY LIMITED (RAC)

# Appendix 4C

# Quarterly cash flow report for entities subject to Listing Rule 4.7B

#### Name of entity

RACE ONCOLOGY LIMITED (RAC)	
ABN	Quarter ended ("current quarter")
61 149 318 749	31 December 2021

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(890)	(1,441)
	(b) product manufacturing and operating costs	(121)	(271)
	(c) advertising and marketing	(111)	(135)
	(d) leased assets	-	-
	(e) staff costs	(173)	(263)
	(f) administration and corporate costs	(501)	(624)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	4	8
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(1,792)	(2,726)

2.	Cash flows from investing activities	
2.1	Payments to acquire or for:	
	(a) entities	-
	(b) businesses	-
	(c) property, plant and equipment	-
	(d) investments	-

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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 equity securities (excluding convertible debt securities)	29,700	29,700
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	709	1,259
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(439)	(439)
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 (shares yet to be issued)	-	-
3.10	Net cash from / (used in) financing activities	29,970	30,520

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,936	9,322
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,792)	(2,726)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
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)	29,970	30,520
4.5	Effect of movement in exchange rates on cash held	(12)	(14)
4.6	Cash and cash equivalents at end of period	37,102	37,102

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 \$A'000	Previous quarter \$A'000
5.1	Bank balances	2,602	3,436
5.2	Call deposits	34,500	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)	37,102	8,936

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	313
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

#### Payment to related parties as disclosed in item 6.1 as follows:

- \$43,200 payments for non-executive director fees for the period;
- \$270,000 payments to executive directors for the period, including annual bonus and superannuation paid during the quarter.

7.	Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at qu	arter end	-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
	N/A		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,792)
8.2	Cash and cash equivalents at quarter end (item 4.6)	37,102
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	37,102
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	20.70
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8. figure for the estimated quarters of funding available must be included in item 8.5.	5 as "N/A". Otherwise, a

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:	
N/A	

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:	
N/A	

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:
N/A
Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

#### **Compliance statement**

- 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.

Date: 28 January 2022

Authorised by: The Board of Race Oncology Limited

(Name of body or officer authorising release – see note 4)

#### **Notes**

- 1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- If this quarterly cash flow 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 cash flow 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.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- 5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.