



26 October 2018

ASX Announcement / Media Release

## September 2018 Quarterly Report

---

**26 October 2018: Race Oncology Limited ("RAC")** is pleased to provide this quarterly activities report together with the Appendix 4C for the quarter ended 30 September 2018.

### **Rare Paediatric Disease designation and PRV**

On 16 July 2018, Race announced that the FDA had granted Bisantrone a *Rare Paediatric Disease* (RPD) designation for treatment of childhood AML. This designation means Bisantrone has the opportunity to be awarded a *Priority Review Voucher* (PRV) at the time of marketing approval for childhood AML (acute myeloid leukaemia). The PRV provides rights to a fast-track FDA review which can be sold to other pharmaceutical companies.

The value of the PRV is additive to the value of the NPP and the current FDA approval program (aimed at adult AML). As such, it added a third important value domain for the Company.

### **Management Changes**

On 23 August 2018, Race announced its representation agreement with CarthaGenetics and the consulting agreement with Gordon Beck had both been terminated. It also advised that Dr John Rothman would step down as full-time Chief Scientific Officer for Race and continue on a part-time basis until the end of December 2018. The Company stated that the changes reflected a strategic refocusing of the Company's NPP and clinical activities around Dr Samar Al-Behaisi and prudent cost management.

### **NSF agreement**

On 17 September 2018, Race announced it had executed an agreement with NSF Health Sciences in Washington DC to facilitate its IND filing (Investigational New Drug application) in the US for Bisantrone. Under the agreement, NSF will incorporate pre-IND and Type C meeting comments from the FDA, assemble the non-clinical and clinical modules for the IND from previous clinical studies and published literature, and incorporate the proposed clinical trial protocol and investigator's brochure. NSF also will act as the US Agent for Race Oncology with the FDA, serving as Race's interface with the FDA regarding agency correspondence, IND amendments, protocol amendments, pharmacovigilance and other reporting. The Company's goal is to file the IND by the end of Q1 2019.



## **IACH Conference**

On 27-29 September 2018, Race attended and sponsored the first annual meeting of the International Academy for Clinical Haematology (IACH) in Paris. The IACH conference was attended by doctors from 45 countries. It was an important opportunity to increase Race's recognition and reputation with international haematological oncologists and to discuss clinical plans and NPP opportunities for Bisantrene.

## **Tom Lee consulting agreement**

Just after the end of the quarter, (1 October 2018), Race announced that it had executed an agreement with Mr Tom Lee to assist with partnering and funding opportunities in the US, with a focus on Houston, Texas.

Under the initial 12-month agreement, Mr Lee has been engaged to:

- Make introductions to opinion leaders and clinical trial groups at MD Anderson Cancer Center, including pursuing funding opportunities for Bisantrene clinical trials
- Make introductions to potential investors for Race
- Make introductions to potential licensing or M&A partners
- Explore Texas grant and other non-dilutive funding opportunities for Race.

## **Outlook**

The Company continues to pursue NPP usage in Europe and remains committed to achieving contemporary usage of Bisantrene by clinicians. During the quarter, Race shipped initial supplies of Bisantrene to its agent in the UK, Durbin, in anticipation of potential usage. Dr Samar Al-Behaisi is based in Switzerland and continues to build the necessary relationships with opinion-leaders towards the goal of NPP usage and sales.

Meanwhile, the Company in conjunction with NSF has commenced the process of assembling the IND for filing in the US and currently expects filing towards the end of Q1 2019.

## **Financial results**

In terms of financial performance, the net cash used in operations (\$838k) was lower than projected, mainly due to personnel and other cost savings as well as the deferral of some third party manufacturing costs. The Company expects to see most of these deferred costs in the next quarter. Cash reserves at the end of the quarter were \$2.845 million, which is projected to be enough cash to at least cover expenses for the remainder of the current financial year.

## **About Bisantrene**



Bisantrene is a chemotherapy drug that was tested in more than 40 clinical studies before it was lost in a series of pharmaceutical mergers in the 1990s. Race is rediscovering and rescuing Bisantrene and the initial clinical opportunity is for treatment of relapsed/refractory AML. Race owns two recent patents on the drug, both of which have been granted in the US. Bisantrene has also been granted an Orphan Drug Designation in the US for AML, which confers seven years of market exclusivity in US from date of FDA approval; and Rare Paediatric Disease designation in the US, which could lead to a valuable Priority Review Voucher.

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

Race Oncology is a specialty pharmaceutical company that listed on the Australian Securities Exchange (ASX) in July 2016. Race's business model is to pursue later-stage drug assets in the cancer field that have been overlooked by big pharma. The company's first asset is Bisantrene. Race has successfully manufactured Bisantrene and is seeking to complete the development necessary to gain FDA approval, while also making the drug available as an unlicensed medication under named patient programs outside the US.

#### Media contact:

Heidi Cuthbert

0411 272 366

E: [heidi.cuthbert@multiplier.com.au](mailto:heidi.cuthbert@multiplier.com.au)

## 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**

RACE ONCOLOGY LIMITED (RAC)

**ABN**

61 149 318 749

**Quarter ended ("current quarter")**

30 September 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(273)	(273)
(b) business development and NPP	(263)	(263)
(d) manufacturing and distribution	(31)	(31)
(d) staff and board remuneration	(92)	(92)
(e) administration and corporate costs	(179)	(179)
(f) other (provide details if material)	-	-
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	7	7
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)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(831)</b>	<b>(831)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$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 - shares	-	-
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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	(33)	(33)
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 issued)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(33)</b>	<b>(33)</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter/year to date	3,710	3,710
4.2	Net cash (used in) operating activities (item 1.9 above)	(831)	(831)
4.3	Net cash from investing activities (item 2.6 above)	-	-
4.4	Net cash (used in) financing activities (item 3.10 above)	(33)	(33)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
4.6	<b>Cash and cash equivalents at end of quarter</b>	<b>2,845</b>	<b>2,845</b>

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	2,845	3,710
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,845</b>	<b>3,710</b>

**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
143
-

Payment to related parties are for salary, non-executive director 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
-
-

-

8. <b>Financing facilities available</b> <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.		

9. <b>Estimated cash outflows for next quarter</b>	<b>\$A'000</b>
9.1 Research and development	278
9.2 Business development and NPP	242
9.3 Manufacturing and distribution	121
9.4 Staff and board remuneration	86
9.5 Administration and corporate costs	163
9.6 Other (provide details if material)	-
<b>9.7 Total estimated cash outflows</b>	<b>890</b>

10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	<b>Acquisitions</b>	<b>Disposals</b>
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	-	-

### Performance Shares

Number of Performance Shares at the beginning of the quarter: 10,000,000

Number of Performance Shares converted or cancelled during the quarter: Nil

Performance Shares milestones met during the quarter: Nil

The Performance Shares milestones were satisfied in the June 2018 quarter and are to be converted into fully paid ordinary shares (Shares) at the election of the holder, Update Pharma, Inc.

Any Performance Share not converted into a Share within 3 years from the Issue Date will be automatically redeemed by the Company for a sum of \$0.0000001 per Performance Share within 10 Business Days;

### 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:  .....  
(Company secretary)

Date: 26 October 2018 .....

Print name: Peter Webse

### 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.