



27 July 2018

ASX Announcement / Media Release

June 2018 Quarterly Report

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

During the June quarter, the Company continued its drive to achieve named patient sales for Bisantrene, while also moving Bisantrene towards FDA approval. Just after the end of the quarter, Race announced that the FDA had granted 'Rare Paediatric Disease' designation to Bisantrene, adding a new and important value stream to the Company.

Patents granted in US

Previously, Race had announced that it had received Notices of Allowance in the US for its two Bisantrene patent applications. During the current quarter, both patents were issued (granted) in the US.

"The US market is the largest AML treatment market in the world and the most important value driver for Bisantrene as a treatment for AML," said Race CEO, Peter Molloy. "Moving closer to US FDA approval remains the primary determinant of Race's mid-term value as a company."

The granted US patents augment the 'Orphan Drug Designation' in the US, which gives Bisantrene protection from competition in AML for seven years after FDA approval.

"The patents extend the protection in the US well beyond the Orphan Drug period and out to 2034," said Mt Molloy.

Both patent applications continue to be prosecuted in all key markets outside the US, including Europe.

Dr John Cullity

On 4 April 2018, Race announced the appointment of New York-based Dr John Cullity as a non-executive director to the Race board. In addition to being a Haematological oncologist with expertise in AML, Dr Cullity is a corporate transactions expert was a principal for Torrey Partners in New York, the internationally-recognised transactions firm, and established Torrey Insights, specialising in transactions advisory.



“As Race considers transaction options for Bisantrane or the Company in the future, John will be an extremely valuable resource for us,” said Mr Molloy.

CRO and CMO Appointed

On 15 May 2018, Race announced that it had signed an agreement with Novotech, an Australian-based CRO (contract clinical research organisation) to manage the Bisantrane clinical trial program globally.

On the same day, Race announced the appointment of Samar Al-Behaisi MD PhD, as Chief Medical Officer and Vice President of Medical Affairs for Race Oncology. Dr Al-Behaisi is based in Switzerland. Dr Al-Behaisi is responsible for the Named Patient Program (NPP) in Europe, while also having oversight and direction of the Company’s clinical trial program.

Since her appointment, Dr Al-Behaisi has been a driving force in building the Company’s presence with AML clinicians across Europe.

“With Samar on board, I am increasingly confident about our future ability to deliver on the NPP,” said Mr Molloy.

Durbin agreement

On 11 April 2018, race announced that it had executed an agreement with Durbin PLC, a UK company with global expertise in managed access programs, including revenue-based NPP.

As noted by Mr Molloy in the announcement: “The Durbin agreement significantly expands our NPP opportunity for Bisantrane.”

MHRA Approval

On 21 June 2018, Race announced that approval has been obtained from the MHRA (UK Medicines and Healthcare products Regulatory Agency) for importation and distribution of Bisantrane as an unlicensed medicine in the UK. This allows Durbin to import Bisantrane into the UK and supply it under a NPP.

“This is important, not only because it adds another NPP country for us, but because no additional regulatory approval is needed in order to supply the product in response to an order from a UK hospital,” said Mr Molloy. This compares to the more time-consuming procedures in France and Italy where the respective governments need to approve every application for named patient use. Race is now actively pursuing named patient use in the UK along with other countries.



Bisantrene's effectiveness in childhood AML

On 5 June 2018, Race announced a French case report describing the long-term use of Bisantrene to treat childhood AML. The report described two girls in France who were successfully treated with Bisantrene in 1984 and 1991. Both of them are alive today.

The report was also published as a poster (available on the Company's website) at the International Conference on Leukaemia and Haematologic Oncology in Paris on 21 June 2018. The authors were Prof. Guy Leverger, a leading French haematology-oncologist from Paris, and Prof. Yves Bertrand, also a leading AML physician from Lyon. Both were involved in the original Bisantrene AML studies during the 1980s and 1990s.

"These case reports are important, not only because they show that Bisantrene has activity in relapsed/refractory AML in children, when other treatments failed," said Mr Molloy, "but that these two eminent French physicians who have used Bisantrene believe that it still has a role to play in AML treatment today."

RPD designation and PRV

Immediately after the end of the quarter (16 July), Race announced that the FDA had granted Bisantrene a *Rare Paediatric Disease* (RPD) designation for treatment of childhood AML. This designation means Bisantrene has the opportunity to be awarded a *Priority Review Voucher* (PRV) at the time of marketing approval for childhood AML.

The value of the PRV is entirely additive to the value of the NPP and the current FDA approval program (aimed at adult AML). As such, it adds a third important value domain for the Company. Over the coming quarter, Race will announce its plans to move forward the clinical program to support the designation and move it closer to the PRV.

Outlook

The next several months are expected to show positive development on several fronts.

"Investors can expect to see progress in all three areas of value creation for the Company: Named patient sales, US registration and a paediatric development program," said Mr Molloy.

Financial results

In terms of financial performance, the net cash used in operations (\$889k) was slightly below the average for the previous three quarters and in line with budget for the year. Most costs were for third party R&D and manufacturing service providers, as well as business development activities related to the NPP.

Cash reserves at the end of the quarter were \$3.7 million.



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.

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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 June 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(290)	(1,877)
(b) business development and marketing	(383)	(1,364)
(d) leased assets	-	-
(e) staff and board remuneration	(89)	(385)
(f) administration and corporate costs	(135)	(449)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	8	21
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	170
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(889)	(3,884)

2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
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)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	15	5,674
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	143
3.4	Transaction costs related to issues of shares, convertible notes or options	(4)	(367)
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)	480	480
3.10	Net cash from / (used in) financing activities	491	5,930

4.	Net increase / (decrease) in cash and cash equivalents for the period	(398)	2,046
4.1	Cash and cash equivalents at beginning of quarter/year to date	4,116	1,697
4.2	Net cash (used in) operating activities (item 1.9 above)	(889)	(3,884)
4.3	Net cash from investing activities (item 2.6 above)	-	-
4.4	Net cash (used in) financing activities (item 3.10 above)	491	5,930

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	(9)	(34)
4.6	Cash and cash equivalents at end of quarter	3,709	3,709

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	3,709	4,116
5.2	Call deposits	-	-
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)	3,709	4,116

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
106
-

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
-
-

-

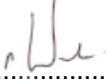
8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities	-	-
8.2 Credit standby arrangements	-	-
8.3 Other (please specify)	-	-
8.4 Include below a description 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.		
-		

9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	775
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	377
9.4 Leased assets	-
9.5 Staff and board remuneration	107
9.6 Administration and corporate costs	77
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	1,336

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: 
(Director/Company secretary)

Date: 27 July 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.