Research as a Service

Race Oncology Ltd

Pursuing a three-pillar strategy to treat cancer

Pharmaceuticals, Biotechnology & Life Sciences

11th March 2022

Race Oncology Ltd (ASX:RAC) is a precision oncology company which listed on the ASX in 2016 following its acquisition the same year of the cancer drug, Zantrene, a small molecule anti-cancer drug that RAC has progressed to multiple Phase II clinical trials treating Acute Myeloid Leukaemia (AML). RAC is exploring the use of Zantrene as a new therapy for melanoma and clear cell renal cell carcinoma (kidney cancer). RAC owns six granted US patents on Zantrene, has secured FDA Orphan Drug designation for AML which provides seven years of post-market approval exclusivity, as well as rare paediatric disease designation. RAC recently raised $29.7m at $3.00/share in Q2 FY22 via an oversubscribed share placement plan (SPP), giving it a cash balance of $37.1m at 31-Dec-2021. RAC has said the capital will fund its expanded three-pillar strategy to pursue new pre-clinical and clinical programmes including clinical programmes for the Fat Mass and Obesity associated protein (FTO)-directed solid tumours, a cardio-protection trial in breast cancer, an expansion of the extramedullary disease (EMD) AML clinical trial into Europe, and enhanced Zantrene formulations to support IV delivery and oral formulations. On 23-Feb-2022, RAC announced that the MD Anderson Cancer Center collaborators had published the results of a pre-clinical study on Zantrene and its efficacy in AML cells, further supporting RAC's Phase Ib/II EMD AML clinical trials starting in Australia and Europe in Q2 2022.

Business model

RAC is pursuing a three-pillar strategy to enhance partnering, licensing or sale opportunities to a scaled pharmaceutical company via advancing Zantrene in pre-clinical and clinical trials across a number of cancer targets, as well as new m^6A RNA regulating molecules. The first pillar, based on the current Zantrene formulation, aims to pursue clinical programmes in EMD AML (including as an FTO-targeted agent) and a cardio-protective opportunity. The second pillar is focussed on improved formulations that will allow an expanded use of Zantrene in solid tumours. The third pillar (beyond Zantrene) is pursuing new ribonucleic acid (RNA) targeting molecules via internal development, partnership or acquisition. RAC has near-term opportunities for FDA approval for Zantrene via the 505(b)(2) approval pathway for AML. The company is also eligible for a Paediatric Priority Review Voucher in Paediatric AML as well as orphan drug designation for AML.

Q2 FY22 activity and expected news-flow in current quarter

RAC completed an SPP to raise $29.7m at $3.00/share to support an expanded three-pillar strategy, with new clinical programmes announced for FTO-directed solid tumours, a cardio-protection trial in breast cancer, an expansion of the EMD AML into Europe, and enhanced Zantrene formulations (28-Jan-2022 ASX release). RAC has new pre-clinical findings that Zantrene prevents drug-induced heart damage from anthracycline and carfilzomib while also improving the cancer-cell-killing effects of the drugs in treating cancer. RAC expects to have updates on the progress on its pre-clinical, in-vitro FTO-directed programs under way in melanoma, clear cell renal cell carcinoma and extramedullary AML in Q1 CY22. RAC also expects to announce results regarding its pre-clinical in vivo mouse model studies exploring the use of Zantrene in melanoma and for EMD AML. RAC also expects to receive human ethics approval for its EMD AML Phase Ib/II clinical trial and subject to patient recruitment, an update on the AML R/R Israel trial progress.

RAC's three-pillar strategy and diverse pipeline Vs peers

Neuren Pharmaceuticals (ASX:NEU) has a similar market cap of ~$450m though not focussed on cancer, and has a Phase II and Phase III clinical trial for different syndromes utilising its lead drug compound, Trofinetide. Both NEU programmes have received fast-track designation by the FDA and orphan drug designation in the US and EU. NEU has licensed Trofinetide to a pharmaceutical company for commercialisation in North America and has retained all rights outside NA. NEU also has a clinical pipeline it is progressing. Prescient Therapeutics (ASX:PTX) has a market cap of ~$100m and is focussed on cancer therapies, with its most progressed clinical therapy in the Phase Ib/IIa stage. KZA has a market cap of ~$136m and is also focussed on clinical stage cancer drug development.

Share Details

ASX code	RAC
Share price	$2.72
Market capitalisation	$433.7M
Shares on issue	159.4M
Net cash at 31-Dec-2021	$37.1M
Free float	86.2%

Share Performance (12 months)

Upside Case

- FDA approval for Zantrene in AML
- Partnering or licensing deals for different targets
- New therapies and RNA-targeting molecules

Downside Case

- Lack of additional clinical trials
- No partnering or licensing opportunities
- Inability to fund growth opportunities and trials

Catalysts

- Results and progress in its pre-clinical and clinical trials under way
- Q3 FY22 result ~April 22

Comparable Companies (Aust/NZ)

Neuren Pharmaceuticals (ASX:NEU), Prescient Therapeutics (ASX:PTX), Kazia Therapeutics (ASX:KZA)

Board and Management

Dr John Cullity	Non-Executive Chair
Phillip R. Lynch	Managing Director/CEO
Dr Daniel Tillett	Executive Director/CSO
Mary Harney	Non-Executive Director
Dr David Fuller	Chief Medical Officer
Prof. Michael Kelso	Principal Scientist

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FINANCIAL SERVICES GUIDE

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