Race Oncology

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1QFY24: Key elements click into place for critical CY24 clinical trials

NEED TO KNOW

- Cash of \$17.83m; strategic review underway
- Gearing up for RC220 human clinical trials in CY2024
- Significant body of work coming together to prepare for these clinical trials

Cash and equivalents of \$17.83m, down 17%: Race has announced its 1QFY24 results, ending the quarter with cash and equivalents of \$17.83m vs. \$21.52m at the end of the last quarter. Key cash outflows were preclinical research expenses, operating costs and production manufacturing for clinical trials. The cash includes a \$1.66m R&D tax incentive refund for FY2022, received in July 2023. The company is currently undertaking a strategic review to optimise its preclinical and clinical programs using its current funds, and plans to announce the results near term.

RC220 being readied for human clinical trials in CY2024: Race has focused its efforts in recent months on laying the groundwork for the human clinical trials of RC220, its proprietary peripheral intravenous formula of bisantrene, planned for CY2024. This has included getting current Good Manufacturing Practice (cGMP) manufacturing underway at Ardena, the leading global contract development and manufacturing organisation. Additionally, good laboratory practice (GLP) toxicology and safety pharmacological studies will begin soon, with Race confident that the required cGMP material will be ready well beforehand.

Investment Thesis

Well-founded proof of concept with historical approval: The history of bisantrene suggests it has a well-understood safety profile, with testing having occurred in over 2,000 patients and previous regulatory approval. Moreover, the previous approvals increase our confidence that the drug will be approved for other indications pursued by Race.

FTO-inhibiting activity looks promising for targeted therapy: Evidence suggests that FTO enzymatic activity is associated with cancer development and metastasis in many cancer types. In-vitro (cell lines) and in-vivo (mouse) studies have shown bisantrene to be a clinically potent inhibitor of FTO enzymatic activity in three different cancer models: AML, breast and glioblastoma. This raises prospects of a new role as a targeted therapy at low doses.

Orphan Drug Designation for AML provides potential exclusivity: Bisantrene has been awarded US Orphan Drug Designation, as AML is an orphan indication. If approved in the US, bisantrene would be protected by 7 years of orphan drug exclusivity. The company is recruiting patients for Phase 2 of its R/R AML combination trial and is also progressing its Phase 1/2 EMD AML trial (in partnership with its CRO), with patients continuing to be screened.

Valuation

Our valuation remains unchanged at A\$5.29 per share (undiluted) pending the outcome of the strategic review. Our valuation incorporates USD/AUD of 0.67.

Risks

Key risks: clinical development delays; unpredictable trial outcomes, regulatory decisions, financing, and commercialisation; and FX assumptions.

Equities Research Australia

Pharmaceuticals, Biotechnology and Life Sciences

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Race Oncology Limited is an ASX-listed specialty pharmaceutical company with a Phase 2/3–ready cancer drug called bisantrene. Race is exploring the use of bisantrene as a new targeted therapy for melanoma and clear cell renal cell carcinoma, which are both frequent fat mass and obesity associated protein (FTO) over-expressing cancers. The company also has compelling clinical data for the use of bisantrene as a chemotherapeutic agent with reduced cardiotoxicity in acute myeloid leukaemia (AML), breast and ovarian cancers and is investigating its use in these areas.

Valuation **A\$5.29** (unchanged)

Current price A\$0.97

Market cap **A\$151m**

Cash on hand **A\$17.8m** (30 September 23)

Upcoming Catalysts/Newsflow

Period	
2HCY23	Final results from Israel Phase 2 AML trial
2HCY23	First patient treated in EMD AML trial
1HCY24	Initiation of cardio protection breast cancer trial (subject to strategic review update)

Share Price (A\$)



Source: FactSet, MST Access.

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Financial Summary

Year end 30 June, AUD unless otherwise noted 12-MONTH SHARE PRICE PERFORMANCE (A\$) MARKET DATA \$ 0.98 4.00 3.50 0.77-2.41 52 week high / low \$ 3.00 \$ 5.29 Valuation 2.50 Market capitalisation \$m 159.0 2.00 Shares on issue (basic) 163.1 1.50 8.7 0.50 Other equity 0.0 0.00 171.7 Shares on issue (diluted) m INVESTMENT FUNDAMENTALS Reported NPAT \$m (11.2) (10.2) (10.2) (10.3) 0.0 0.0 0.0 0.0 0.0 Underlying NPAT (11.2) (9.9) (10.2)(10.2)(10.3)Other income \$m 0.7 3.1 3.3 3.3 3.3 \$m \$m 0.7 3.1 3.3 3.3 3.3 Reported EPS (diluted) (7.3)(6.2)(6.2)(6.3)(6.3)(12.0)(13.6)(13.6)(13.6)(13.6)Operating expenses \$m Underlying EPS (diluted) (7.3)(6.2) (6.2) (6.3)(6.3) **EBITDA** \$m (11.0) (10.2)(10.1)(10.1)(10.1)% -15.5% 1.0% 0.6% 1.1% Depreciation & Amortisation \$m (0.3)(0.3) (0.3) (0.3) (0.3)Underlying PER EBIT (11.3) (10.5) (10.3) (10.3) (10.3) nm 0.1 0.6 0.2 0.1 Net interest \$m 0.0 -6.2 Pretax Profit (11.2)(9.9) (10.2)(10.2)(10.3) Operating cash flow per share -4.1 -6.6 -6.1 -6.1 \$m Free cash flow per share -4.1 -6.6 -6.1 -6.1 -6.2 Tax expense \$m 0.0 0.0 0.0 0.0 0.0 Price to free cash flow per share nm nm nm nm Reported NPAT \$m (11.2) (9.9) (10.2) (10.2) (10.3) FCF Yield Weighted average diluted shares 153.3 163.1 163.1 m Dividend 0.0 0.0 0.0 0.0 0.0 Payout % 0.0% 0.0% 0.0% 0.0% 0.0% Yield % 0.0% 0.0% 0.0% 0.0% 0.0% % 66.6 342.8 5.4 0.0 0.0 % 0.0% 0.0% 0.0% EBITDA 80.6 0.0 0.0 Franking 0.0% 0.0% (1.7)% 77.0 (6.6) (1.6) 0.0 0.0 157.3 149.7 137.5 Reported NPAT Enterprise value 125.5 125.5 76.7 (11.4)\$m 2.4 0.6 1.1 DPS % EV/EBITDA nm nm nm nm nm nm nm nm nm EV/EBIT nm nm nm nm nm Price to book (NAV) 4.3 6.2 10.4 31.2 35.8 FY22. FY23A FY24E FY26E 12.7 33.5 Price to NTA 4.8 7.1 62.1 68.0 21.5 Receivables \$m 0.1 1.7 1.7 1.7 1.7 KEY RATIOS Inventory \$m 0.0 0.0 0.0 0.0 0.0 FBITDA margin nm nm nm Other \$m 0.5 0.3 0.3 0.3 0.3 EBIT margin nm Current assets \$m 34.2 23.5 13.7 3.7 3.7 nm 0.0 NPAT margin % 0.0 0.0 0.0 0.0 nm nm \$m ROE 3.1 2.8 2.5 2.2 nm nm nm nm nm Intangible assets \$m % ROA 0.0 0.0 0.0 0.0 0.0 nm nm nm nm nm Other \$m Non current assets \$m 3.4 3.1 2.8 2.5 2.2 Net tangible assets per share \$ 0.2 0.1 0.1 0.0 0.0 Total assets \$m 37.5 26.6 16.5 6.2 5.9 \$ 0.2 0.1 0.0 0.0 0.2 Book value per share \$m (33.5) (1.7) (33.5) (21.5) \$m 1.3 1.1 1.1 Net debt/(cash) (9.3)Trade and other payables 1.1 1.1 Interest cover/ (EBIT/net interest) 0.1 0.1 0.1 0.1 0.1 nm nm nm nm nm Provisions & Tax \$m Gearing (net debt/EBITDA) nm nm nm nm nm Other \$m 0.0 0.0 0.0 0.0 0.0 Leverage (net debt/(net debt + equity)) nm nm nm nm nm Current liabilities \$m 14 12 12 12 12 Borrowing and leases \$m 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 Net Profit Margin Non current liabilities \$m 0.0 0.0 % nm nm nm nm nm 0.0 0.0 0.0 0.0 0.0 Total liabilities \$m 1.4 1.2 1.2 1.2 1.2 Return on Assets % nm nm nm nm nm Net assets \$m 36 1 25.5 15.3 5.1 47 0.0 0.0 0.0 0.0 0.0 Return on Equity nm nm 62.0 61.7 71.7 nm nm Retained earnings \$m (33.7) (43.6) (53.8) (64.0) (74.3) KEY PERFORMANCE INDICATORS Other \$m 7.8 7.4 7.4 7.4 7.4 Clinical development pipeline Indication Status Total equity \$m 36.1 25.5 15.3 5.1 4.7 Phase 2 ready Zantrene® (bisantrene dihydrochloride) - BISECT AML with extramedullary disease + MDS CASH FLOW Zantrene® (bisantrene dihydrochloride) - (ISRAEL) AML (Relapsed or Refractory) Phase 2 ready Net loss for period \$m (11.2) (9.9) (10.2) (10.2) (10.3) Zantrene® (bisantrene dihydrochloride) Breast cancer (late-stage metastatic) 0.3 0.3 Zantrene® (bisantrene dihydrochloride) Anthracycline-naïve metastatic breast cancer Phase 2b ready Depreciation & Amortization \$m 0.3 0.3 0.3 Zantrene® (bisantrene dihydrochloride) Pre-clinical Changes in working capital \$m 1.6 (1.7)0.0 0.0 0.0 Melanoma Kidney cancer (clear cell renal cell carcinoma) Pre-clinical Other \$m 3.1 0.7 0.0 0.0 0.0 Zantrene® (bisantrene dihydrochloride) Pre-clinical Operating cash flow \$m (10.7) (9.9) (10.1) (6.3)(9.9) Zantrene® (bisantrene dihydrochloride) Heart safety study Payments for PPE Other \$m 0.7 1.8 \$m 0.0 0.0 0.0 0.0 0.0 Total Revenue 1.3 Operating expenses \$m (4.3)(5.5)(6.4)(5.9)(7.8)Investing cash flow \$m 0.0 0.0 0.0 0.0 0.0 EBITDA \$m (4.1)(4.7)(6.3)(4.4)(5.8)Equity \$m 292 0.0 0.0 0.0 10.0 Net borrowing \$m (4.3) (4.8) (6.4) (4.5) (6.0) 0.0 0.0 0.0 0.0 0.0 \$m (4.3)(4.8) (6.4) (4.4) (5.5) (1.3) 30.5 0.0 \$m (4.3)(4.8)(6.4)(4.4)(5.6)Financing cash flow \$m (1.3)0.0 10.0 Reported NPAT 33.5 \$m 21.5 11.6 1.7 1.6 Cash year end Free cash flow Source: Company reports, MST Access estimates (6.3)(10.7)(9.9)(9.9)(10.1)

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