Race Oncology

RAC.ASX

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Phase 2 AML interim data strongly support more studies of bisantrene

NEED TO KNOW

- Combination with chemotherapy regime shows promise
- Bisantrene found safe without cardiotoxicity issues
- Interim results to be presented at American Society of Hematology (ASH) Conference in December 2023

Interim efficacy and safety results support further studies of bisantrene: Interim clinical results from an ongoing investigator-initiated Phase 2 trial showed bisantrene (RC110 formulation) in combination with chemotherapy (fludarabine and clofarabine) administered over four days induced a clinical response in 6 of 15 trial patients (40%) with advanced relapsed or refractory acute myeloid leukaemia, with five patients receiving a potentially curative stem cell transplant.

Meaningful results in treatment-resistant patients: This result was highly significant given the response in the heavily pre-treated patient cohort (with the group having failed a median of four lines of prior treatment), and strongly supports further studies of bisantrene-based combinations. Of the five transplanted patients, two remain disease free and in complete remission. Further, bisantrene was found to be safe and well tolerated and without clinically relevant signs of cardiotoxicity or tumour lysis syndrome.

Result to be presented at prestigious ASH conference: A peer-reviewed abstract of this result will be presented at the American Society of Hematology Annual Conference in December 2023. This represents an important opportunity to showcase bisantrene data to clinicians and potential partners for Race.

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 ongoing strategic review and incorporates USD/AUD of 0.67. (refer to update note 30 November 2022 here)

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 2023)*

Upcoming Catalysts/Newsflow

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

Share Price (A$)

Source: FactSet, MST Access.

Financial Summary

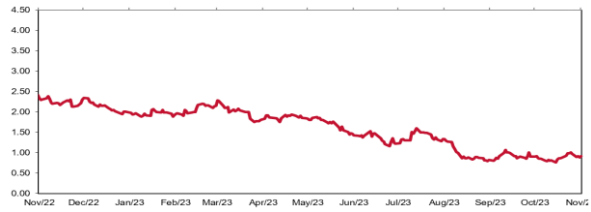
Race Oncology — **RAC-AU**

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.92**
52 week high / low	$	0.77-2.41
Valuation	**$**	**5.29**
Market capitalisation	$m	149.2
Shares on issue (basic)	**m**	163.1
Options / rights	m	8.7
Other equity	m	0.0
Shares on issue (diluted)	**m**	**171.7** *does not include new shares in cap raise ~11m @0.9*

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY22A	FY23A	FY24E	FY25E	FY26E
Reported NPAT	$m	(11.2)	(9.9)	(10.2)	(10.2)	(10.3)
Underlying NPAT	**$m**	(11.2)	(9.9)	(10.2)	(10.2)	(10.3)
Reported EPS (diluted)	¢	(7.3)	(6.2)	(6.2)	(6.3)	(6.3)
Underlying EPS (diluted)	**¢**	**(7.3)**	**(6.2)**	**(6.2)**	**(6.3)**	**(6.3)**
Growth	%		-15.5%	1.0%	0.6%	1.1%
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**nm**
Operating cash flow per share	¢	-4.1	-6.6	-6.1	-6.1	-6.2
Free cash flow per share	¢	-4.1	-6.6	-6.1	-6.1	-6.2
Price to free cash flow per share	**x**	**nm**	**nm**	**nm**	**nm**	**nm**
FCF Yield	%	nm	nm	nm	nm	nm
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%**
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	**$m**	**115.7**	**147.5**	**139.9**	**115.7**	**127.7**
EV/EBITDA	x	nm	nm	nm	nm	nm
EV/EBIT	x	nm	nm	nm	nm	nm
Price to book (NAV)	x	4.0	5.9	9.7	29.3	33.6
Price to NTA	x	4.5	6.7	11.9	58.2	63.8

KEY RATIOS		FY22A	FY23A	FY24E	FY25E	FY26E
EBITDA margin	%	nm	nm	nm	nm	nm
EBIT margin	%	nm	nm	nm	nm	nm
NPAT margin	%	nm	nm	nm	nm	nm
ROE	%	nm	nm	nm	nm	nm
ROA	%	nm	nm	nm	nm	nm
Net tangible assets per share	$	0.2	0.1	0.1	0.0	0.0
Book value per share	$	0.2	0.2	0.1	0.0	0.0
Net debt/(cash)	$m	(33.5)	(1.7)	(9.3)	(33.5)	(21.5)
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	nm	nm
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm

DUPONT ANALYSIS		FY22A	FY23A	FY24E	FY25E	FY26E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	0.0	0.0	0.0	0.0	0.0
Return on Assets	%	nm	nm	nm	nm	nm
Financial Leverage	x	0.0	0.0	0.0	0.0	0.0
Return on Equity	%	nm	nm	nm	nm	nm

KEY PERFORMANCE INDICATORS

Clinical development pipeline	Indication	Status
Zantrene® (bisantrene dihydrochloride) - BISECT	AML with extramedullary disease + MDS	Phase 2 ready
Zantrene® (bisantrene dihydrochloride) - (ISRAEL)	AML (Relapsed or Refractory)	Phase 1b/2
Zantrene® (bisantrene dihydrochloride)	Breast cancer (late-stage metastatic)	Phase 2 ready
Zantrene® (bisantrene dihydrochloride)	Anthracycline-naïve metastatic breast ca	Phase 2b ready
Zantrene® (bisantrene dihydrochloride)	Melanoma	Pre-clinical
Zantrene® (bisantrene dihydrochloride)	Kidney cancer (clear cell renal cell carci	Pre-clinical
Zantrene® (bisantrene dihydrochloride)	Heart safety study	Pre-clinical

HALF YEARLY DATA		2H21	1H22	2H22	1H23	2H23
Total Revenue	$m	-	0.7	-	1.3	1.8
Operating expenses	$m	(4.3)	(5.5)	(6.4)	(5.9)	(7.8)
EBITDA	$m	(4.1)	(4.7)	(6.3)	(4.4)	(5.8)
EBIT	$m	(4.3)	(4.8)	(6.4)	(4.5)	(6.0)
PBT	$m	(4.3)	(4.8)	(6.4)	(4.4)	(5.5)
Reported NPAT	$m	(4.3)	(4.8)	(6.4)	(4.4)	(5.6)

Source: Company reports, MST Access estimates

PROFIT AND LOSS		FY22A	FY23A	FY24E	FY25E	FY26E
Revenue	**$m**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Other income	$m	0.7	3.1	3.3	3.3	3.3
Total Revenue	**$m**	**0.7**	**3.1**	**3.3**	**3.3**	3.3
Operating expenses	$m	(12.0)	(13.6)	(13.6)	(13.6)	(13.6)
EBITDA	**$m**	**(11.0)**	**(10.2)**	**(10.1)**	**(10.1)**	(10.1)
Depreciation & Amortisation	$m	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
EBIT	**$m**	**(11.3)**	**(10.5)**	**(10.3)**	**(10.3)**	(10.3)
Net interest	$m	0.1	0.6	0.2	0.1	0.0
Pretax Profit	**$m**	**(11.2)**	**(9.9)**	**(10.2)**	**(10.2)**	**(10.3)**
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(11.2)**	**(9.9)**	**(10.2)**	**(10.2)**	**(10.3)**
Weighted average diluted shares	m	153.3	160.7	163.1	163.1	163.1

GROWTH PROFILE		FY22A	FY23A	FY24E	FY25E	FY26E
Revenue	%	66.6	342.8	5.4	0.0	0.0
EBITDA	%	80.6	(6.7)	(1.7)	0.0	0.0
EBIT	%	77.0	(6.6)	(1.6)	0.0	0.0
Reported NPAT	%	76.7	(11.4)	2.4	0.6	1.1
DPS	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY22A	FY23A	FY24E	FY25E	FY26E
Cash	$m	33.5	21.5	11.6	1.7	1.6
Receivables	$m	0.1	1.7	1.7	1.7	1.7
Inventory	$m	0.0	0.0	0.0	0.0	0.0
Other	$m	0.5	0.3	0.3	0.3	0.3
Current assets	**$m**	**34.2**	**23.5**	**13.7**	**3.7**	**3.7**
PPE	$m	0.0	0.0	0.0	0.0	0.0
Intangible assets	$m	3.4	3.1	2.8	2.5	2.2
Other	$m	0.0	0.0	0.0	0.0	0.0
Non current assets	**$m**	**3.4**	**3.1**	**2.8**	**2.5**	**2.2**
Total assets	**$m**	**37.5**	**26.6**	**16.5**	**6.2**	**5.9**
Trade and other payables	$m	1.3	1.1	1.1	1.1	1.1
Provisions & Tax	$m	0.1	0.1	0.1	0.1	0.1
Other	$m	0.0	0.0	0.0	0.0	0.0
Current liabilities	**$m**	**1.4**	**1.2**	**1.2**	**1.2**	**1.2**
Borrowing and leases	$m	0.0	0.0	0.0	0.0	0.0
Other liability	$m	0.0	0.0	0.0	0.0	0.0
Non current liabilities	**$m**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Total liabilities	**$m**	**1.4**	**1.2**	**1.2**	**1.2**	**1.2**
Net assets	**$m**	**36.1**	**25.5**	**15.3**	**5.1**	**4.7**
Share capital	$m	62.0	61.7	61.7	61.7	71.7
Retained earnings	$m	(33.7)	(43.6)	(53.8)	(64.0)	(74.3)
Other	$m	7.8	7.4	7.4	7.4	7.4
Total equity	**$m**	**36.1**	**25.5**	**15.3**	**5.1**	**4.7**

CASH FLOW		FY22A	FY23A	FY24E	FY25E	FY26E
Net loss for period	**$m**	**(11.2)**	**(9.9)**	**(10.2)**	**(10.2)**	**(10.3)**
Depreciation & Amortization	$m	0.3	0.3	0.3	0.3	0.3
Changes in working capital	$m	1.6	(1.7)	0.0	0.0	0.0
Other	$m	3.1	0.7	0.0	0.0	0.0
Operating cash flow	**$m**	**(6.3)**	**(10.7)**	**(9.9)**	**(9.9)**	**(10.1)**
Payments for PPE	$m	0.0	0.0	0.0	0.0	0.0
Other	$m	0.0	0.0	0.0	0.0	0.0
Investing cash flow	**$m**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Equity	$m	29.2	0.0	0.0	0.0	10.0
Net borrowing		0.0	0.0	0.0	0.0	0.0
Other	$m	1.3	(1.3)	0.0	0.0	0.0
Financing cash flow	**$m**	**30.5**	**(1.3)**	**0.0**	**0.0**	**10.0**
Cash year end	**$m**	**33.5**	**21.5**	**11.6**	**1.7**	**1.6**
Free cash flow	**$m**	**(6.3)**	**(10.7)**	**(9.9)**	**(9.9)**	**(10.1)**

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