Race Oncology

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Protecting the Heart, Fighting the Disease: Bisantrene's Dual Action

Equity Research Australia

Pharmaceuticals, Biotechnology/Life Sciences

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NEED TO KNOW

- **Bisantrene is the enabler for higher dosing of anthracyclines**
- **RC220 to enter human clinical trials in 2HCY24**
- **FY24 result and cash on hand – fully funded for current programs**

Bisantrene cardioprotection and anti-cancer effects to enable higher dosing of doxorubicin: Race Oncology aims to develop bisantrene (RC220) as a cardioprotective and anti-cancer agent in settings where anthracyclines are typically used. This approach seeks to enhance the anti-cancer efficacy of this standard-of-care treatment while significantly reducing the risk of heart damage, a common and severe side effect associated with anthracyclines.

RC220 human clinical trials: RC220 is expected to commence human clinical trials in Australia in 2HCY24. These trials will explore RC220's potential as a treatment option for patients with solid tumours.

Funding in place to complete current programs: With $17m as of 30 June 2024 and another $25m expected through the exercise of piggyback options, Race is fully funded to complete its current clinical programs.

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 (m6A RNA pathway) 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 potent inhibitor of FTO enzymatic activity, raising prospects of a role as a targeted therapy at low doses.

Orphan Drug Designation (ODD) for AML provides potential exclusivity: The ODD for AML as an orphan indication means that, if approved for use in the US, bisantrene would be protected by 7 years of orphan drug exclusivity.

Valuation

We value Race Oncology at A$6.37 per share (versus A$3.22 previously) and A$5.30 per share on a fully diluted basis. Our revised valuation now reflects the use of bisantrene in combination with all anthracyclines and incorporates shares on issue of 170,268,843 and options on issue of 34,569,371.

Risks

Race is subject to typical biotech company development risks, including unpredictable outcomes of trials, difficulties in patient recruitment, regulatory decisions, unforeseen delays in clinical program timelines for any number of reasons, and financing and commercial risks.

Race Oncology is a specialty pharmaceutical company with a Phase 2/3—ready cancer drug called bisantrene. Race is investigating the potential of its new proprietary reformulation of bisantrene (RC220) across multiple cancer indications. The company's clinical focus is on combining RC220 with anthracyclines, to mitigate the permanent heart damage associated with chemotherapy while simultaneously enhancing anti-cancer activity in a range of solid tumours. Race is also investigating the potential of bisantrene as a targeted therapy for cancers associated with dysregulation of the m6A RNA pathway. This follows the discovery that bisantrene inhibits FTO, a key enzyme involved in this pathway. www.raceoncology.com

Valuation	**A$6.37** *(from A$3.22)*
Current price	**A$1.78**
Market cap	**A$302m**
Cash on hand	**A$17.2m** *(30 June 2024)*

Upcoming Catalysts / Next News

Period	
2HCY24	First patient in Phase 1a/b clinical trial
2HCY24	Updates on the m6A RNA program
2HCY24	Publication of Sheba Phase 2 data
2HCY24	Commence Phase 1/2 AML study

Share Price (A$)

Source: FactSet, MST Access

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Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**1.78**
52 week high / low	$	0.67-2.02
Valuation	**$**	**6.37**
Market capitalisation	$m	302.3
Shares on issue (basic)	**m**	170.3
Options / rights	m	34.6 *includes ~20m piggyback options*
Other equity	m	0.0
Shares on issue (diluted)	**m**	**204.9**

12-MONTH SHARE PRICE PERFORMANCE (A$)

INVESTMENT FUNDAMENTALS		FY23A	FY24A	FY25E	FY26E	FY27E
Reported NPAT	$m	(9.9)	(9.9)	(13.8)	(6.2)	(27.1)
Underlying NPAT	**$m**	(9.9)	(9.9)	(13.8)	(6.2)	(27.1)
Reported EPS (diluted)	¢	(6.2)	(6.2)	(8.4)	(3.7)	(15.9)
Underlying EPS (diluted)	**¢**	**(6.2)**	**(6.2)**	**(8.4)**	**(3.7)**	**(15.9)**
Growth	%		0.0%	36.1%	-56.4%	333.9%
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**nm**
Operating cash flow per share	¢	-6.5	-5.6	-3.5	-14.1	-3.4
Free cash flow per share	¢	-6.5	-5.6	-3.5	-14.1	-3.4
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**	**268.7**	**300.6**	**293.0**	**268.7**	**280.8**
EV/EBITDA	x	nm	nm	nm	nm	nm
EV/EBIT	x	nm	nm	nm	nm	nm
Price to book (NAV)	x	11.1	15.8	25.0	30.3	107.0
Price to NTA	x	12.6	18.7	31.7	39.1	284.0

KEY RATIOS		FY23A	FY24A	FY25E	FY26E	FY27E
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	$	0.1	0.1	0.1	0.0	0.0
Book value per share	$	0.2	0.1	0.1	0.1	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		FY23A	FY24A	FY25E	FY26E	FY27E
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
RC110 (Israel)	AML (Relapsed or Refractory)	Phase 2 (Israel) completed
RC220	Cardioprotection + m6A RNA + anticancer efficacy - solid tumours	Phase 1a/b
RC220	AML (Relapsed or Refractory)	Phase 1/2*
m6A RNA molecule development	Next generation bisantrene	Preclinical

** Investigator sponsored*

HALF YEARLY DATA		2H22	1H23	2H23	1H24	2H24
Total Revenue	$m	-	1.3	1.8	4.0	-
Operating expenses	$m	(6.4)	(5.9)	(7.8)	(10.1)	(8.5)
EBITDA	$m	(6.3)	(4.4)	(5.8)	(6.0)	(8.4)
EBIT	$m	(6.4)	(4.5)	(6.0)	(6.1)	(8.5)
PBT	$m	(6.4)	(4.4)	(5.5)	(5.6)	(8.2)
Reported NPAT	$m	(6.4)	(4.4)	(5.6)	(5.6)	(8.2)

Source: Company reports, MST Access estimates

PROFIT AND LOSS		FY23A	FY24A	FY25E	FY26E	FY27E
Revenue	**$m**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Other income	$m	3.1	4.0	4.8	3.0	11.3
Total Revenue	**$m**	**3.1**	**4.0**	**4.8**	**3.0**	**11.3**
Operating expenses	$m	(13.6)	(18.7)	(11.1)	(30.1)	(18.1)
EBITDA	**$m**	**(10.2)**	**(14.4)**	**(6.1)**	**(26.8)**	**(6.5)**
Depreciation & Amortisation	$m	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
EBIT	**$m**	**(10.5)**	**(14.7)**	**(6.4)**	**(27.1)**	**(6.8)**
Net interest	$m	0.6	0.8	0.1	0.0	0.0
Pretax Profit	**$m**	**(9.9)**	**(13.8)**	**(6.2)**	**(27.1)**	**(6.8)**
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(9.9)**	**(13.8)**	**(6.2)**	**(27.1)**	**(6.8)**
Underlying NPAT	$m	**(9.9)**	**(13.8)**	**(6.2)**	**(27.1)**	**(6.8)**
FY end shares on issue	m	163.1	170.3	170.3	190.3	190.3

GROWTH PROFILE		FY23A	FY24A	FY25E	FY26E	FY27E
Revenue	%	nm	nm	nm	nm	nm
EBITDA	%	nm	nm	nm	nm	nm
EBIT	%	nm	nm	nm	nm	nm
Reported NPAT	%	nm	nm	nm	nm	nm
DPS	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY23A	FY24A	FY25E	FY26E	FY27E
Cash	$m	21.5	17.2	11.2	9.4	2.9
Receivables	$m	1.7	0.1	0.1	0.1	0.1
Inventory	$m	0.0	0.0	0.0	0.0	0.0
Other	$m	0.3	0.1	0.1	0.1	0.1
Current assets	**$m**	**23.5**	**17.4**	**11.5**	**9.6**	**3.1**
PPE	$m	0.0	0.0	0.0	0.0	0.0
Intangible assets	$m	3.1	2.8	2.5	2.2	2.0
Other	$m	0.0	0.0	0.0	0.0	0.0
Non current assets	**$m**	**3.1**	**2.8**	**2.5**	**2.2**	**2.0**
Total assets	**$m**	**26.6**	**20.2**	**14.0**	**11.9**	**5.1**
Trade and other payables	$m	1.1	1.8	1.8	1.8	1.8
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**	**1.2**	**1.9**	**1.9**	**1.9**	**1.9**
Borrowing and leases	$m	0.0	0.0	0.0	0.0	0.0
Other liability	$m	0.0	48.3	48.3	48.3	48.3
Non current liabilities	**$m**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Total liabilities	**$m**	**1.2**	**1.9**	**1.9**	**1.9**	**1.9**
Net assets	**$m**	**25.5**	**18.3**	**12.1**	**10.0**	**3.2**
Share capital	$m	61.7	66.9	66.9	91.9	91.9
Retained earnings	$m	(43.6)	(57.4)	(63.7)	(90.8)	(97.6)
Other	$m	7.4	8.8	8.8	8.8	8.8
Total equity	**$m**	**25.5**	**18.3**	**12.1**	**10.0**	**3.2**

CASH FLOW		FY23A	FY24A	FY25E	FY26E	FY27E
Net loss for period	**$m**	**(9.9)**	**(13.8)**	**(6.2)**	**(27.1)**	**(6.8)**
Depreciation & Amortization	$m	0.3	0.3	0.3	0.3	0.3
Changes in working capital	$m	(1.7)	2.6	0.0	0.0	0.0
Other	$m	0.7	1.4	(0.0)	0.0	(0.0)
Operating cash flow	**$m**	**(10.7)**	**(9.5)**	**(6.0)**	**(26.8)**	**(6.5)**
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	0.0	5.2	0.0	25.0	0.0
Net borrowing		0.0	0.0	0.0	0.0	0.0
Other	$m	(1.3)	(0.0)	0.0	0.0	0.0
Financing cash flow	**$m**	**(1.3)**	**5.2**	**0.0**	**25.0**	**0.0**
Cash year end	**$m**	**21.5**	**17.2**	**11.2**	**9.4**	**2.9**
Free cash flow	**$m**	**(10.7)**	**(9.5)**	**(6.0)**	**(26.8)**	**(6.5)**

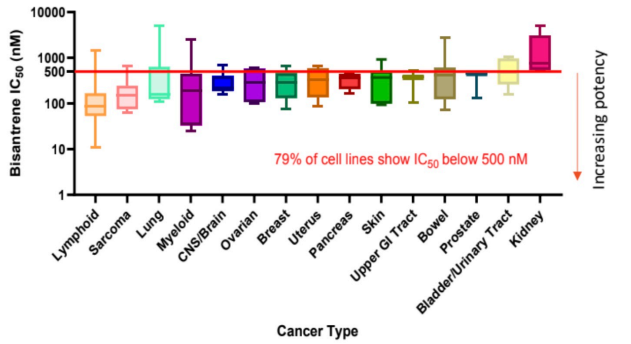
Optimising Anthracycline Cancer Therapy

Bisantrene delivers a 2X benefit for cancer patients

Benefit 1: more destruction of cancer cells vs. anthracyclines alone

Race Oncology discovered that combining bisantrene with doxorubicin significantly enhanced cancer cell destruction across various tumour types. This additive effect, observed in 143 tumour cell lines, suggests the potential of this combination for treating solid tumours such as lung, prostate, pancreas, breast, and head and neck cancers. As such, bisantrene improves doxorubicin's anti-cancer activity in 85% of all cancers.

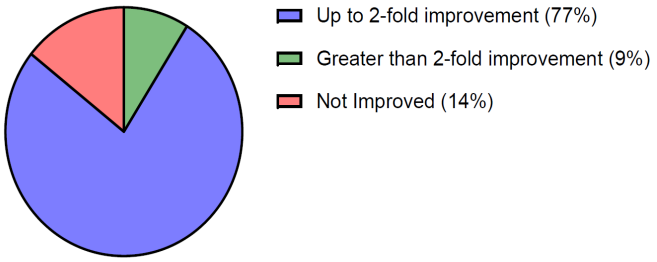
Figure 1: Bisantrene shows broad anti-cancer activit.y



Bisantrene shows broad anti-cancer activity. The half-maximal inhibitory concentration (IC_{50}) was determined for bisantrene against 143 cancer cell lines derived from diverse human tumour types. Boxes show the 25%-75% range, with the line within each box representing the median IC_{50} value. The upper and lower edges of the box represent the 75th and 25th percentiles, respectively. Whiskers show the minimum and maximum IC_{50} values observed for each cancer cell type.

Source: Race Oncology.

Figure 2: Combining bisantrene with doxorubicin increases cell-killing activity



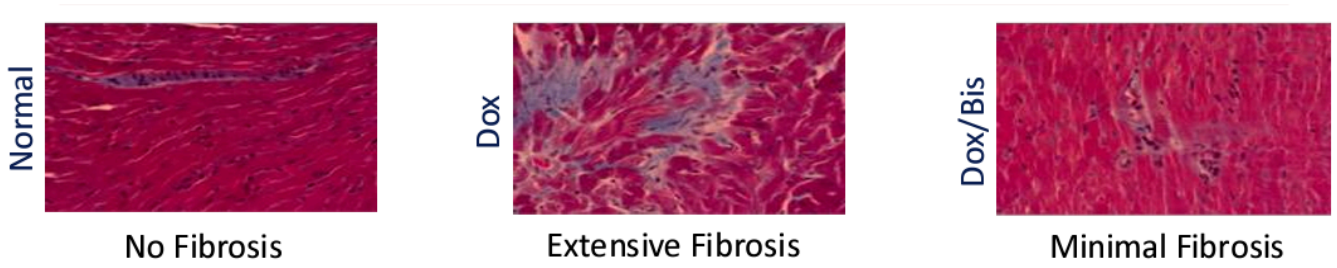
Source: Race Oncology.

Benefit 2: protection from long-term heart damage caused by anthracyclines

Race Oncology's preclinical research also identified bisantrene as a promising agent for mitigating the cardiotoxicity associated with anthracycline-based cancer therapies. In vitro and in vivo studies have demonstrated that bisantrene is cardioprotective, in contrast to conventional anthracyclines. Moreover, when combined with anthracyclines, bisantrene has shown a protective effect on the heart, potentially minimising the long-term cardiac damage often observed with these chemotherapeutic agents.

Specifically, in vitro studies in human primary cardiomyocytes and in vivo studies in mice have demonstrated cardioprotection for the bisantrene + doxorubicin combinations, including increased cardiac function and reduced fibrosis when compared to doxorubicin alone.

Figure 3: Strong protection from anthracycline-induced cardiomyopathy



Source: Race Oncology.

Clinical rationale/strategy – enable higher dosing of anthracycline.s

Current strategies to mitigate anthracycline-induced cardiotoxicity primarily focus on risk stratification and dose modification. High-risk patients are often excluded from anthracycline-based regimens, while dose reduction is implemented to minimise the likelihood of cardiac-adverse events. As such, the rationale behind the development of bisantrene is to overcome the drawbacks of anthracyclines. By reducing the risk of cardiotoxicity while maintaining or even enhancing the anti-cancer activity, bisantrene could potentially offer a more favourable therapeutic profile.

The role of bisantrene in mitigating dose-dependent anthracycline-induced cardiotoxicity

How and why anthracyclines are used

The anthracyclines, such as doxorubicin, daunorubicin, and epirubicin, are a class of broad-spectrum anti-cancer drugs extracted from *Streptomyces* bacterium. These compounds are used to treat different adult and pediatric hematologic cancers, such as leukemia and lymphomas, as well as many solid tumours, including breast, stomach, uterine, ovarian, bladder and lung cancers.

The problems with anthracyclines – damage to the heart

As a class of chemotherapy drugs, anthracyclines have proven to be highly effective in treating a wide variety of cancers (see Appendix). However, they are also known for their potential to cause heart damage, a condition known as anthracycline-induced cardiotoxicity (AIC).

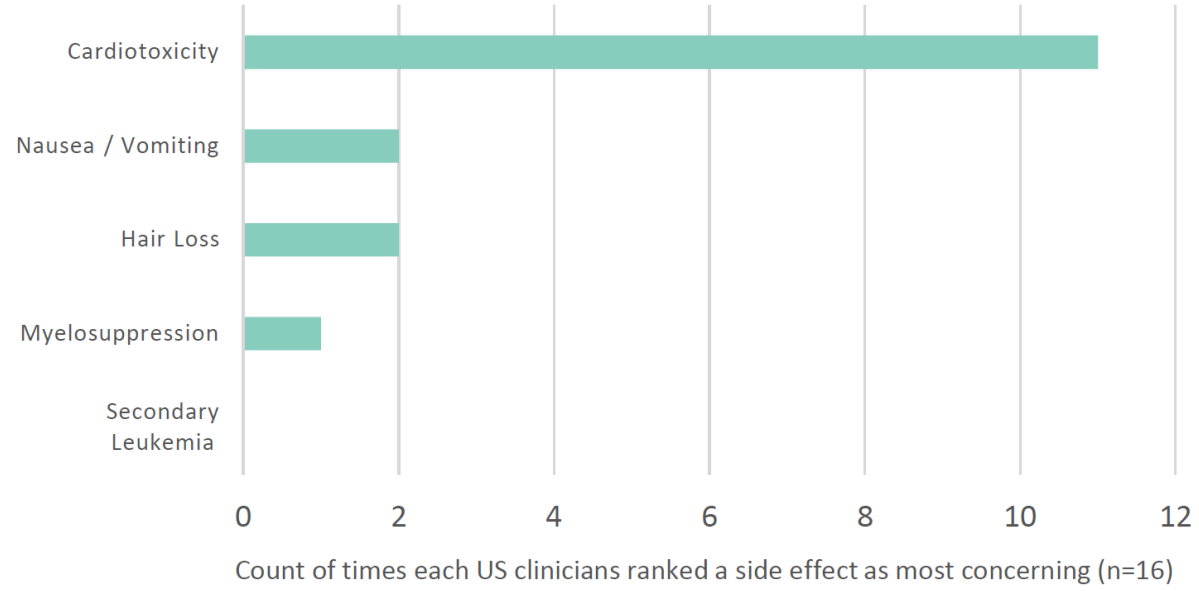
The risk of AIC can vary depending on several factors, including:

- **Total cumulative dose:** The higher the total dose of anthracycline received, the greater the risk of heart damage. The risk of anthracycline-induced heart failure increases as the cumulative dose administered increases: 3–5% at 400 mg/m2 and as high as 18–48% at 700 mg/m2 (Cardinale et al: 2020).
- **Type of anthracycline:** Some anthracyclines, such as doxorubicin and daunorubicin, are more likely to cause heart damage than others.
- **Individual factors:** Factors such as age, pre-existing heart conditions, and other medications can also influence the risk of AIC.

Common side effects on the heart associated with anthracyclines include:

- **Heart failure:** This is the most serious complication of AIC and can lead to symptoms such as shortness of breath, fatigue, swelling in the legs and death.
- **Heart rhythm abnormalities:** Anthracyclines can cause irregular heart rhythms, such as atrial fibrillation or ventricular tachycardia.
- **Heart muscle damage:** The drugs can damage the heart muscle, leading to decreased heart function.

Figure 4: Independent surveys suggest strong US clinician interest in new agents able to reduce anthracycline cardiotoxicity.y



Source: Race Oncology. (Primary market research conducted by Triangle Insights)

Cardiotoxicity biomarker advancement: using VO2peak as a more sensitive means of identifying patients at increased risk of heart failure

Current standards for monitoring heart health: The current standard for monitoring cardiac function (periodic assessment of left ventricular ejection fraction – LVEF) detects cardiotoxicity at a late stage when a significant impairment has already occurred. While LVEF is the standard measure for assessing chemotherapy-associated cardiotoxicity, global longitudinal strain (GLS) has emerged as a promising alternative. However, neither LVEF nor GLS has consistently been linked to short-term symptoms, functional capacity, or long-term heart failure risk.

The Baker Institute recently conducted a study on 206 cancer patients to evaluate the effectiveness of standard cardiac measures in predicting functional capacity and long-term heart failure risk. The results revealed that these measures were not strongly correlated with these outcomes.

What is VO2peak and how does it help measure heart damage? VO2peak is a measure of functional capacity (peak oxygen uptake) and can be easily assessed in minutes using a cycle ergometer test. A VO2 peak below 18 mL/kg/min indicates functional disability, limiting daily activities and significantly increasing the risk of heart failure.

Patients exposed to anthracycline chemotherapy experienced a significant decline in VO2peak, equivalent to 8–11 years of normal aging. This reduction was accompanied by a nearly twofold increase in functional disability rates, rising from 15% to 26%. Additionally, 43% of patients exposed to anthracyclines experienced a 10% or greater reduction in their VO2peak.

For these reasons, the American Heart Association has endorsed the measurement of functional disability as an important clinical endpoint for older adults with or at risk of cardiovascular disease (Howden et 2021).

Why is VO2peak more relevant to RC220 development and an important clinical endpoint? VO2peak has been strongly associated with heart failure risk and found to be more sensitive to cardiac damage induced by cancer treatment than LVEF, GLS, or cardiac biomarkers. As such, Race is incorporating VO2peak in its Phase 1a trial of RC220 in any solid tumour patient where anthracycline use is indicated.

New bisantrene formulation, RC220, on track to enter human clinical trials

After successfully producing a cGMP-compliant batch of RC220, in collaboration with Ardena Holding NV, Race Oncology is well-positioned to proceed with the planned clinical trials in Australia (figure 5).

As such, RC220 is expected to enter human clinical trials in 2HCY24 to be evaluated as a therapeutic option for solid tumour patients.

Figure 5: Clinical pipeline

Asset	Indication	Sponsor	Discovery	IND enabling	Phase 1	Phase 2	Phase 3	Next milestone
RC110	Acute Myeloid Leukaemia	Chaim Sheba Medical Centre, Israel	Phase 2					In final stages of trial
RC220	Cardioprotection + m6A RNA + anti-cancer efficacy - solid tumours	Race Oncology	Phase 1a/b		H2 CY24	2026		Ethics / governance approvals First patient dosed
RC220	Acute Myeloid Leukaemia	Investigator sponsored[3]	Phase 1/2		H2 CY24			Confirmation of trial
m^6A RNA molecule development	Next generation bisantrene	Race Oncology	Preclinical					Preliminary results

Source: Race Oncology.

RC220 PHASE 1A/B TRIAL

The initial Phase 1/2 study, designed as an open-label Bayesian dose escalation trial, will enrol patients with solid tumours where doxorubicin is the standard of care. This approach allows for a flexible and adaptive design to optimise dosing while ensuring patient safety. As such, bisantrene potential will be expanded beyond breast cancer to all cancers where anthracyclines are used.

Design

- Primary endpoints: Safety and optimal Phase 2 dose
- Exploratory endpoints: Standard and advanced cardiac markers including VO2peak, m6A RNA levels, and anti-cancer efficacy
- Race Oncology anticipates enrolling the first of 25–50 patients in its clinical trial by the end of the year. The trial will be conducted at up to 10 Australian sites
- Timeline: 12–18 months

Purpose:

- Phase 1a establishes optimal bisantrene–anthracycline dosing and safety
- Phase 1b generates proof-of-concept cardioprotection efficacy data in combination with anthracyclines
- Exploratory data generated on single-agent anti-cancer efficacy and the effects on the m6A RNA system
- Builds robust data set to support Phase 2 efficacy trial

RC220 CARDIOPROTECTION & M6A RNA PHASE 2 TRIAL

Following the Phase 1a/b trial of RC220, Race intends to conduct a randomised, placebo-controlled, double-blind clinical trial to evaluate the efficacy and safety of RC220 in combination with standard treatments for breast cancer and other cancers. The trial will employ a Bayesian adaptive design, allowing for the inclusion of additional patient populations that demonstrate exceptional responses to treatment in the initial phase.

Design

- Size: 80–120 patients; up to 20 sites in Australia and internationally
- Sponsor: Race Oncology
- Primary endpoints: Cardioprotection assessed by standard and advanced cardiac markers including VO2peak
- Secondary and exploratory endpoints: Anti-cancer efficacy and effect on m6A RNA levels
- Start: After completion of Phase 1
- Uses Phase 1a/b protocol with a 7-day lead-in dosing regimen of bisantrene to collect comprehensive clinical data on its impact on the m6A RNA system and its single-agent anti-cancer efficacy
- Timeline: 18–24 months due to Bayesian design leading to uncertainty around total patient number (patient recruitment)

Purpose

- Provides rigorous placebo-controlled clinical trials to establish bisantrene's efficacy as a cardioprotective agent. Additionally, the trials will generate data supporting bisantrene's anti-cancer activity and its potential impact on the m6A RNA system.

Valuation

We have revised our valuation to reflect a potential role for bisantrene in optimising the use of anthracyclines and its subsequent use in combination across all cancer indications. This scenario recognises both bisantrene's cardioprotective qualities and its anti-cancer potential and assumes its use in all anthracycline regimens. This contrasts with our previous view of bisantrene as only a monotherapy for AML, breast cancer, melanoma and kidney cancer.

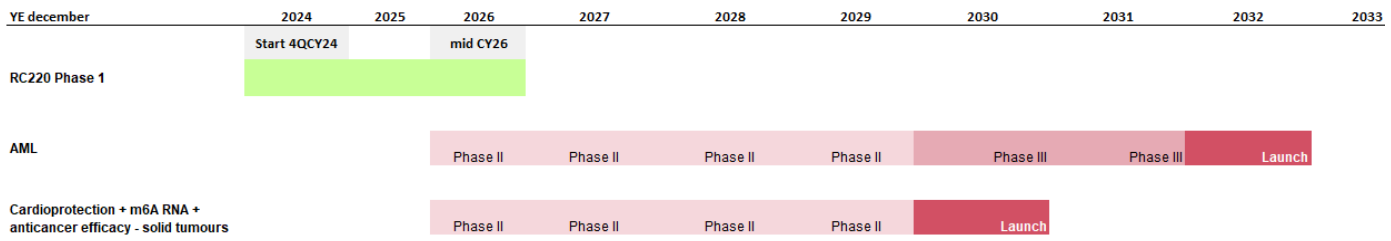
As such, we value Race Oncology at A$6.37 per share (versus A$3.22 previously) and A$5.30 per share on a fully diluted basis. This figure is derived using the risk-adjusted net present value (rNPV) method, which discounts future cash flows until 2044, aligning with the expiration of the IP protection afforded by the new RC220 formulation. Our valuation incorporates shares on issue of 170,268,843 and options on issue of 34,569,371, including 20,141,793 piggyback options.

The sum-of-the-parts breakdown of our rNPV model uses a 12.5% discount rate and assumes all programs will be out-licensed in Phase 2 with all subsequent costs (R&D, launch and marketing) paid by the licensor, in return for a 10% royalty. We use AUD/USD of 0.66.

Our key considerations:

- Patent life of RC220 through to 2044
- Launch of bisantrene in 2030 subject to supportive Phase 2 efficacy data in the planned Phase 2 trial investigating the impact of bisantrene on cardioprotection + m6A RNA + anti-cancer efficacy in solid tumours
- Launch of bisantrene in 2032 for AML subject to supportive Phase 2 efficacy data in the investigator-sponsored Phase 2 trial
- A probability of success of 32% (based on industry clinical development success rates published by the Biotechnology Innovation Organization) in both clinical programs, given the well-understood safety profile of bisantrene, which increases our confidence in progressing beyond Phase 1
- Our target market opportunity reflects current anthracycline usage only in the United States and Europe of 739k doses and 1.2m doses respectively (see Appendix 3). We assume a modest low single-digit percentage penetration upon launch peaking at around 10% penetration by 2039
- Cost of treatment @ US$60,000 based on 4 cycles with a 3% yearly increase in net price per annum
- Cash on hand as of 30 June 2024 of A$17m
- Discount rate of 12.5%

Figure 6: Clinical program timeline



Source: MST Access.

Figure 7: Breakdown of sum-of-the-parts, rNPV-based valuation model

Product	Indication	Launch	NPV*(US$m)	Probability of success		rNPV (A$m)
Bisantrene	AML (relapsed/refractory)	2032	147	32%		221
Bisantrene	Cardioprotection + m6A RNA + anticancer efficacy - solid tumours	2030	551	32%		847
Net cash (30 June 2024)						17
Shares outstanding						170
rNPV/share					A$	6.37
* Assumes 10% royalty for all indications				*fully diluted (34,569,371 options including 20,141,793 piggyback options)*	A$	5.30

Source: MST Access.

Sensitivities and risks

Race is subject to various sensitivities common to specialty pharmaceutical companies engaged in drug development, including clinical development delays and the unpredictable outcome of trials, regulatory decisions, financing, and commercial risks. The key stock-specific sensitivities are outlined below.

Reformulation of bisantrene to RC220

RC220 is a patentable new formulation of bisantrene that will enable safer and more patient-friendly peripheral infusions, and while it contains the same active pharmaceutical ingredient (API) as previous formulations, RC220 is considered a 'new drug product'. As such, RC200 will need to undergo Phase 1 dose-escalation studies. This risk is largely offset by the significant clinical history of bisantrene and its well-understood safety profile in previous formulations.

Single product risk offset by lower development risk and now dual mechanism of action as an anti-cancer therapy

Arguably, Race is exposed to a very high single-product risk given its focus on bisantrene. However, we think this is partially offset by:

- bisantrene's substantial history of clinical development as a chemotherapeutic agent dates back to the 1980s, which included approval to market bisantrene in France in 1990 for AML, an indication the company is currently targeting in clinical trials and for which it has been granted Orphan Drug Designation.
- the rendering of promising data in breast cancer when compared to doxorubicin. As such, bisantrene has a well-understood safety profile which we have assumed will allow it to advance rapidly in Phase 2 trials for all indications.

Further, bisantrene has been recently identified as a potent inhibitor of the RNA modification enzyme FTO (the fat mass and obesity-associated protein) which has been implicated in several cancer types. Inhibiting FTO enzymatic activity has been shown to elicit anti-tumour effects in vitro and in vivo. This raises the prospect of bisantrene being used as a targeted therapy agent, an area Race is currently investigating. As such, this represents a new mechanism of action based on the inhibitory impact of bisantrene on FTO enzyme activity, diversifying to some extent its clinical risk beyond its uses as a pure chemotherapy agent.

Pricing risk associated with clinical strategy and sequencing of clinical development programs

Race seeks to optimise bisantrene's commercial value by targeting the highest-value clinical opportunity of r/r AML in the first instance, thereby establishing its highest price point protected by market exclusivity afforded by its Orphan Drug Designation. As such, Race's commercial prospects rely heavily on the success of the AML trial, where it targets patients presenting with extramedullary forms of the disease. Prior approval in AML, in 1990, and recent positive trial data in this patient population bode well for bisantrene in this indication.

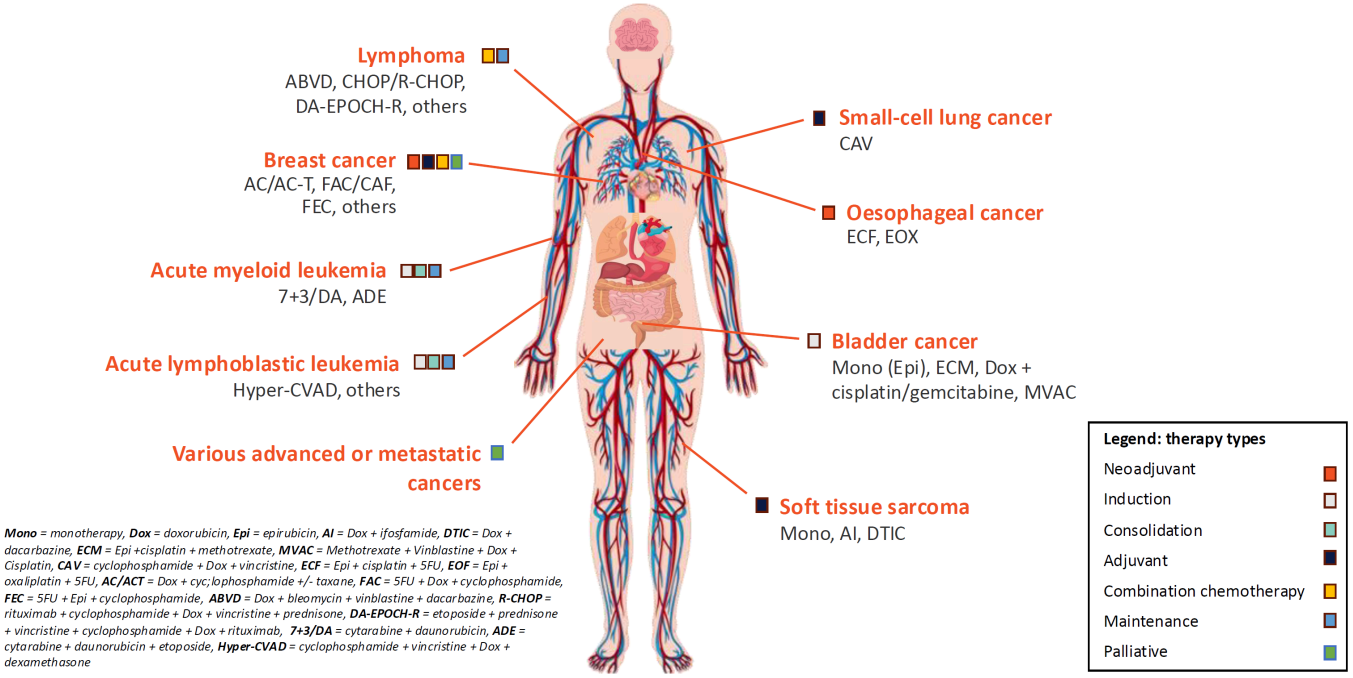
Appendix 1: Introduction to Anthracyclines

Anthracyclines were first isolated from the bark of the *Streptomyces* genus of bacteria in the 1950s. Their mechanism of action involves intercalation into DNA, inhibiting topoisomerase II enzymes, and inducing DNA strand breaks. This ultimately leads to apoptosis of cancer cells. The discovery of daunorubicin, the first anthracycline to be clinically evaluated, marked a significant milestone in cancer treatment and was first trialled against acute myeloid leukemia. The development of doxorubicin in the 1970s delivered a more potent anthracycline with a wider range of applications.

FDA-approved anthracyclines include:

- **Doxorubicin:** Doxorubicin is the most commonly used anthracycline in chemotherapy for cancer. Its broad spectrum of activity against various cancers and extensive clinical experience make it a cornerstone of many chemotherapy regimens. Used for treating various cancers, including breast cancer, lung cancer, and lymphoma.
- **Daunorubicin:** Used for treating acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL).
- **Liposomal doxorubicin (Doxil):** A formulation of doxorubicin that is encapsulated in liposomes, and used for treating ovarian cancer, multiple myeloma, and AIDS-related Kaposi's sarcoma.
- **Epirubicin:** Used for treating breast cancer, lung cancer, and stomach cancer.
- **Idarubicin:** Used for treating AML and ALL.
- **Mitoxantrone:** Used for treating prostate cancer, multiple myeloma, and acute leukemia.
- **Valrubicin:** Used for treating bladder cancer.

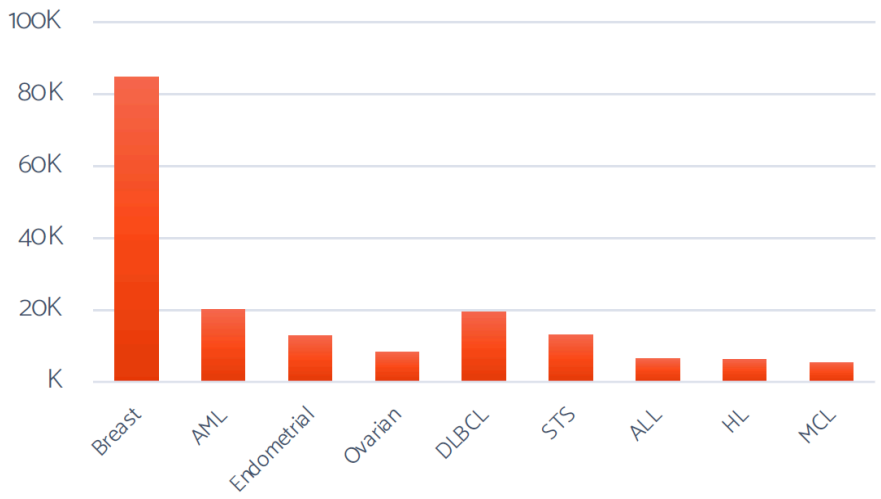
Figure 8: Anthracyclines are one of the most widely used classes of chemotherapeutic agents.



Source: Race Oncology.

Appendix 2: Anthracycline - Use in the USA

Figure 9: Estimated number of patients that receive an anthracycline cycle in the USA each year

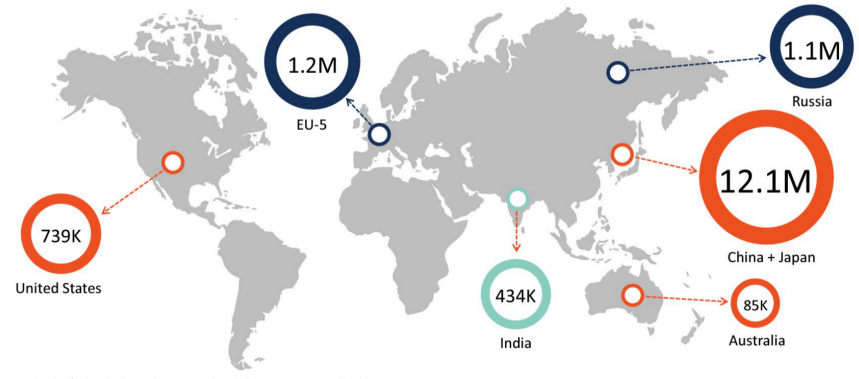


AML = acute myeloid leukaemia; DLBCL = diffuse large B cell lymphoma; STS = soft tissue sarcoma; ALL = acute lymphoblastic leukaemia; HL = Hodgkin's lymphoma; MCL = mantle cell lymphoma

Source: Race Oncology.

Appendix 3: Anthracycline Use Globally

Figure 10: Estimated number of anthracycline doses used per year



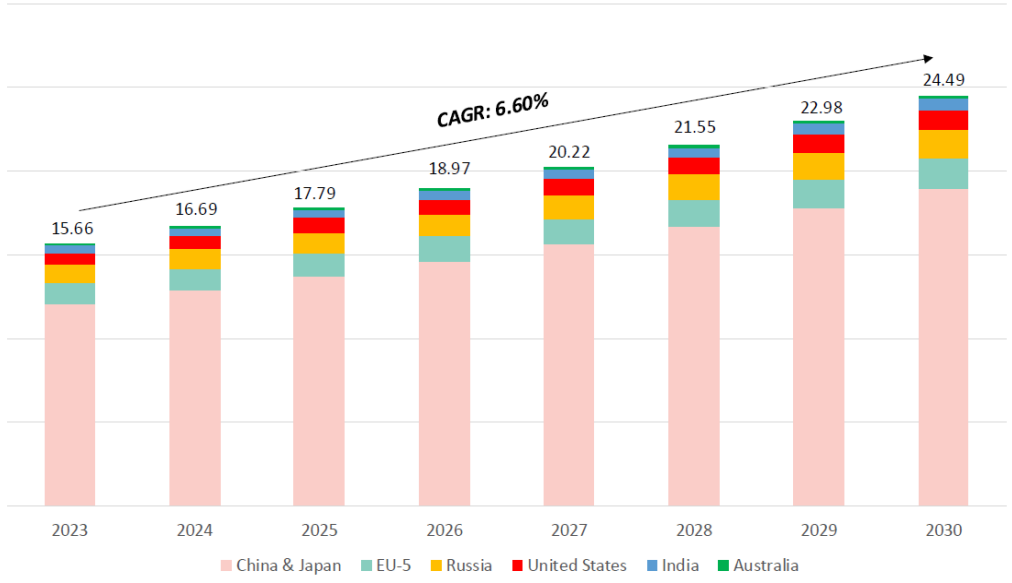
FDA approved uses[2,3]		Other uses[2,3]
Acute lymphocytic leukemia	Ewing sarcoma	Advanced Endometrial Cancer
Acute nonlymphocytic leukemia	Soft tissue sarcoma	Uterine Sarcoma
Acute myelogenous leukemia	Bone sarcoma	Metastatic Hepatocellular Cancer
Hodgkin's lymphoma	Thyroid sarcoma	Advanced Renal Cell Carcinoma
Non-Hodgkin's lymphoma	Neuroblastoma	Thymomas & Thymic Malignancies
Bladder cancer	Wilms tumor	Waldenstrom Macroglobulinemia
Breast cancer	Small cell lung cancer	
Ovarian cancer	Gastric carcinoma	
Osteogenic sarcoma	Bronchogenic carcinoma	
AIDS-related Kaposi's sarcoma	Prostate cancer	
	Multiple myeloma	

1. Estimated number of anthracycline doses used per year – Triangle Insights (ASX Announcement: 14 April 2023)
2. Daunorubicin, doxorubicin, liposomal doxorubicin (Doxil), epirubicin, idarubicin, mitoxantrone, and valrubicin
3. Triangle Insights (ASX Announcement: 14 April 2023)

Source: Race Oncology.

Appendix 4: Anthracycline Use Globally

Figure 11: Estimated number of anthracycline doses used per year (current and projected) (millions)



- According to Data Bridge Market Research, global anthracycline usage is expected to increase by a CAGR of 6.60% between 2023 and 2030

1. IQIVIA MIDAS AUDITED US VOLUME Anthracycline Data, Triangle Insights (ASX Announcement, slide 16: 14 April 2023)
2. Daunorubicin, doxorubicin, liposomal doxorubicin (Doxil), epirubicin, idarubicin, mitoxantrone, and valrubicin
3. Triangle Insights (ASX Announcement: 14 April 2023)

Source: Race Oncology.

Personal disclosures

Chris Kallos, CFA received assistance from the subject company or companies in preparing this research report. The company provided them with communication with senior management and information on the company and industry. As part of due diligence, they have independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in this report. They have taken care to maintain honest and fair objectivity in writing this report and making the recommendation. Where MST Financial Services or its affiliates has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid has, or will, directly or indirectly impact the content provided in this report.

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Race Oncology (RAC.AX) | Price A$1.78 | Valuation A$6.37;

Price and valuation as at 30 September 2024 (not covered)*

Additional disclosures

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