

## Why invest in Race Oncology now?

#### Race is approaching several critical data/value inflection points



#### Validated drug

Used in numerous clinical trials. Established safety and anti-cancer activity



#### Improved drug - RC220

Reformulated for easier administration. 20 years of IP protection



#### Patient focused

Increasing focus on the health of cancer survivors



#### **Data imminent**

Open label RC220 clinical trial starts this quarter



#### Many value drivers

Significant news flow throughout 2025. Positive sentiment in sector



#### **Investor focused**

Ethos, communication and funding strategies



## Original bisantrene

#### A highly effective, but commercially unviable anticancer drug



Approved in France in 1988



Excellent patient outcomes. Complete response rates above 40% as a salvage drug in leukaemia



In a large Phase 3 breast cancer trial bisantrene equalled standard of care, but with less heart damage and hair loss



Lederle (Pfizer) ended commercial development after more than 50 trials due to the difficulty administering the drug to patients



## RC220 – our new, improved bisantrene

#### Race has...

- Created RC220, a new formulation of bisantrene which is more soluble and can be delivered peripherally <sup>1</sup>
- RC220 preserves the PK/PD properties of the earlier clinically validated formulations of bisantrene
- Created new intellectual property (patents) with a long lifespan (20 years)
- Leveraged new science to understand the anti-cancer and cardioprotective mechanism of action of bisantrene<sup>2</sup>
- Built on the >1,500 patients' worth of clinical data across a broad range of cancer indications and generated new
   Phase 2 clinical data



RC220 is a clinically & commercially attractive formulation with long IP life

## RC220 + doxorubicin = improved activity

RC220 shows potent cell-killing activity against a diverse range of human cancers when used alone and in combination with doxorubicin, the most frequently used anthracycline<sup>1</sup>

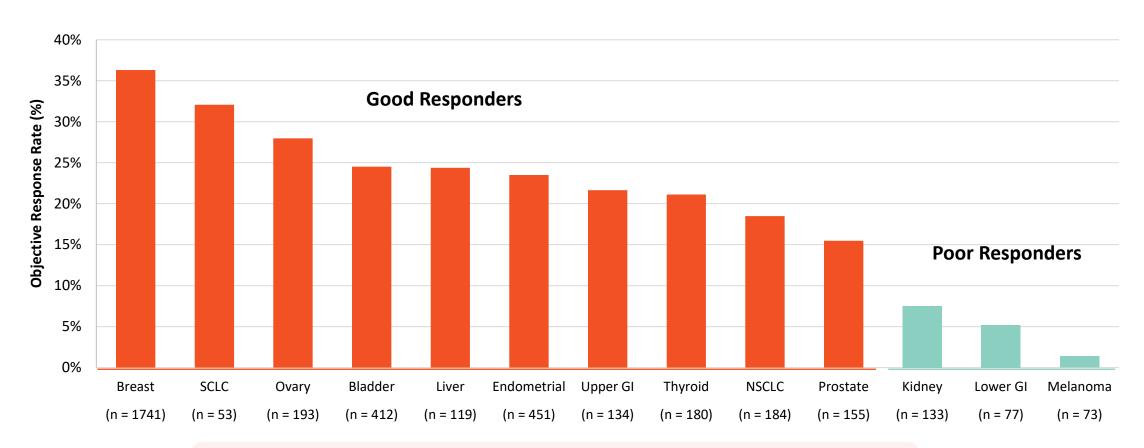
RC220 improves doxorubicin anti-cancer activity in:

85% of all cancers<sup>2</sup>

Cancers where bisantrene improved doxorubicin

	Lung		Prostate	
Lymphoid		Myeloid	Bowe	el
	Sarcoma		Breast	
CNS / Brain		Ovarian	Uterus	
Skin		Pancreas	Upper GI t	tract

# Doxorubicin single agent efficacy in the advanced or metastatic stage of common solid cancers<sup>1</sup>



Doxorubicin can achieve objective response rates of 15% to 40% in advanced/metastatic cancers across many common cancer types<sup>2</sup>

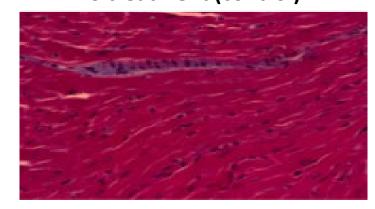
<sup>1.</sup> Common solid cancers evaluated included the ten most prevalent solid tumour types based on the number of new cases diagnosed annually in the United States, China, and Australia.

<sup>2.</sup> Data on file from 73 studies published between 1969 and 2008. Cancer types with treatment data from <50 evaluable patients were excluded (pancreatic and cervical cancer).

GI, gastrointestinal. Upper GI includes esophageal and stomach cancers; Lower GI includes colon and rectal cancers. NSCLC, non-small cell lung cancer. SCLC, small cell lung cancer.

## RC220 = protecting the heart

#### No treatment (control)



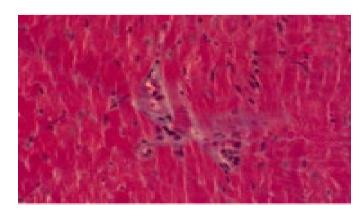
No Fibrosis (scarring)

#### **Doxorubicin**



**Extensive Fibrosis** 

#### RC220 + doxorubicin



**Minimal Fibrosis** 

Animal studies demonstrated cardioprotection by RC220 including increased cardiac function and reduced fibrosis when compared to doxorubicin alone<sup>1</sup>

RACE



## Doxorubicin damages the cardiovascular system

#### VO2peak is the 'gold standard' measure of cardiovascular function



A VO2peak below 18mL/kg/min leaves a patient 'functionally disabled'



Prevents patients performing basic daily living activities



Low VO2peak associated with a 7-9-fold increased risk of heart failure <sup>1</sup>



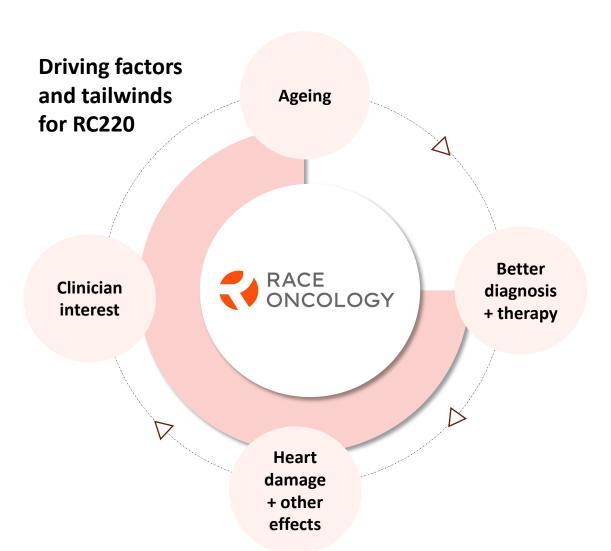
- Equivalent to 8-11 years of ageing

VO2peak will be used in up coming clinical trials to demonstrate clinical benefit of RC220



- 1. Howden, E. J. et al. Traditional markers of cardiac toxicity fail to detect marked reductions in cardiorespiratory fitness among cancer patients undergoing anti-cancer treatment. Eur. Hear.
- J. Cardiovasc. Imaging 22, 451-458 (2021).

## Cancer survivorship – life after treatment



#### **Pressing need for better approaches**

- → 18m cancer survivors in the US ¹ with a 37% increased risk of cardiovascular disease ²
- → A single dose of chemotherapy can cause cardiotoxicity <sup>3</sup> and muscle atrophy <sup>4</sup>
- → Cardiovascular damage is **permanent** <sup>4</sup>

New specialties such as **cardio-oncology** are focused on reducing the damage caused by cancer treatments

<sup>1.</sup> www.cancer.gov

<sup>2.</sup> Florido R, et al. J Am Coll Cardiol, 2022

<sup>3.</sup> Dillon HJ, et al. J Am Coll Cardiol, 2024

<sup>4.</sup> Mallard J, et al. J Cachexia Sarcopenia Muscle, 2024

## **Chemotherapy needs improvement**



**Doxorubicin** is the most widely used chemotherapy. It is highly effective, but can **cause permanent damage** to the cardiovascular system



Current solution – exclude use in high-risk patients and limit dosing of the drugs



Issue – patients not given full effective dose, and heart damage with serious long-term health consequences remains



Opportunity – if the cardiovascular toxicity could be reduced, more patients could be treated <u>and</u> more effective regimens delivered



"Cardiotoxicity, which includes heart failure, is one of the main side effects limiting the use of these effective therapies."

Professor Aaron Sverdlov, University of Newcastle





## Clinical pipeline

Asset	Indication	Sponsor	Discovery	IND enabling	Phase 1	Phase 2	Phase 3	Results & milestones
Bisantrene (RC110)	Acute Myeloid Leukaemia	Chaim Sheba Medical Centre, Phase 2 Israel					Impressive 40% clinical response rate in Phase 2 AML trial completed in June 2020	
Bisantrene (RC110)	Acute Myeloid Leukaemia	Chaim Sheba Medical Centre, Israel	Phase 2					Successfully concluded with 40% response rate in July 2024 <sup>2</sup> . Publication of clinical data anticipated
RC220	Cardioprotection + m <sup>6</sup> A RNA + anti-cancer efficacy - solid tumours <sup>3</sup>	Race Oncology	Phase 1a/b		Q1 CY25	2026		Ethics / governance approvals First patient dosed
RC220	Acute Myeloid Leukaemia <sup>4</sup>	Investigator sponsored	Phase 1/2		H1 CY25			Confirmation of trial
m <sup>6</sup> A RNA molecule development	Next generation bisantrene	Race Oncology	Preclinical					Preliminary results

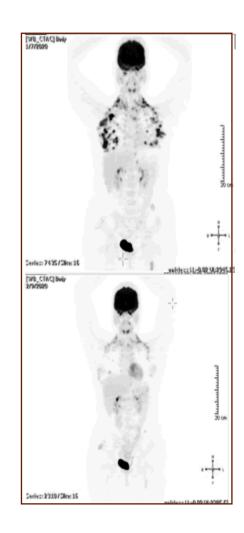
<sup>1.</sup> https://announcements.raceoncology.com/announcements/3617104 | 2. https://announcements.raceoncology.com/announcements/6454612 |

<sup>3.</sup> https://announcements.raceoncology.com/announcements/6429352 | 4. https://announcements.raceoncology.com/announcements/5437127

### Recent clinical trial results

 Sheba 1 (2020) – 40% response rate in 10 AML salvage patients using bisantrene as a single agent – 4/4 clinical response in EMD AML<sup>1</sup>

 Sheba 2 (2024) – 40% response rate in 15 heavily pre-treated AML salvage patients with combination treatment<sup>2</sup>



- Data from these two recent clinical studies is further evidence that RC220 is an effective anti-cancer therapy
- Patients treated in these studies were very unwell, and some had failed up to 9 prior lines of other therapies
- Results from these studies were compelling and beyond expectations of the clinicians

## RC220 Phase 1 open label cardioprotection trial

**Up to 53 patients** across the two stages

Primary endpoints: Safety & optimal Phase 2 dose determination

#### **Exploratory endpoints:**

Standard & advanced cardiac markers including VO<sub>2</sub>peak, m<sup>6</sup>A levels & anticancer efficacy

**Start:** First patient expected Q1 CY2025

Part 1: Advanced solid tumour patients with potential to benefit from doxorubicin therapy

Safety lead in cycle: RC220 IV 21d cycle

Combination cycle 1
RC220 IV + Dox IV

Combination cycles 2-6 RC220 IV + Dox IV

Part 2: Anthracycline naïve solid tumour patients with potential to benefit from doxorubicin therapy

Combination cycle 1
RC220 IV + Dox IV

Combination cycle 2-6
RC220 IV + Dox IV



## Planned clinical trial geographies



- Australia: 4 Sites
- O Hong Kong: 2 Sites
- O South Korea: 4 Sites

# Market opportunity



## RC220 market opportunity

Annual revenue generic doxorubicin - 2023<sup>1</sup>



Annual revenue RC220 cardioprotection + anti-cancer<sup>2</sup>



Note: Forecasted revenue reflect a 50% reduction to the physician-stated adoption rate

USD\$100 base price/cycle for 4 cycles

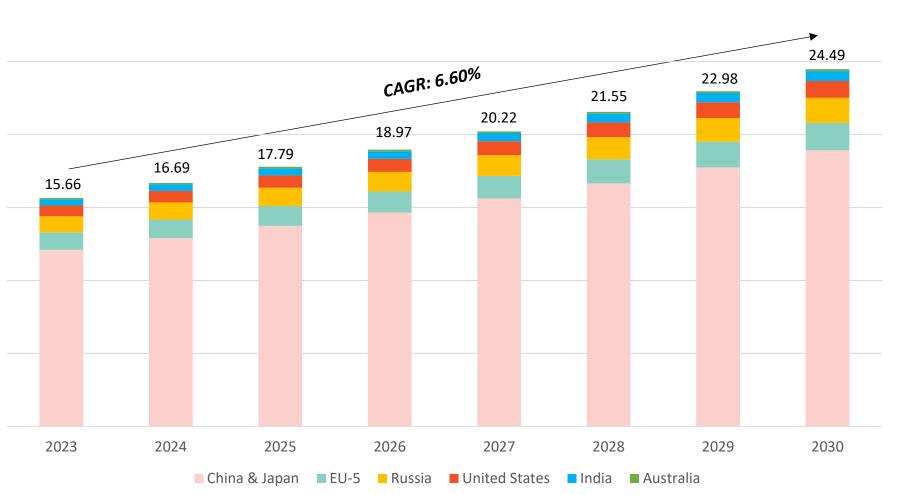
1. https://www.theinsightpartners.com/reports/doxorubicin-market

2. Triangle Insights (ASX Announcement: 14 April 2023)

USD\$15,000 base price/cycle for 4 cycles with a 3% yearly net price increase after launch

## Use of doxorubicin & other anthracyclines is growing<sup>1, 2, 3</sup>

Annual doses of doxorubicin and other anthracyclines (m)<sup>1</sup>



According to <u>Data Bridge Market</u>
<u>Research</u>, 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)

## Views of key opinion leaders

Scope for new cardioprotective therapy in addition to doxorubicin if it increases anticancer efficacy

9-14% of patients on anthracycline regimens develop symptomatic cardiac dysfunction It depends how carefully you look, but at least 30% of patients who are treated with anthracyclines have evidence of cardiac toxicity

Toxicity is highest in the first year, but risk of heart failure remains increased for the rest of their life

I am passionate about reducing the burden of cardiovascular disease for cancer patients



Dr Chau Dang
Medical Oncologist
(Breast Cancer)
Memorial Sloan
Kettering Cancer Center
NY, USA



Prof Aaron Sverdlov
Cardiologist
University of Newcastle,
NSW, Australia



Prof Tom Neilan Cardio-Oncologist Harvard Medical School, Boston, MA, USA



Prof Josh Mitchell
Cardio-Oncologist
Washington University,
St Louis, MO, USA



A/Prof Erin Howden
Head of the Cardiometabolic
Health and Exercise Physiology Lab
Baker Heart and Diabetes Institute,
Melbourne, Australia











## **Corporate snapshot**

Race Oncology is an ASX-listed, clinical stage biopharmaceutical company with a dedicated mission to be at the heart of cancer care. We are well funded to support our current programs.

Key Data				
ASX code	RAC			
Share price	\$1.25 <sup>1</sup>			
Market capitalisation	\$217.15m <sup>1</sup>			
Cash at bank	\$18.78m <sup>2</sup>			
Debt	Nil			
Enterprise value	\$198.37m <sup>1</sup>			
Shares on issue	173,721,858 <sup>1</sup>			
Options on issue	33,136,559 <sup>1</sup>			

- 1. As at 14 March 2025
- 2. As at 31 December 2024



#### **Current Funding**

On 22 November 2023, Race issued a 1 for 20 bonus and piggyback option series to existing shareholders. The conversion of bonus options (\$0.75) raised \$5m and the 19.9m piggyback options (\$1.25) could raise an additional \$25m before expiry 29 May 2026

## **Race Oncology Board**



**Dr Daniel Tillett PhD** Managing Director / CEO

- Former CSO and Executive Director of Race Oncology (2019-2023)
- Responsible for development of RC220 & cardioprotection discoveries
- >25 years of biotech management experience (Nucleics)
- Largest Race Oncology shareholder (>10%)





**Dr Peter Smith PhD Executive Chair** 

- >30 years' experience in healthcare with focus on therapeutics / oncology
- · Founder and CEO of Amala Therapeutics
- Former top-rated pharma analyst with UBS and HSBC







Dr Serge Scrofani PhD MBA Non-Executive Director

- >28 years' experience in healthcare including research, strategy, licensing, M&A
- Principal at Poplar Advisory Pty Ltd, Executive Director at FinCap Pty Ltd, Non-Executive Director at Burnet Institute & The Centre for Eve Research Australia
- Former Vice President of Strategy & Corporate Development at CSL





Dr Megan Baldwin PhD Non-Executive Director

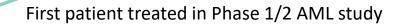
- >25 years' experience in therapeutic drug development in oncology and ophthalmology
- Experienced CEO and currently Founder and Chief Innovation Officer of Opthea Ltd (Nasdag:ASX:OPT)
- Non-Executive Director on public and private company boards and Ausbiotech
- Previously at Genentech in R&D and commercial roles

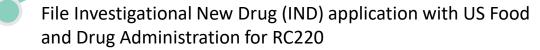




## **Upcoming milestones**

For CY25





Additional preclinical results on bisantrene mechanism of action

Publication of results from Sheba Phase 2 clinical study in AML

Updates on clinical trial progress

First patient treated in Phase 1a/1b RC220 solid tumours (all comers) trial

Governance approval for Phase 1a/1b trial in solid tumours

Ethics approval for Phase 1a/1b trial in solid tumours

Contract executed with CRO to support Phase 1a/1b RC220 trial in sold tumours

The RC220 trial is open label so regular news is expected

## Typical risks in drug development (illustrative)

	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III NE	A MKT		
	Key risks Failure to find suitable molecule	Lack of preclinical efficacy or toxicity	Toxic in man	Lack of efficacy	Lack of efficacy, emerging toxicity	Data insufficient for approval		
ug maning it to mai net	Known molecule	Preclinical efficacy and toxicity known for combination	Known toxicity as single agent and in other combinations	Efficacy established for single agent and other combinations	Efficacy and safety established for single agent	advanta due to th	ce has a distinct ntage with RC220 to the prior clinical tess of bisantrene	
م م								
כוומוונע כו מ מ						80%	96%	
					50%			
	1%	3%	10%	25%				
·	1 2	3 4 5	5 6 7	7 8 9	10 11 12	13	14	Years

## **Key highlights of Race Oncology**

- 1 RC220 derisked & clinically proven anticancer drug offering ~80% chance of success - not ~3% common in oncology
- Solves a real & significant health problem
   permanent damage caused by
   chemotherapy, increasing due to longevity
   and increasing population
- RC220 builds on a major existing market of 20m anthracycline doses/year, potential sales >US\$5B/year
- Low-cost development with an opportunity for a rapid pathway to market via the FDA accelerated approval process from Phase 2
- Management invested with proven technical, deal & ASX track record





## Questions

Race Oncology

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## Contact

#### **PETE SMITH**

**Executive Chair** 



+61 2 8051 3043



peter.smith@raceoncology.com



www.raceoncology.com

#### **JANE LOWE**

Investor & Media Relations



+61 411 117 774



iane.lowe@irdepartment.com.au