

July 2024



# AT THE HEART OF CANCER CARE

Pete Smith PhD, Executive Director

Bioshares 2024

ASX: RAC | RACE ONCOLOGY LIMITED | ABN 61 149 318 749



# Important Notice and Disclaimer

The material in this presentation has been prepared by Race Oncology Limited (ACN 149 318 749) (Company).

## THIS IS NOT A PROSPECTUS

This presentation is not a prospectus, product disclosure statement or disclosure document for the purposes of the Corporations Act 2001 (Cth) (Corporations Act). It has not been lodged with the Australian Securities and Investments Commission, or otherwise.

Statements in this presentation are made only as of the date of this presentation unless otherwise stated and the information in this presentation remains subject to change without notice. No representation or warranty, express or implied, is made as to the fairness, accuracy or completeness of the information, opinions and conclusions contained in this presentation or any other information the Company or any other person otherwise provides to you.

This presentation does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. Any securities described in this presentation have not been, and will not be, registered under the US Securities Act of 1933, as amended (Securities Act) or the securities laws of any state or other jurisdiction of the United States and may not be offered or sold in the United States except in transactions exempt from, or not subject to, registration under the Securities Act and applicable US state securities laws. This presentation may not be released to US wire services or distributed in the United States. The distribution of this presentation in other jurisdictions outside Australia may also be restricted by law and any such restrictions should be observed.

## NOT FINANCIAL PRODUCT ADVICE

No attempt has been made to independently verify the information contained in this presentation. The information in this presentation is of a general nature and does not constitute financial product advice, investment advice or any recommendation. Nothing in this presentation constitutes legal, financial, tax or other advice. The information in this presentation does not take into account your particular investment objectives, financial situation or needs, or those of any other person. You should make your own assessment of an investment in the Company and should not rely on this presentation. In all cases, you should conduct your own investigations and analysis of the financial condition, assets and liabilities, financial position and performance, profits and losses, prospects and business affairs of the Company and its business, and the contents of this presentation. You should seek legal, financial, tax and other advice appropriate to your jurisdiction.

## THIS PRESENTATION DOES NOT CONSTITUTE AN OFFER OR ADVERTISEMENT

This presentation does not constitute an invitation, offer or recommendation to apply for or purchase Shares and does not contain any application form for Shares. This presentation does not constitute an advertisement for an offer or proposed offer of Shares.

## NO LIABILITY

The Company has prepared this presentation based on information available to it at the time of preparation, from sources believed to be reliable and subject to the qualifications in this presentation. No representation or warranty, express or implied, is made as to the fairness, accuracy, completeness or correctness of the information, opinions and conclusions contained in this presentation. To the maximum extent permitted by law, none of the Company or its subsidiaries or affiliates or the directors, employees, agents, representatives or advisers of any such party, nor any other person accepts any liability for any loss arising from the use of this presentation or its contents or otherwise arising in connection with it, including without limitation, any liability arising from fault or negligence on the part of the Company or its subsidiaries or affiliates or the directors, employees, agents, representatives or advisers of any such party.

## FORWARD-LOOKING STATEMENTS

This presentation may contain forward-looking statements that are subject to risk factors associated with an oncology company. Forward looking statements can be identified by the use of forward-looking terminology, including, without limitation, the terms “believes”, “estimates”, “anticipates”, “expects”, “predicts”, “intends”, “plans”, “goals”, “targets”, “aims”, “outlook”, “guidance”, “forecasts”, “may”, “will”, “would”, “could” or “should” or, in each case, their negative or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors because they relate to events and depend on circumstances that may or may not occur in the future and may be beyond the Company’s ability to control or predict which may cause the actual results or performance of the Company to be materially different from the results or performance expressed or implied by such forward-looking statements. Forward looking statements are based on assumptions and are not guarantees or predictions of future performance. No representation is made that any of these statements or projections will come to pass or that any forecast result will be achieved, nor as to their accuracy, completeness or correctness. Similarly, no representation is given that the assumptions upon which forward looking statements may be based are reasonable.

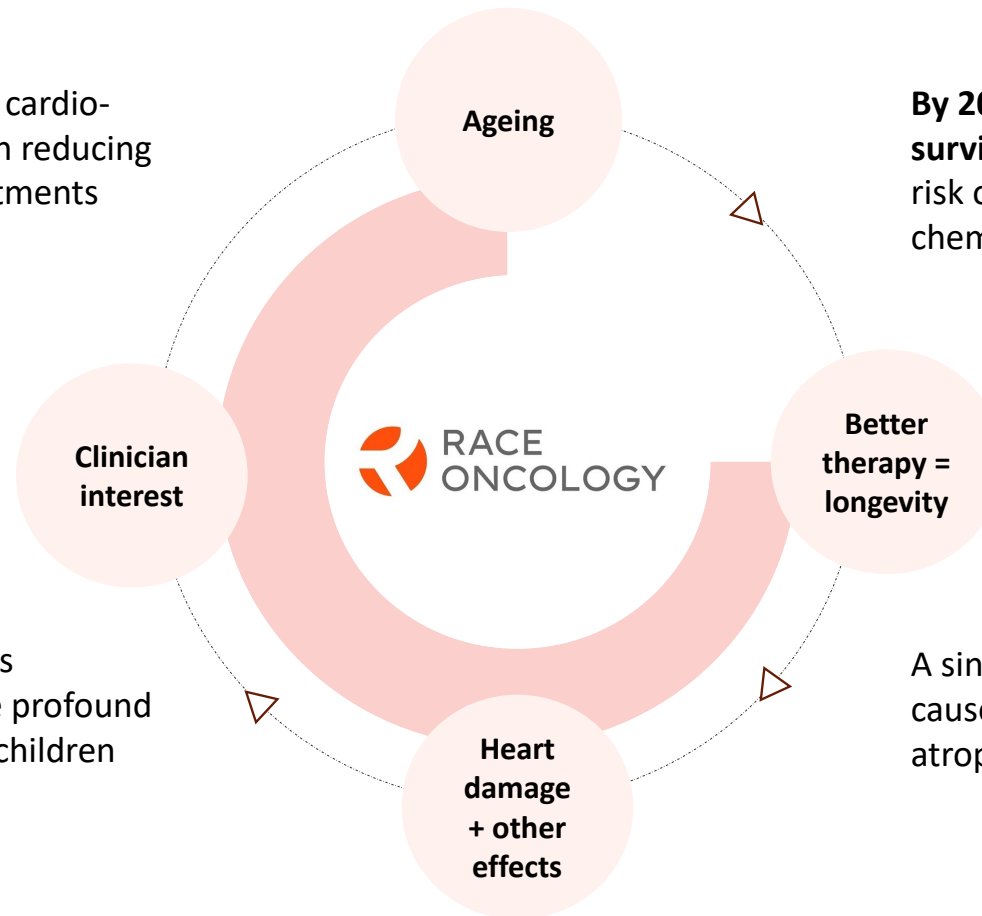
# Cancer survivorship



# Cancer survivorship – life after treatment

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

By 2023, there will be 22.5m cancer survivors in the US<sup>1</sup> with a 37% increased risk of cardiovascular disease for post-chemotherapy patients<sup>2</sup>



Cardiovascular toxicity is permanent<sup>4</sup> and can be profound for certain groups, e.g. children

A single dose of chemotherapy can cause cardiotoxicity<sup>3</sup> and muscle atrophy<sup>4</sup>

1. Miller KD, *et al.* Cancer J Clin, 2022  
2. Florido R, *et al.* J Am Coll Cardiol, 2022

3. Dillon HJ, *et al.* J Am Coll Cardiol, 2024  
4. Mallard J, *et al.* J Cachexia Sarcopenia Muscle, 2024

# Chemotherapy needs improvement



**Anthracyclines\*** are the most widely used class of chemotherapeutics. They are 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 and more effective regimens delivered**



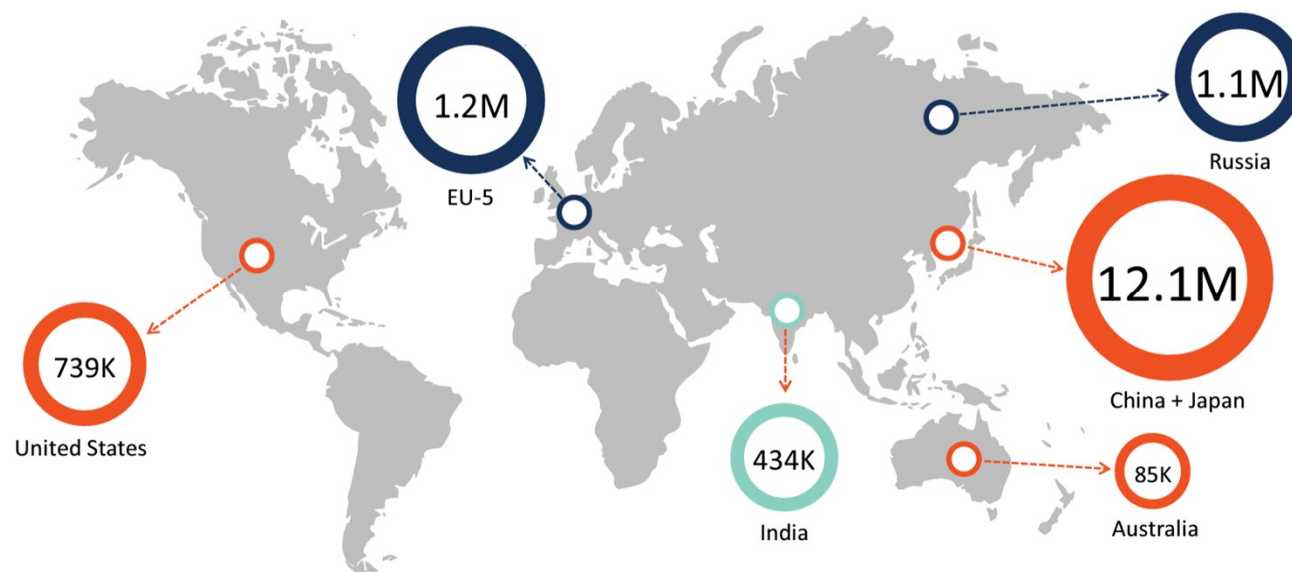
*“Cardiotoxicity, which includes heart failure, is one of the main side effects limiting the use of these effective therapies.”*

Professor Aaron Sverdlov, University of Newcastle

\* Approved anthracyclines include doxorubicin, daunorubicin, epirubicin, idarubicin and valrubicin

# Global anthracycline chemotherapy use<sup>1</sup>

## Global anthracycline usage<sup>1</sup>



## FDA approved uses<sup>2, 3</sup>

Acute lymphocytic leukemia	Ewing sarcoma
Acute nonlymphocytic leukemia	Soft tissue sarcoma
Acute myelogenous leukemia	Bone sarcoma
Hodgkin's lymphoma	Thyroid sarcoma
Non-Hodgkin's lymphoma	Neuroblastoma
Bladder cancer	Wilms tumor
Breast cancer	Small cell lung cancer
Ovarian cancer	Gastric carcinoma
Osteogenic sarcoma	Bronchogenic carcinoma
AIDS-related Kaposi's sarcoma	Prostate cancer
	Multiple myeloma

## Other uses<sup>2, 3</sup>

Advanced endometrial cancer
Uterine sarcoma
Metastatic hepatocellular cancer
Advanced renal cell carcinoma
Thymomas & thymic malignancies
Waldenstrom macroglobulinemia

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)



# Clinical development of bisantrene



# Corporate snapshot

Race Oncology is an ASX-listed, clinical stage biopharmaceutical company with a dedicated mission to be at the heart of cancer care.

## Key data

ASX code	RAC
Share price	\$1.70 <sup>1</sup>
Market capitalisation	\$289.52m <sup>1</sup>
Cash at bank	\$16.2m <sup>2</sup>
Debt	Nil
Enterprise value	\$273.32m <sup>1</sup>
Shares on issue	170,311,803 <sup>1</sup>
Options on issue	29,169,753 <sup>1</sup>

1. As at 5 July 2024
2. As at 31 March 2024

## Race 12-month trading history



## Current Bonus & Piggyback Options Offer

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 piggyback options (\$1.25) could potentially raise an additional \$25M before expiry 29 May 2026



# Bisantrene's history of clinical success

## Breast cancer <sup>1</sup>

471 patients across 9 Phase 2 & 3 clinical trials

Less toxic than standard-of-care doxorubicin

- reduced myelosuppression
- reduced alopecia (hair loss)
- no cardiac failures

**Phase 3.** Overall patient survival greater in bisantrene treated patients (HR 0.92 95%CI = 0.7-1.21)

1. Cowan, J. D. et al. . Natl. Cancer Inst. 83, 1077–1084 (1991)

## Acute Myeloid Leukaemia

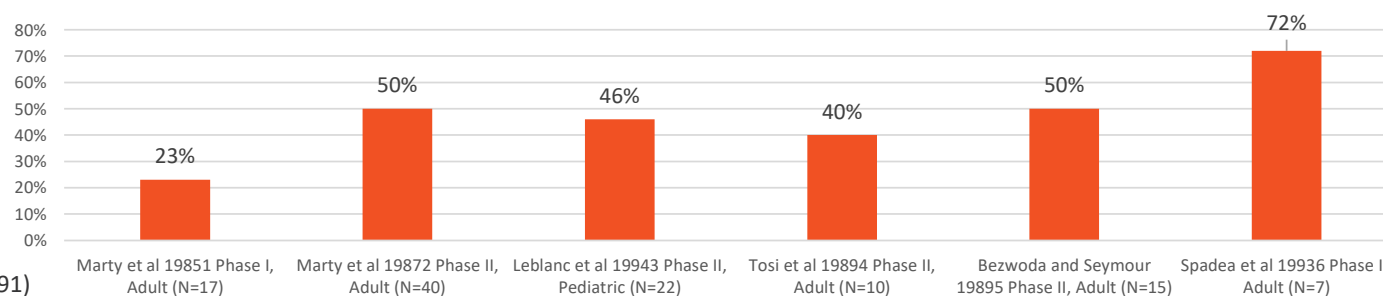
Approved in France in 1988, but Lederle (Pfizer) ended commercial development of bisantrene due to solubility issues

Complete response rates above 40% as a salvage agent for Acute Myeloid Leukaemia (AML)

Bisantrene cured two French girls with r/rAML in the 1980 & 90s. Both women are alive today and have their own families

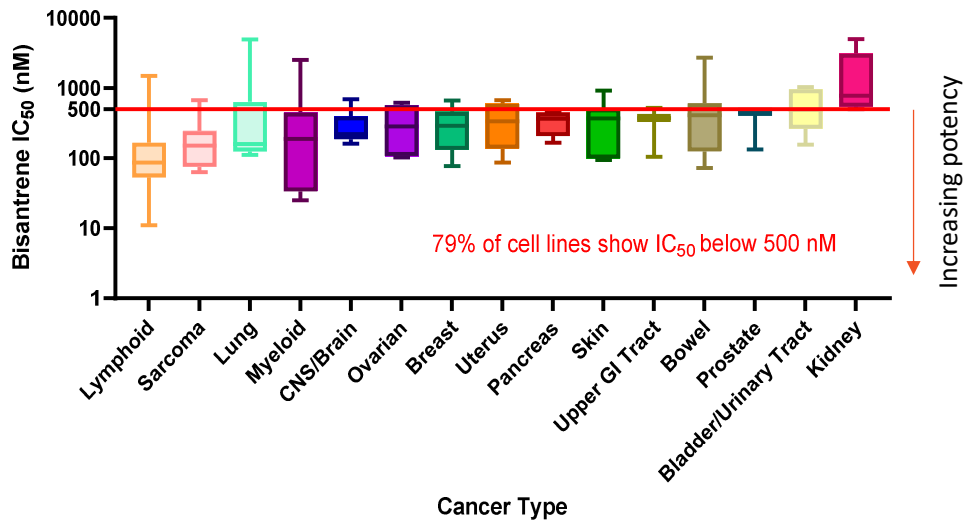


Complete responses with bisantrene in paediatric and adult Acute Myeloid Leukaemia patients



# Bisantrene + doxorubicin = improved anti-cancer activity<sup>1</sup>

Bisantrene shows potent cell-killing activity against a diverse range of human cancers when used alone and in combination with doxorubicin, the most commonly used anthracycline



Bisantrene improves doxorubicin anti-cancer activity in

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

**Bisantrene shows broad anti-cancer activity.** The half-maximal inhibitory concentration (IC<sub>50</sub>) 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<sub>50</sub> value. The upper and lower edges of the box represent the 75th and 25th percentiles, respectively. Whiskers show the minimum and maximum IC<sub>50</sub> values observed for each cancer cell type.

1. ASX Announcement: 21 September 2023 | 2. 143 cancer cell lines screened.

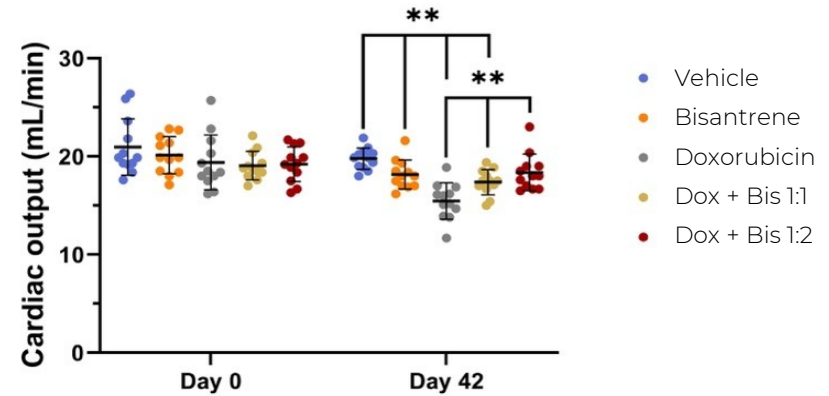
# Bisantrene + doxorubicin = protecting the heart <sup>1</sup>

Bisantrene protects the hearts of mice from permanent damage caused by the anthracycline, doxorubicin

Heart protection was achieved using higher levels of chemotherapy treatment with no extra toxicity observed

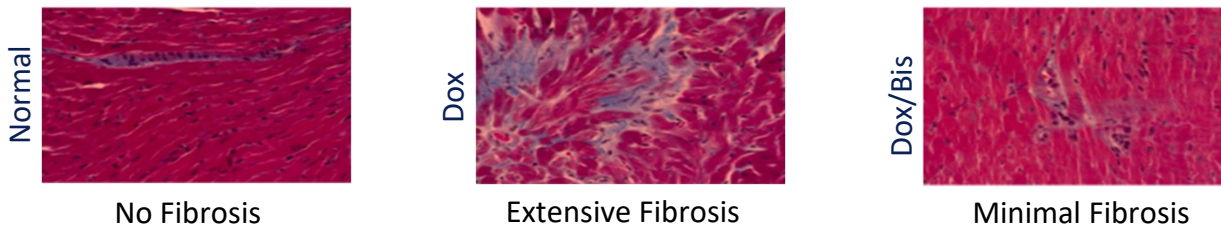
Data supports using bisantrene with anthracyclines to protect the hearts of patients from chemotherapy

Promise of better cancer treatment with reduced side effects



Cardiac output of C57BL/6 mice treated with either vehicle control (blue), bisantrene alone (orange), doxorubicin alone (grey), 1:1 molar ratio doxorubicin + bisantrene (yellow), or 1:2 molar ratio doxorubicin + bisantrene (red) at Day 0 and Day 42. All mice were dosed intravenously weekly with either: vehicle control, 7.33 mg/kg bisantrene, 5 mg/kg of doxorubicin, 5 mg/kg of doxorubicin + 3.67 mg/kg of bisantrene, 5 mg/kg of doxorubicin + 7.33 mg/kg of bisantrene. n=12 per group. Error bars = SEM. \*\*p < 0.01.

## Strong protection from anthracycline-induced cardiomyopathy



*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*

1. ASX Announcement: 30 June 2022

# Building on bisantrene's history

## Race has...

- Created RC220, a **new formulation** of bisantrene which is more soluble and can be delivered intravenously <sup>1</sup>
- RC220 **preserves the PK/PD** properties of the earlier clinically validated formulations of bisantrene
- Created **new intellectual property** with a long lifespan (20 years)
- Leveraged new science to understand bisantrene's **anti-cancer** and **cardioprotective** mechanism of action <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 in AML**
- RC220 is a new drug product, requiring a full non-clinical toxicology & safety data package – **delivered in June 2024** <sup>3</sup>



**RC220 is a clinically and commercially attractive formulation with long IP life**

1. ASX Announcement: 9 November 2023 | 2. ASX Announcement: 21 September 2023 | 3. ASX Announcement 27 June 2024

# RC220 cardioprotection clinical program

An 'all comers' Bayesian dose escalation Phase 1a/1b trial of RC220 in any solid tumour patient where anthracycline use is indicated

**Size:** 25-50 patients; up to 10 sites in Australia and internationally

**Sponsor:** Race Oncology

**Primary endpoints:** Safety & optimal Phase 2 dose

**Exploratory endpoints:** Standard & advanced cardiovascular markers including VO<sub>2</sub>Peak; m<sup>6</sup>A RNA levels and anti-cancer efficacy

**Start:** First patient H2 CY2024

**Timeline:** 12-18 months due to Bayesian design uncertainty around total patient number (patient recruitment)

Cohort extension (Phase 1b) in patient sub-groups to optimise bisantrene dosage in different drug combination settings

Expands market potential of bisantrene beyond breast cancer to all cancers where anthracyclines are used

Effect of bisantrene on the m<sup>6</sup>A RNA system will be collected by using a lead-in dose of bisantrene given 7 days prior to the first anthracycline combination dose – provides 'clean' PK/PD, m<sup>6</sup>A RNA & single-agent anti-cancer efficacy data

**Cost: A\$9 million, fully funded (based on 40 patients)**



*VO<sub>2</sub>Peak offers a clinically relevant endpoint that can provide clear evidence of cardioprotection and improvement in patient Quality of Life<sup>1</sup>*

1. Foulkes SJ *et al.* Circulation, 2023

# 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 <sup>3</sup>	Phase 1/2		H2 CY24			Confirmation of trial
m <sup>6</sup> A RNA molecule development	Next generation bisantrene	Race Oncology	Preclinical					Preliminary results



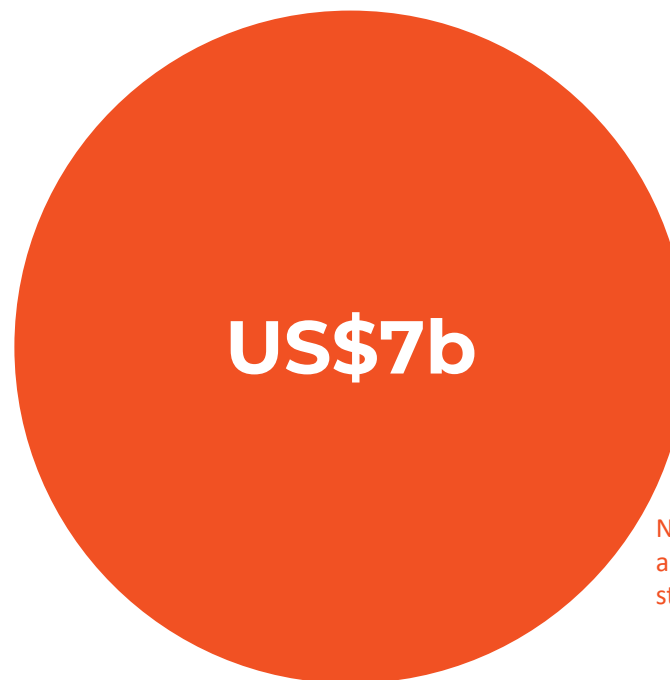
# Bisantrene Market Potential – World

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



USD\$100 base price/cycle for 4 cycles

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



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

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

1. <https://www.theinsightpartners.com/reports/doxorubicin-market>  
2. Triangle Insights (ASX Announcement: 14 April 2023)

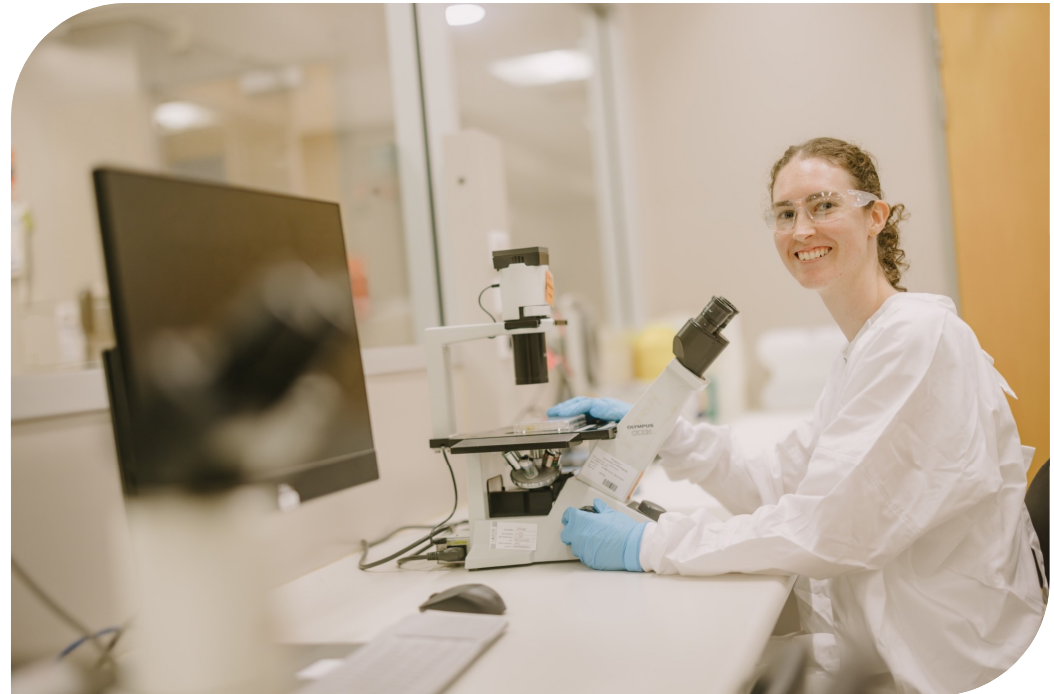
# Recent & upcoming milestones<sup>1</sup>

H2 CY2023 / H1 CY2024	H2 CY2024	H1 CY2025
<ul style="list-style-type: none"> <li>Interim results released from Sheba 2 study of bisantrene RC110 in AML patients – 40% response rate</li> </ul>	<ul style="list-style-type: none"> <li>Distinguished Oncologist Daniel Von Hoff Joins as Consultant</li> </ul>	<ul style="list-style-type: none"> <li>Additional preclinical results on bisantrene mechanism of action</li> </ul>
<ul style="list-style-type: none"> <li>Proposal received for investigator led study of RC220 in AML patients</li> </ul>	<ul style="list-style-type: none"> <li>Ethics submission for Phase 1a/1b trial in solid tumours</li> </ul>	<ul style="list-style-type: none"> <li>File Investigational New Drug (IND) application with US Food and Drug Administration for RC220</li> </ul>
<ul style="list-style-type: none"> <li>cGMP RC220 manufacturing campaign completes</li> </ul>	<ul style="list-style-type: none"> <li>Governance approval for Phase 1a/1b trial in solid tumours</li> </ul>	<ul style="list-style-type: none"> <li>First patient treated in Phase 1/2 AML study</li> </ul>
<ul style="list-style-type: none"> <li>Leading cardiorespiratory expert, A/Prof Erin Bowden joins SAB</li> </ul>	<ul style="list-style-type: none"> <li>First patient treated in the RC220 solid tumour (all comers) Phase 1a/b Trial</li> </ul>	<ul style="list-style-type: none"> <li>Initial results from RC220 Phase 1 solid tumour trial</li> </ul>
<ul style="list-style-type: none"> <li>cGMP RC220 released by Ardena for use in human clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>Updates on new molecules to target the m<sup>6</sup>A RNA pathway</li> </ul>	
<ul style="list-style-type: none"> <li>Bisantrene shows potent anti-cancer activity in AML models</li> </ul>	<ul style="list-style-type: none"> <li>Publication of results from Sheba Phase 2 clinical study in AML</li> </ul>	
<ul style="list-style-type: none"> <li>Completion of RC220 non-clinical safety and toxicology studies</li> </ul>	<ul style="list-style-type: none"> <li>Updates on clinical trial progress for RC220 cardioprotection study</li> </ul>	
<ul style="list-style-type: none"> <li>Appoints George Clinical as CRO</li> </ul>	<ul style="list-style-type: none"> <li>Commence Phase 1/2 AML study</li> </ul>	

1. All dates are estimates and subject to change

# Key highlights of Race Oncology

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



# Questions

---



Race Oncology