



# AGM PRESENTATION 2018

Managing Director, Peter Molloy

# Corporate Snapshot

## Shares on Issue (RAC)

Ordinary		77m
Performance Shares		10m
Options		26m
Shareholders (22/11/18)		876

## Market Capitalization (AUD)

Share price (23/11/18)		\$0.13
Market Capitalisation		\$10 m
Cash (30/9/18)		\$2.8 m

## Major Shareholders

Update Pharma, Inc.	12 m	16.0%
Peter Molloy (loan shares)	4 m	5.2%



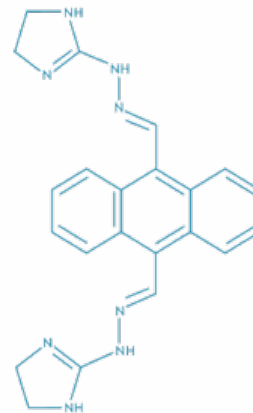
# Overview

- Bisantrene is a chemotherapy drug that was tested against a range of cancers in the 1980s
- Race is rediscovering and repurposing bisantrene for the treatment of Acute Myeloid Leukaemia (AML)
- Race owns new patents, *Orphan Drug* designation and a *Rare Paediatric Disease* designation in the US
- In 2019, Race intends to start an adult clinical trial in r/r AML to obtain US FDA approval and a paediatric trial to obtain a valuable *Priority Review Voucher*
- Race is seeking a licensing partner to fund these trials and commercialise bisantrene



## A small molecule chemotherapy drug with promise

- Originally developed by Lederle in the 1980s with the goal of creating a non-cardiotoxic anthracycline
- Numerous clinical studies confirmed its lack of cardiotoxicity and higher tolerability than anthracyclines, but in a US Phase 3 breast cancer study (1991), it showed inferior activity to doxorubicin (a widely-used anthracycline at the time)
- After Wyeth acquired Lederle in 1994 – and despite impressive clinical activity in AML – Bisantrone was abandoned and the original patent expired in 1998



*small-molecule  
cancer drug,  
related to the  
anthracyclines*



# Bisantrene's performance in previous Phase 2 AML studies

## Impressive activity in AML

- 136 r/r AML patients treated in nine Phase 2 studies
- Clinical response was nearly 50% overall

## Approval in France

- Bisantrene was approved in France in 1988 for r/r AML, but never commercialised
- The approval lapsed and was later withdrawn by Wyeth

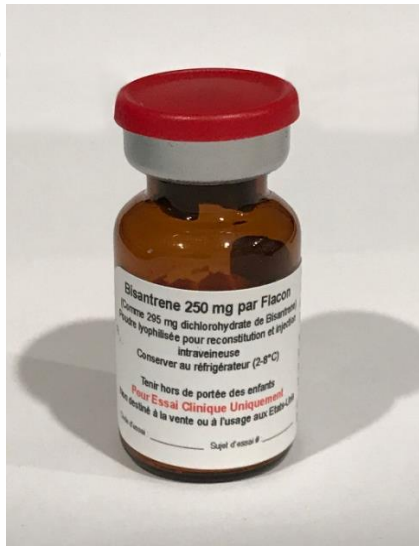
Study	Adult or Pediatric	AML pts treated with bisantrene	CR	CR rate
Marty et al., 1984	Adult	10	8	80%
Isnard et al., 1987	Adult	37	25	68%
Tosi et al., 1989	Adult	10	4	40%
Mills et al., 1989	Adult	27	3	11%
Bezwoda, 1989	Adult	15	7	47%
Fenaux et al., 1991	Adult	4	3	75%
Spadea et al., 1993	Adult	7	5	71%
Leblanc et al., 1994	Pediatric	13	5	38%
Leblanc et al., 1995	Pediatric	13	2	15%
Total		136	62	46%

Patients were heavily pre-treated with chemotherapy, i.e., relapsed or refractory AML

# Race is rediscovering and repurposing Bisantrene

## Race now effectively owns Bisantrene

- Race owns new patents that are granted in US and expire 2034
- Race owns the original trademark (Zantrene®)
- Race owns a US Orphan Drug Designation in AML (7 years exclusivity after approval)
- Race has access to the original IND from NCI
- Race has manufactured GMP drug substance (API) and drug product



### GMP drug product:

250mg lyophilised powder in vials for reconstitution & infusion via central venous catheter



# Race's goals

Race's goal is to create value for our investors in three ways:

1. Move Bisantrene towards FDA approval for adult AML
2. Develop Bisantrene for paediatric AML and secure a *Priority Review Voucher* that can be sold
3. Generate usage and revenues through Named Patient Programs outside US

→ Race is endeavouring to monetise these via an active licensing program

# 2018 Review: Operations





# Named Patient Program

## Initiatives and achievements

- Completed manufacturing of 1<sup>st</sup> batch of Bisantrene for NPP supply
- Completed market research studies with haem-oncologists in France, Italy and UK
- Conducted three group meetings with doctors (two in France, one UK) to discuss Bisantrene clinical use
- Executed agreement with Durbin PLC to provide NPP distribution and market access
- Secured MHRA approval for importation and supply of Bisantrene under NPP
- Terminated agreement with CarthaGenetics; recruited Dr Samar Al-Behaisi to drive NPP
- Despite our best efforts, NPP sales have so far eluded the Company

## Plan

- Continue to build awareness of Bisantrene, pursue contemporary clinical use of Bisantrene under NPP



# FDA approval pathway: adult r/r AML

## Initiatives and achievements

- Bisantrene patents were granted in US
- Secured NCI collaboration giving RAC right to all NCI Bisantrene data
- FDA confirmed Bisantrene qualifies for 505(b)(2)
- Appointed CRO (Novotech) to run the international clinical trial
- Appointed Chief Medical Officer (Dr Samar Al-Behaisi) to manage the CRO and the trial

## Plan

- Complete manufacturing of new Bisantrene stock for the clinical trial
- Finalise the clinical protocol based on investigator feedback
- File the IND (Investigational New Drug) application with FDA by end Q1 2019
- Gain FDA acceptance of the protocol
- Prepare to start the trial in 2<sup>nd</sup> half of 2019



# Paediatric program

## Initiatives and achievements

- Bisantrene was awarded a 'Rare Paediatric Disease' designation by FDA, which opens the door to a 'Priority Review Voucher' (PRV)
- Published case reports on the use of Bisantrene in two French girls, who are still alive today because of Bisantrene
- Drafted a paediatric clinical protocol based on discussions with paediatric haematologists
- Executed agreement with Mr Tom Lee in Houston to pursue potential paediatric co-development program with M.D. Anderson Cancer Center

## Plan

- Add paediatric protocol to IND, once opened
- Map investigational sites for a paediatric trial
- Prepare to start the paediatric trial in parallel with the adult trial



# Licensing program: Biosynergy

## Initiatives and achievements

- Agreement with Biosynergy (Dr John Cullity, RAC director) to undertake partnering of Bisantrene

## Plan

- Active outreach to prospective licensing partners for Bisantrene (focus on US rights), including meetings at various conferences over next 6-9 months

## Goal

- Partnership that sees Race receiving:
  - non-dilutive license fees
  - funding for the adult and/or paediatric trials



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## 2019 prospects



# Cash position and expenses

- At 30 Sept 2018, RAC had \$2.845 m in cash reserves
- Based on projected operating expenses, this is expected to more than cover operational costs through 30 June 2019
- Expenses management for remainder of FY19
  - Payroll expenses (management and board) expected to decline
  - Business development expenses associated with NPP activities in Europe expected to decline
  - Clinical trial expenses deferred until FY20 and may be defrayed through partnerships



## Objectives for remainder of FY19

- See Bisantrene used in treating AML patients under NPP
- Complete manufacturing of Bisantrene stock for the clinical trial(s)
- Finalise the clinical protocol and file IND for the adult AML trial
- Gain FDA acceptance of the protocol
- Finalise the paediatric trial protocol and establish clinical sites to conduct the trial
- Through Biosynergy, generate interest from licensing partners to fund the trials

