

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



What is 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 – Bisantrene 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- The approval lapsed and was later withdrawn by Wyeth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



GMP drug product:

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

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



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





Named Patient Program

Initiatives and achievements

- Completed manufacturing of 1st 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 2nd 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





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

