AUSTRALIAN
RESEARCH
INDEPENDENT INVESTMENT RESEARCH

Race Oncology (RAC)

July 2016

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INVESTMENT RESEARCH

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INVESTMENT RESEARCH

Race Oncology (RAC)

Note: This report is based on information provided by Race Oncology as at July 2016

Investment Profile	
Share Price ($) as at 19 July 2014	$0.22
Issue Capital:	53
Ordinary Shares (M)	52.7
Options (M)	19.0
Performance Shares	10.0
Fully Diluted (M)	81.7
Market Capitalisation (M)	11.6
12 month L/H ($)	0.22/0.28

Board and Management

Directors:

Dr Bill Garner (Chairman)

Peter Molloy (CEO)

Brendan De Kauwe

Chris Ntoumenopoulos

Management:

Dr John Rothman (Chief Scientific Officer)

The investment opinion in this report is current as at the date of publication. Investors and advisers should be aware that over time the circumstances of the issuer and/or product may change which may affect our investment opinion.

SIGNIFICANT MARKET OPPORTUNITY WITH THE RE-DEVELOPMENT OF BISANTRENE

Race Oncology is a drug development company focused on the re-development of Bisantrene for the treatment of Acute Myeloid Leukaemia (AML). We say 're-development' because Bisantrene, a small molecule anthracene derivative, gained its first marketing approval 26 years ago. The drug originated back in the 1980s in a successful development programme overseen by the major US pharma company Lederle. That company had secured the regulatory approval in France in 1990, however, unusually, corporate interest in the new drug waned after this, due to a succession of pharma company mergers. In 2013 the US bio-entrepreneurs Dr John Rothman and Dr Bill Garner, attracted by Bisantrene's apparent efficacy and safety profile, and taking advantage of knowledge in oncology that had arisen since the 1990s, started work on a new patent-protected Bisantrene. Their company, Update Pharma, backdoored the Bisantrene technology into an Australian unlisted shell called Coronado Resources, culminating in an ASX IPO during June 2016, in which $4.3m was raised at 20 cents per share. Renamed Race Oncology Ltd, this company commenced trading on the ASX during July 2016. Race Oncology intends to launch Bisantrene in Europe under a Named Patient Programme for AML during 2017/18, while in the US the company is hoping to gain approval for its drug in AML via the 505(b)(2) route. To that end preparations are underway for an IND filing ahead of an envisaged Phase II 'bridging' study to be followed by a pivotal study. Race believes that, subject to favourable performance in the pivotal, it will be in a position to seek FDA approval for Bisantrene around 2020/21.

KEY POINTS

Key point 1 – Bisantrene is a safe and effective drug for the treatment of Acute Myeloid Leukaemia (AML). Compared with the regular anthracyclines that have been the standard of care for AML, Bisantrene has considerably less cardiotoxicity. The drug gained approval in France after a number of studies showing that around half of relasped and refractory AML patients could enjoy a Complete Response.

Key point 2 - Demand for the drug is likely to be favourable, given the fact that there have been relatively few new treatment options for AML over the last three decades, particularly for 'salvage' patients that have failed first line chemotherapy.

Key Point 3 - Bisantrene is an early revenue opportunity, with Race believing that it will be able to launch the product in Europe through a Named Patient Programme (NPP) during 2017/18. The market potential of this NPP could be in the order of US$30-50m.

Key Point 4 - Bisantrene's path to a US launch is relatively straightforward, with the company envisaging a Phase II bridging study under an IND from the FDA, potentially using the 505(b)(2) pathway, to be followed by, potentially, a single Phase III. Race envisages that subject to clinical and regulatory success Bisantrene could be ready to launch around 2020/21. As an Orphan Drug, it would then enjoy seven years' US exclusivity in AML.

Key Point 5 - Bisantrene is one of a newly defined class of chemotherapeutic agents with immunostimulatory properties. This aspect of the drug not only increases its potential efficacy but opens the door to synergies with other immune-oncology agents.

Key Point 6 - **There is potential to expand the usage of Bisantrene** given the effectiveness which the original drug showed in breast and ovarian cancer and in lymphoma.

Key Point 7 - Race has a solid management team. Chairman Bill Garner has helped build a number of US drug development companies. CEO Peter Molloy has a marketing background likely to be valuable for the building of the NPP and has built value in a number of biotech companies including the anti-microbial drug developer Biota. CSO Dr John Rothman has a number of successful drugs to his credit as well as valuable experience in immune-oncology with Advaxis.

Key Point 8 - **The Bisantrene programme may prove the base for a larger specialty pharma company**, with the Race leadership team likely to look for other programmes to bolt on.

VALUATION

Our base case valuation of $94.2 million is 44 cents per share.

EARNINGS FORECAST

Y/E June	2014A	2015A	2016E	2017E	2018E
Revenue ($M)	0.0	0.0	0.0	0.0	6.2
EBITDA ($M)	-0.1	-0.2	-0.1	-3.0	-4.4
Reported NPAT ($M)	-0.1	-0.2	-0.1	-3.0	-4.3
Normalised NPAT ($M)	-0.1	-0.2	-0.1	-3.0	-4.3
Reported EPS (A$)	-0.0	-0.1	-0.6	-5.4	-6.7
Normalised EPS (A$)	-0.0	-0.1	-0.6	-5.4	-6.7
PER	N/A	N/A	N/A	N/A	N/A
DPS	0.0	0.0	0.0	0.0	0.0
Price/Cash (x)	55.9	127.7	2.9	2.4	8.3
Price/Book (x)	N/A	N/A	N/A	N/A	N/A

PROFIT & LOSS ($M)					
Y/E June	2014A	2015A	2016E	2017E	2018E
Sales Revenue	0.0	0.0	0.0	0.0	6.2
Total Costs	-0.1	-0.2	-0.1	-3.0	-10.5
EBITDA	-0.1	-0.2	-0.1	-3.0	-4.4
Depreciation/Amortisation	0.0	0.0	0.0	-0.0	-0.0
EBIT	-0.1	-0.2	-0.1	-3.0	-4.4
Interest	0.0	0.0	0.0	0.0	0.0
Pre-Tax Profit	-0.1	-0.2	-0.1	-3.0	-4.3
Tax expense	0.0	0.0	0.0	0.0	0.0
Net Profit After Tax	-0.1	-0.2	-0.1	-3.0	-4.3
Abnormals	0.0	0.0	0.0	0.0	0.0
Reported Net Profit After Tax	-0.1	-0.2	-0.1	-3.0	-4.3

CASH FLOW (M)					
Y/E June	2014A	2015A	2016E	2017E	2018E
Receipts from customers	0.0	0.0	0.0	0.0	0.0
Payments to suppliers	-0.1	-0.2	-0.1	-2.6	-4.3
Net interest	0.0	0.0	0.0	0.0	0.0
Tax Paid	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Operating Activities	-0.1	-0.2	-0.1	-2.6	-4.3
Capital Expenditure	0.0	0.0	0.0	0.0	0.0
Exploration, Development, Evaluation	0.0	0.0	0.0	0.0	0.0
Asset Sales/Acquisitions	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Investment Activities	0.0	0.0	0.0	0.0	0.0
Share Issues /(Buybacks)	0.0	0.2	4.1	4.8	0.0
Debt Drawdown/ (Repaid)	0.0	0.0	0.0	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Financing Activities	0.0	0.2	4.1	4.8	0.0
Net Cash	-0.1	0.0	3.9	2.1	-4.3
Cash at beginning	0.1	0.0	0.0	4.0	6.0
Cash at end	0.0	0.0	4.0	6.0	1.7

BALANCE SHEET (M)					
Y/E June	2014A	2015A	2016E	2017E	2018E
Cash	0.0	0.0	4.0	6.0	1.7
Trade and other Receivables	0.0	0.0	0.0	0.0	0.2
Inventories	0.0	0.0	0.0	0.0	0.2
Investments	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.1	0.1	0.1	0.1
Current Assets	0.1	0.1	4.1	6.2	2.3
PPE	0.0	0.0	0.0	0.0	0.1
Investment in Joint Venture	0.0	0.0	0.0	0.0	0.0
Exploration & Evaluation	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Non-current Assets	0.0	0.0	0.0	0.0	0.1
Total Assets	0.1	0.1	4.1	6.2	2.3
Trade and other Payables	0.1	0.1	0.1	0.1	0.3
Short-term Debt	0.0	0.0	0.0	0.0	0.0
Long-term Debt	0.0	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Total Liabilities	0.1	0.1	0.1	0.1	0.3
Net Assets	-0.1	0.0	4.0	6.1	2.1
Share Capital	0.1	0.3	4.4	9.5	9.8
Reserves	0.0	0.0	0.0	0.0	0.0
Retained Earnings	-0.2	-0.3	-0.4	-3.4	-7.7
Shareholders' Equity	-0.1	0.0	4.0	6.1	2.1
Minorities	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Total Equity	-0.1	0.0	4.0	6.1	2.1
Shares on Issue (M)	12.2	12.2	52.7	65.2	65.2
Options Outstanding (M)	0.0	5.0	19.0	19.0	19.0
Fully Diluted (M)	12.2	17.2	71.7	84.2	84.2

SWOT ANALYSIS

STRENGTH

- Lead product, Bisantrene, for the treatment of Acute Myeloid Leukemia, is a safe and effective drug
- Bisantrene has already been through 44 clinicals and gained approval in France
- Bisantrene has a relatively fast path to market, via a Named Patient Programme in Europe and two clinical studies in the US
- Bisantrene is a chemotherapeutic agent with immunostimulatory properties
- Bisantrene is likely to be well received given the lack of new drugs for AML in recent decades
- Race Oncology's management team is seasoned

WEAKNESS

- Product life for Bisantene is potentially short, at only seven years (US) or ten years (Europe)
- The clinical data for Bisantrene dates from the 1980s, when measurement criteria were different
- The product is still being formulated for better solubility
- It will be around a year to eighteen months before the Named Patient Programme and clinical studies can commence
- Bisantrene will be used for treatment of 'salvage' patients
- It is not clear why Lederle/American Cyanamid did not further develop Bisatrene in the 1990s

OPPORTUNITIES

- Bisantrene may prove synergistic with other cancer agents including immune-oncology drugs
- There is potential to bolt on other programs to build a specialty pharma company
- There is an opportunity to move Bisantrene into other indications including breast cancer
- There is potential to secure partners for Bisantrene in valuable Asian markets
- Race can potentially develop other anthracene analogues for which there may be composition-of-matter patent coverage
- The Named Patient Programme can potentially grow beyond the five markets that are initially intended

THREATS

- The FDA and other regulators may require more safety data than has been collected before allowing the Phase II bridging study in AML
- Other agents may move forward in the clinic which are more effective than Bisantrene
- The company may be unsuccessful in its reformulation efforts
- Drug prices in Europe may come under pressure due to economic austerity
- Recruiting into the US studies may prove difficult given competing studies
- Bone Marrow Transplant treatment may become considerably cheaper than today due to changes in stem cell expansion technology.

OVERVIEW

Race Oncology is a drug development company focused on the re-development of Bisantrene for the treatment of Acute Myeloid Leukaemia (AML). We say 're-development' because Bisantrene, a small molecule anthracene derivative, gained its first marketing approval 26 years ago. The drug originated back in the 1980s in a successful development programme overseen by the major US pharma company Lederle. That company had secured the regulatory approval in France in 1990, however, unusually, corporate interest in the new drug waned after this, due to a succession of pharma company mergers. In 2013 the US bio-entrepreneurs Dr John Rothman and Dr Bill Garner, attracted by Bisantrene's apparent efficacy and safety profile, and taking advantage of knowledge in oncology that had arisen since the 1990s, started work on a new patent-protected Bisantrene.

STRATEGY

Race Oncology intends to launch Bisantrene in Europe under a Named Patient Programme for AML during 2017/18, while in the US the company is hoping to gain approval for its drug in AML via the 505(b)(2) route. To that end preparations are underway for an IND filing ahead of an envisaged Phase II 'bridging' study to be followed by a pivotal study. Race believes that, subject to favourable performance in the pivotal, it will be in a position to seek FDA approval for Bisantrene around 2020/21.

FINANCIAL POSITION

Race Oncology raised $4.3m in a placement at 20 cents per share in mid-2016. This funds the company for the next 12-15 months, after which we expect the company will seek to raise $5m.

RACE ONCOLOGY'S BISANTRENE PROJECT

- **Bisantrene - How an old drug became new again**. Race Oncology in its current form was put together in 2016 to pursue the re-development of an old cancer drug called Bisantrene, real name 9,10-anthracene dicarboxaldehyde. This compound is an 'anthracene analogue', meaning that it is related to a class of oncology drug called the anthracyclines. This in effect gives Bisantrene a long history ultimately stretching back to the 1960s
  - The anthracyclines, which are antibiotics with anti-tumour properties, were the most notable anti-cancer breakthrough of the mid-1960s. Two drug discovered at that time – daunorubicin[1] and doxorubicin[2] – came on the market in the 1970s[3] and were commercially successful[4].
  - The anthracyclines proved highly effective in terms of their initial response rates in malignant haematological and solid tumours. Their importance can be gauged by the fact that in the second half of the 1970s and into the 1980s more than half of pediatric cancer patients in the US likely received anthracycline treatment[5]. However, the drugs came with two big problems – cardiotoxicity[6] and, as with other antibiotics, the development of multi-drug resistance[7]. Around 2% of patients on doxorubicin in the 1970s ended up with heart failure and the drug was found to reaches an acceptable cumulative maximum at around 500mg/m2[8]. Consequently, most clinicians these days limit the cumulative dose of doxorubicin to 400–450 mg/m^2.
  - Bisantrene was invented around 1980 by scientists at the major US pharma company Lederle[9] in order to harness the anti-tumour properties of the anthracyclicines without the cardiotoxicity and multidrug resistance issues. The drug is not an

1 Isolated in 1963 from the soil bacterium *Streptomyces peuceticus*. The drug was identified independently by groups at Rhone-Poulenc in France and at Farmitalia in Italy. See Cancer Treat Rep. 1981;65 Suppl 4:3-8.

2 A hydroxylated side chain derivative of daunomycin obtained from *Streptomyces peucetius var. caesius* and first reported in 1969.

3 As Adriamycin, doxorubicin gained FDA approval in 1974, while, as Cerubidine, daunorubicin was approved in 1979.

4 For example, Adriamycin (doxorubicin) enjoyed 1991 sales for Farmitalia Carlo Erba of US$190m – source: *World Anticancer / Immunology Market*, The Pharma Letter, 2 August 1993.

5 See, for example, Krischer et. al., J Clin Oncol. 1997 Apr;15(4):1544-52.

6 Circulation. 2015 Jun 2;131(22):1946-9. Epub 2015 May 6.

7 Semin Oncol. 1997 Aug;24(4 Suppl 10):S10-11-S10-17.

8 See Ann Intern Med. 1979 Nov;91(5):710-7.

9 Pronounced 'led-er-lee'.

anthracycline but an anthracene derivative. It retains the DNA intercalation capability of anthracyclines[10] but has other mechanisms of action.

- Lederle and the National Cancer Institute, which was a strong proponent of the drug, are understood to have spent the equivalent in modern dollars of $US200m over the course of the 1980s to develop Bisantrene. With this investment Lederle was able to demonstrate the drug's effectiveness in Acute Myeloid Leukaemia (AML) in a series of clinical studies before the drug's first regulatory approval in France in 1990 for that indication.
- Following a succession of pharma company mergers in the 1990s the drug effectively 'fell between the cracks'.
- In 2013 Bill Garner and John Rothman formed Update Pharma in order to re-develop Bisantrene, filing for patent protection and bringing together a dossier to take to regulators.
- Garner and Rothman's company, Update Pharma, backdoored the Bisantrene technology into an Australian unlisted shell called Coronado Resources[11], culminating in an ASX IPO during June 2016, in which $4.3m was raised at 20 cents per share. Renamed Race Oncology Ltd, this company commenced trading on the ASX during July 2016.

- **Bisantrene is safe and effective in the treatment of Acute Myeloid Leukemia**. Over the years Bisantrene was the subject of 44 clinical studies[12] covering in excess of 2,000 patients across a range of cancers. AML was an obvious target given the historic use of anthracyclines in this disease. For evidence of the safety and effectiveness of bisantrene against AML, three published studies tell the story well:
  - Tosi et. al., 1989[13]. This study evaluated Bisantrene at 250 mg/m^2 per day in ten AML patients and found Complete Responses (CRs) in four patients within ten days. Hypotension was observed in only in one patient who soon recovered without residual effects.
  - Spadea et. al., 1993[14]. This study saw Bisantrene administered at 250 mg/m^2 daily for seven days to relapsed/refractory AML patients as a single agent. The result was a CR in five out of seven patients and a Partial Response in a sixth. No patient saw any cardiovascular dysfunction.
  - Leblanc et. al., 1994[15]. This study evaluated 250 mg/m^2 Bisantrene daily for five days plus cytarabine in 26 relapsed/refractory pediatric leukemia patients, 13 of whom had AML. Five of the 13 AML patients enjoyed a CR. Again, no significant cardiotoxicity was observed.
  - In addition to the above three studies the Update Pharma founders, Garner and Rothman, point to two other AML studies – one in 40 patients that reported a 50% CR rate in 1987[16] and one in 15 patients where the CR rate as reported in 1989 was 46%[17]. Taken together, these five studies suggest that around half of relapsed/refractory AML is treatable with Bisantrene (range 38%-72%, n=85 patients), so long as a daily dose of 250 mg/m^2 is used, at which dose there does not appear to be cross-reactivity with anthracyclines, and no cardiotoxicity[18]. It's worth noting that definitions of 'response' have changed since the 1980s to accommodate a number of different systems of investigation and that the older system used during the Lederle trials was more stringent.

10 With DNA intercalation a drug binds to the DNA in the cancer cell nucleus and interferes with its transcription process, thereby preventing cell replication.

11 Receiving 15 million Race Oncology shares. The Update Pharma vendors will also receive 5 million shares if within 24 months from listing the FDA permits the 505(b)(2) route for Bisantrene and the commencement of the Phase II bridging study for the drug; and 5 million shares if within 24 months the Named Patient Programme for Bisantrene is authorised for Europe.

12 33 conducted by the National Cancer Institute.

13 Haematologica. 1989 Nov-Dec;74(6):555-8.

14 Leuk Lymphoma. 1993 Feb;9(3):217-20.

15 Med Pediatr Oncol. 1994;22(2):119-24.

16 Marty et. al., *Bisantrene: an anthracycline derivative active in ANLL: Phase 2 Study*. Fourth Int. Symp. on Therapy of Acute Leukemia, F. Mandelli (ed). Rome. 447. (abstr. 598) 1987.

17 Bozwoda and Seymour, *Bisantrene in the treatment of relapsed acute non-lymphocytic leukemia (ANLL)*. Bone Marrow Transplant. 4(Suppl3):65. 1989.

18 As for multidrug resistance, that is less of an issue for drugs of the anthracycline class, as well as Bisantrene. We know that in each case it is caused by overexpression of p-glycoprotein (Oncol Res. 1994;6(7):291-301) but that can be knocked down with verapamil (Int J Cancer. 1994 Mar 1;56(5):749-54).

- **If Bisantrene is so good, why did it effectively die in the 1990s?** It's a good question, and no-one really knows the answer. There are, however, three ways to address this piece of history
  - **Perceptions in the early 1990s of inadequate market size**. Bisantrene had been shown to be effective in relapsed/refractory AML, but in terms of patient numbers the market was small – we estimate only around 6,000-7,000 patients p.a. in the US at the time[19]. The drug was second line because it didn't have the cytotoxicity of cytarabine and doxorubicin[20], and second line drugs tend to be vulnerable to changes in the first line. Even though the regulatory environment had changed in 1983 to encourage Orphan Drugs, it wasn't until Novartis brought Gleevec to market in 2001 that small patient numbers became less of an issue in cancer drug development for Big Pharma[21].
  - **The rise of the taxanes**. The FDA approval of Taxol for Bristol-Myers Squibb in December 1992 was a landmark in oncology because of the data in breast and ovarian cancer. In the 1990s the taxanes generated the same sort of excitement in the clinical community as the anthracyclines had in the 1970s. We argue that this new Big Thing would have caused the anthracyclines, and by extension anthracene derivatives, to be overshadowed[22], just at the time when Bisantrene was ready to move forward.
  - **Lack of attention on the part of Bisantrene's owners**. Race Oncology thinks that this is the most likely explanation. In 1990 Lederle was a unit of American Cyanamid, a large chemical conglomerate. In 1992 American Cyanamid, then under some financial pressure, took a controlling stake in a Seattle-based biotech company called Immunex and merged the Lederle oncology business into it, but Bisantrene wasn't included in the list of products that were transferred[23]. Two years later American Cyanamid was bought by American Home Products for US$9.5bn. AHP, while involved in pharmaceuticals, historically did not have an oncology franchise, which explains in part why Bisantrene continued to languish through to 2002 when the company renamed itself Wyeth[24]. That said, the end of patent life would have been a deterrent to further development of Bisantrene whether or not there were champions within Wyeth. Consequently, the drug was lost to the clinical community until Update Pharma began the process of reviving it.
- **There are precedents for what has happened with Bisantrene**. It doesn't happen often, but there have been a number of occasions in recent pharmaceutical history where drugs with good clinical records have languished before development efforts moved them to the finish line:
  - Taxol had been known about since the mid-1960s, but it didn't make it to the US market until the 1990s, in part because synthesis issues hindered the rise of a pharma 'champion'[25];
  - Synribo (omacetaxine mepesuccinate), for which Cephalon gained FDA approval in 2012 for the treatment of Chronic Myeloid Leukemia, was first identified in 1970[26].
  - Bendamustine, an alkylating agent, was used clinically in East Germany for decades beginning in the late 1960s but only systematically studied after German reunification. It gained FDA approval in 2008 as Treanda for the treatment of indolent B-cell non-Hodgkin lymphoma.
  - Occasionally even approved drugs languish for a while before finding a new use. J&J's Fentanyl opioid analgesic went off-patent in the early 1980s but was revived in patch form as Duragesic in mid-1990. By 2004 the patch was a blockbuster[27].

19 Estimated from the National Cancer Institute's SEER data.

20 See Cancer Res. 1983 Jun;43(6):2648-53.

21 For perspective on go/no-go decision making at Big Pharma in the 1990s see *Magic Cancer Bullet: How a Tiny Orange Pill May Rewrite Medical History* by Daniel Vasella (New York: Harper Business, 2003).

22 As they were in clinical usage in the 2000s - anthracycline-based chemotherapy for breast cancer declined from around 2005 in the US in favour of taxane-based chemotherapy – see J Clin Oncol. 2012 Jun 20;30(18):2232-9. Epub 2012 May 21.

23 Immunex eventually hit the big time in 1998 with Enbrel, for the treatment of Rheumatoid Arthritis. Amgen paid US$16bn in 2002 to acquire Immunex largely because of this drug.

24 Acquired by Pfizer in 2009.

25 For the whole three decades' journey of that drug see *The Story of Taxol – Nature and Politics in the Pursuit of an Anti-Cancer Drug* by Jordan Goodman and Vivien Walsh (Cambridge, Cambridge University Press, 2001)

26 See Clin Lymphoma Myeloma Leuk. 2013 Oct; 13(5): 530–533.

27 Br J Pharmacol. 2015 May; 172(9): 2179–2209.

- **Why Bisantrene's time has now come**. We argue that several factors will work in Bisantrene's favour this time around:
  - **Orphan Drugs are much more attractive than even a decade ago**. As we noted above, the success of Gleevec showed that it was possible to develop a large market opportunity in cancer from a small patient population. Orphan Drugs generally have boomed since 2008 due to a recognition of the favourable economics of the sector.
  - **The AML market is a lot bigger today**. Not only has AML incidence doubled in America between 2000 and 2016, but five-year survival rates have increased markedly, from 11% in 1990 to 24% today, mainly due to increased usage of Bone Marrow Transplantation (BMT) in relapsing patients**.**
  - **Beyond BMT, there remains a demand for AML new drugs**. The standard of care for AML as developed in the 1980s was induction of remission through '7+3', that is, seven days of the antimetabolite cytarabine[28] followed by three days with an anthracycline, usually daunorubicin because its toxicity is lower than doxorubicin. Apart from the BMT to consolidate the remission nothing has changed, with the possible exception of two hypomethylating agents approved for use in myelodysplastic syndrome (MDS[29] - Celgene's Vidaza[30] and Otsuka's Dacogen[31]) that are often used off-label in AML.
  - **We know more about Bisantrene.** In particular, we know that the drug can inhibit telomerase activity by inhibiting its binding to DNA, and that it can enhance tumour immunotherapy, mechanisms that were of little interest to investigators at the time the drug was being developed.
  - **J&J's launch of Doxil shows that there is still demand for drugs that have the firepower of an anthracycline.** Doxil, which is a doxorubicin liposomal formulation[32] launched by J&J in 1995 (in effect the world's first nano-technology drug), allows the anti-tumour properties of doxorubicin to be used without the cardiotoxicity, since the liposomes can't get through to myocardial tissue[33]. The drug is understood to have had global sales of around US$500m in 2010[34]. The fact that the drug ran into shortages in 2011 due to manufacturing problems, and these lasted into 2014[35], shows that clinicians value the product highly. We believe that Bisantrene can tap into this underlying demand.
- **What is the 'new' Bisantrene?** In mid-2013 Bill Garner and John Rothman filed two patent applications over Bisantrene:
  - Compositions to improve the therapeutic benefit of bisantrene, WO/2015/013579, priority date 26 July 2013, covering a number of Bisantrene analogues; and
  - Combinatorial methods to improve the therapeutic benefit of bisantrene, WO/2015/013581, also priority date 27 July 2013, covering the combination of bisantrene with other anti-cancer agents.
  - Race hasn't set out to develop a Bisantrene analogue, preferring instead to use the original composition of matter but with an improved formulation. The original Bisantrene, which was administered via intravenous infusion because it was not water-soluble[36], was observed to cause frequent local complications of phlebitis and thromboses when the patients received the drug via the peripheral veins. This was because of the low solubility of the drug at physiological pH.[37] The company will be working through the second half of calendar 2016 to reformulate Bisantrene for improved solubility and remove this issue.

28 Another old drug – FDA approved in 1969.

29 The myelodysplastic syndromes are a group of cancers in which immature blood cells in the bone marrow do not mature or become healthy blood cells. MDS turns into AML in about 10% of cases within three years (see J Clin Oncol. 2010 Jun 10;28(17):2847-52. Epub 2010 Apr 26).

30 Generic name azacitidine, see www.vidaza.com. This drug was FDA approved for myelodysplastic syndromes in 2004. For AML Vidaza gained European approval in 2008.

31 Generic name decitabine, see www.dacogen.com. This drug was FDA-approved for myelodysplastic syndromes in 2006.

32 See www.doxil.com.

33 That's because liposomes leave blood vessels at points where they are disrupted by tumour growth. Myocardial tissue is too tight for them.

34 See *J&J warns doctors of Doxil cancer-drug shortage*, Reuters, 21/7/2011. A generic was launched by Sun Pharma on the US market in 2013.

35 See J&J's Doxil shortage to last until at least end of 2014 by Eric Palmer, Fierce Pharma, 7/10/2013.

36 It does solubilise in DMSO.

37 Cancer Res. 1983 Feb;43(2):925-9.

- **Bisantrene is chemotherapeutic with an immunological mechanism of action**. Anthracyclines work primarily by DNA intercalation, and Bisantrene as an anthracene analogue retained this ability, as well as the ability of anthracyclines to target topoisomerase II, one of the enzymes that control changes in DNA structure. However, with Bisantrene we also know that the drug can:
  - **inhibit telomerase** – In 2010 scientists at the Istituto Nazionale dei Tumori in Milan established that Bisantrene was a telomerase inhibitor by stabilising guanine-rich areas of DNA within the cancer cell[38]. Given the important role that telomerase plays in cell survival, and the fact that the 2009 Nobels for Medicine were handed out for work on telomerase, this was an important finding.
  - **activate tumour-specific macrophages** – This capability has been known about since in the mid-1980s[39] but takes on a new meaning in the post-2011 era of checkpoint inhibitors and immune-oncology generally.
  - **work through other immunological mechanisms**. In recent years a body of work has grown up showing that anthracyclines can harness both the innate and adaptive immune systems[40] to prevent cancer progression[41]. We now know that anthracyclines can induce translocation of calreticulin, HSP70, and HSP90 to the cell surface, augmenting the presentation of antigens from tumour cells to dendritic cells[42]. We also know that anthracyclines stimulate the rapid production of type I interferons by cancer cells[43]. Additionally we know that anthracyclines are synergistic with tumour-infiltrating lymphocytes.[44]

At least one other paper, albeit from the 1980s[45], has shown that Bisantrene inherits this ability to augment the work of immune effector cells. We believe that as Bisantrene re-enters the clinic there will be interest in combining it with immune-oncology agents such as the checkpoint inhibitors to further enhance this phenomenon.

- **The path forward for Bisantrene - A new drug for relapsing/refractory patients**. Race will be seeking to indicate Bisantrene for patients after their second or more relapse
  - **Race will be initiating a Named Patient Programme in Europe**, 'named patients' being those allocated the drug under compassionate use ahead of pivotal data. The NPP is expected to happen in France as well as four other countries (Italy, Spain, Turkey and Finland). The precedent here is that Celgene's Revlimid drug was commercialised in Europe via an NPP. Race sees a potential market of US$30-50m from its programme, which is reasonable given there are probably 16,000 patients that are treatable and US$30-50m could accrue from this population at only US$2,000-3,000 per patient p.a. Obviously once pivotal data becomes available Race can transition from an NPP to a more conventional marketing approach subject to regulatory approval, and in this case a pre-existing NPP can provide a distribution system ready-made that would ordinarily take three or more months to get up and running. In addition to this, the NPP will be vital in establishing an appropriate pricing for the drug that fits with the currently austere atmosphere surrounding European healthcare spending.
  - **Race is preparing for a Phase II bridging study to be conducted into an IND**. The company is currently completing formulation and manufacturing development on Bisantrene, and this will take the rest of 2016, after which it will bring the dossier to the FDA and file for an IND in the first half of 2017. This would put the company on track for a 2020/21 approval, other things being equal. The company is hoping to go down the 505(b)(2) path with the drug. In terms of the timing of the study, Race is a beneficiary of the fact that patients after their second relapse often don't have long to reach a survival endpoint – possibly 2-7 months[46].

38 Biochem Pharmacol. 2010 Jun 15;79(12):1781-90. Epub 2010 Mar 3.
39 Cancer Res. 1984 Jun;44(6):2363-7.
40 Cancer Res. 2011 Jul 15;71(14):4809-20. Epub 2011 Jun 6.
41 For a review see Cancer Lett. 2015 Dec 28;369(2):331-5. Epub 2015 Oct 11.
42 Cancer Res. 2011 Jul 15;71(14):4821-33. Epub 2011 May 20.
43 Nat Med. 2014 Nov;20(11):1301-9. Epub 2014 Oct 26.
44 Breast Cancer Res. 2011;13(6):R126 Epub 2011 Dec 8.
45 Cancer Res. 1989 Mar 15;49(6):1429-33.
46 Leukemia. 2000 Dec;14(12):2059-63.

- **The market opportunity for Bisantrene is significant**. Acute Myeloid Leukemia (AML), which accounts for 80% of adult leukemias, is a cancer characterised by proliferation and accumulation of myeloid blasts in the bone marrow that are blocked at various stages of differentiation[47]. The disease is called acute because patients develop abnormal numbers of these cells very quickly. In the US in 2016 there will be an estimated 19,950 new cases of AML and 10,430 deaths[48].
  - **Why the Standard-of-Care hasn't changed much for AML**. We noted above that 7+3 cytarabine plus an anthracycline has been the standard of care for AML since the 1980s. The reason little progress has been made beyond the addition of BMT and the hypomethylating agents is the cytogenetic diversity of the disease[49]. This in turn means that any new agent with a track record of success is attractive to Pharma in a way that it may not have been 25 years ago. While a few companies are working on anti-CD33 antibodies and other targeted approaches, we see little in the near term that can displace the current cytarabine plus anthracycline backbone for AML.
  - **Bisantrene's market opportunity will be in salvage patients that have failed chemotherapy and BMT**. We estimate that represents around 10,000 patients p.a. in the US, and in Europe another 16,000 patients.
  - **Breast cancer may provide a second indication for Bisantrene**. The original data from breast cancer studies was promising. Yap et. al. in 1983[50], evaluating 40 metastatic breast cancer patients, noted 9 partial responses, and 18 patients with stable disease, and these were patients who had failed to respond or were refractory to doxorubicin. Osborne et. al. in 1984[51] had six complete or partial responses out of 30 advanced breast cancer patients that were refractory to standard agents. What makes breast cancer a significant opportunity for Bisantrene today has been the rise of the monoclonal antibody drug Herceptin for the 20% of patients that are HER-2 positive. Since its FDA approval in 1998 Herceptin has become a US$6bn bestseller for Roche in spite of the fact that its cardiotoxicity issues affect as many as one-third of all patients[52].
  - **Bisantrene also seems to work in lymphoma**. McLaughlin et. al. in 1987[53] obtained a 30% response rate in 50 relapsing lymphoma patients where the Bisantrene was given by central iv catheter every 3 weeks, at doses of 350 mg/m^2 for patients with adequate marrow reserve and 300 mg/m^2 otherwise.
  - **Celator provides an indication of the potential upside for Bisantrene**. Celator Pharmaceuticals[54], which has been built on technology to optimise drug combinations, has as its lead candidate a liposomal formulation of cytarabine and daunorubicin called Vyxeos, where the two drugs formulate in a 5:1 ratio. In March 2016 Celator announced that Vyxeos in a Phase III study in secondary AML (that is, AML which arises from a pre-existing myeloproliferative disease) had boosted median overall survival compared to 7+3 from 5.95 months to 9.56 months for a hazard ratio of 0.69 (p=0.005). At Phase 2 Vyxeos improved overall survival in secondary AML to 12.1 months, versus 6.1 months with 7+3 (p=0.01). Shortly after the Phase III data, in May 2016, Celator agreed to be acquired by the specialty pharma Jazz Pharmaceuticals[55] for US$1.5bn.
- **Bisantrene is probably good for seven years**. We argue that a reasonable estimate of the life of Bisantrene in the US market is seven years, since
  - **Patent protection isn't a factor at the moment**. While WO/2015/013579 and WO/2015/013581, which have a July 2013 priority date, potentially protect the compound until 2034, there is no new data in these compounds. That said, Race's reformulation work has potential to add new IP to the programme so our assumption is probably conservative;

47 Myeloid blasts, or simply 'blast cells' are the earliest and most immature cells of the myeloid cell line derived from hematopoietic stem cells. Myeloid cells mature into platelets, red blood cells, neutrophils and other types of white blood cells. The other cell line derived from hematopoietic stem cells, called lymphoid cells, ultimately results in B lymphocytes and T lymphocytes.

48 Source: American Cancer Society, Cancer Facts and Figures 2015,

49 See, for example, Ann Hematol. 2016 May 26. [Epub ahead of print].

50 Cancer Res. 1983 Mar;43(3):1402-4.

51 Cancer Treat Rep. 1984 Feb;68(2):357-60.

52 J Clin Oncol. 2010 Sep 1;28(25):3910-6. Epub 2010 Aug 2.

53 Cancer Treat Rep. 1987 Jun;71(6):631-3.

54 Ewing, NJ, Nasdaq: CPXX, www.celatorpharma.com.

55 Dublin, Ireland, Nasdaq: JAZZ, www.jazzpharma.com.

- **Bisantrene is an Orphan Drug in AML**, with Orphan Drug Status in the US having been conferred by the FDA in February 2014. In the US Orphan Drugs have seven years' exclusivity from approval date.
- **Bisantrene likely has five years US exclusivity outside AML**. The generic drug rules confer three years' market exclusivity for drugs that go down the 505(b)(2) route where the compound in question is judged not to be a New Chemical Entity (NCE). The exclusivity becomes five years if the FDA judges that Bisantrene is an NCE, which Race believes is the case since the drug never gained regulatory approval in the US.

INVESTMENT CASE

- **We value Race Oncology at $0.44-$1.24 per share**, using a probability-weighted DCF approach. We arrived at this figure using the following approach which we regard as conservative:
  - We assume the AUD/USD exchange converges on 0.7 over a three-year period from now;
  - We valued only the US and European market opportunity for Bisantrene and assumed that Race did not partner the programme in either market;
  - We assume that Bisantrene is approved only for use in AML and finds no use in breast cancer or lymphoma;
  - We assumed a seven-year exclusivity period in the US for Bisantrene and a ten year exclusivity period in Europe;
  - We assumed an FY19 (base) or FY18 (optimistic) launch for Europe and an FY22 (base) or FY21 (optimistic) launch for US;
  - We modelled peak sales for Bisantrene of US$25-40m in Europe (market penetration 12-19%) and US$50-75m in the US (penetration 19-29%);
  - We assumed gross margins for the drug of 75-85%, rising 0.1-0.2% p.a. over time;
  - We assumed that the field force to distribute Bisantrene cost 20-25% of European revenue and 10-15% of US revenues – the difference accounts for a less efficient drug distribution infrastructure in Europe;
  - We used a discount rate of 12.4% (RFR of 2%, an MRP of 9.5% and a beta of 1.1);
  - We assumed a 60% probably of clinical success for the Phase II bridging study and subsequent US registration study;
  - We assumed that the clinical work required for Bisantrene over the next four years would cost US$5m (optimistic case) to US$10m (base case). The final figure will in part depend on how comfortable the FDA is with the existing safety profile of Bisantrene from the available data;
  - We assumed another A$5m capital raising at A$0.40 per share.
- **Our target price is $0.45 per share**. $0.45 sits near our base case valuation.
- **We see newsflow over the course of FY17 as helping to drive a re-rating of the stock**, with potential events including:
  - Completion of formulation work and filing of new IP
  - Completion of pre-IND development
  - The pre-IND meeting with the FDA and filing of IND
  - IND allowance in US
  - Announcement of further details of the NPP
  - Potentially a licensing deal for Bisantrene in Asia
  - Potential clinical collaborations with hospitals in the US and Europe

CAPITAL STRUCTURE

- 52.69 million ordinary shares
- 19 million options with an average exercise price of 25 cents and an average exercise date of December 2019
- 10 million performance shares, 5 million granted when 505(b)(2) status is granted and the Bridging study commences, and 5 million granted when the Named Patient Program commences.

RISKS

- **Funding risk**. The $4.3m which Race raised in early 2016 only funds the company for the next 15-18 months. While there is potential for the Named Patient Programme to begin contributing revenue after this we expect that further capital will be required to fund the Phase II bridging study among other things.
- **Regulatory risk**. There is the risk that the FDA and other regulators may require more data from Race, thereby increasing the timelines that we have estimated in this note.
- **Clinical risk**. There is the risk that the Phase II bridging study may fail.
- **Formulation risk**. There is the risk that reformulation of Bisantrene may prove more difficult than expected.
- **IP risk**. There is the risk that that the patent applications which Update Pharma have made over Bisantrene may not make it through national phase.

BOARD AND MANAGEMENT

- **CEO Peter Molloy**, brings to Race a solid background in pharmaceuticals marketing from his years as a senior executive at Pharmacia, as well as his experience rebuilding the drug developer Biota (now Aviragen Therapeutics[56]) after that company's disappointing early experience with Relenza, the anti-influenza drug that had been licensed to GSK and gained FDA approval in 1999.
- **CSO Dr John Rothman** brings valuable drug development smarts to Race. He is probably best known for his leadership in the development team at Schering that brought the first interferon to market. He subsequently served as the Senior Director of Clinical Data Management at Roche and later was Executive Vice President of Clinical and Scientific Operations at the cancer immunotherapy company Advaxis[57], which we think will be vital at Race given the growing role of immune-oncology in the treatment of cancer.
- **Chairman Dr Bill Garner**, a licensed MD[58], brings to Race insights into drug repurposing, gained at a number of previous startup companies including Urigen[59], Inverseon[60] and Del Mar Pharmaceuticals[61].
- **The Race board**. Also on the Race board alongside Bill Garner and Peter Molloy are Brendan De Kauwe of the Perth corporate finance house Otsana Capital and Chris Ntoumenopoulos of the Perth stockbroking firm CPS Capital. Both directors bring solid links to the Australian investment community.

56 Alpharetta, Ga, Nasdaq: AVIR, www.aviragentherapeutics.com.

57 Princeton, NJ, Nasdaq: ADXS, www.advaxis.com. Advaxis develops cancer vaccines based on a live-attenuated version of *Listeria monocytogenes* where the bacterium has been engineered to secrete an antigen/adjuvant fusion protein. The company's lead product, Axalimogene filolisbac, is an HPV vaccine targeting cervical cancer, head and neck cancer and anal cancer. Advaxis is currently planning registration trials for Axalimogene filolisbac in cervical cancer.

58 In the state of New York.

59 North Brunswick, NJ, www.urigen.com.

60 This company merged with CBio to become Invion, ASX IVX, www.inviongroup.com.

61 Vancouver, BC, OTCQX: DMPI, www.delmarpharma.com

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