AUSTRALIAN
RESEARCH
INDEPENDENT INVESTMENT RESEARCH

Race Oncology Limited (ASX: RAC)

Update

October 2018

INDEPENDENT
INVESTMENT RESEARCH

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INDEPENDENT INVESTMENT RESEARCH

Race Oncology Limited (ASX: RAC)

Update - October 2018

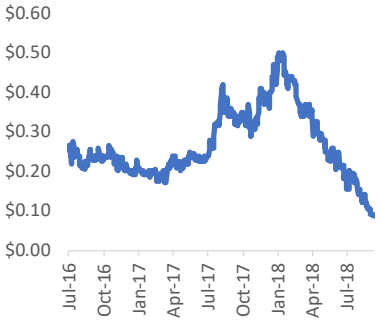
Investment Profile	
Share price ($) as at 5 October 2018	0.14
Base Case Value ($) per share	**0.40**
Issued capital:	
Ordinary shares (M)	77.2
Options (M)	35.0
Performance Rights (M)	10.0
Fully Diluted (M)	122.2
Fully Diluted Market capitalisation ($M)	17.1
12-month Share Price Low/High ($)	0.089/0.52

Board
Dr. Bill Garner (Chairman)
Peter Molloy (Managing Director)
Dr. John Cullity
Chris Ntoumenopoulos

Major Shareholders	%
William Garner	19.7
Peter Molloy	5.4
Freeman Road Pty Ltd	3.2
Top 19 Shareholders	**40.8**

Source: IRESS

Share Price



PRV POTENTIAL PROVIDES THIRD VALUE DRIVER

RAC 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. RAC intends to make Bisantrene available for use in Europe, UK and South Korea under a Named Patient Program (NPP) and is also seeking to gain approval by the FDA for its drug via the 505(b)(2) route. Given the development stage of the company, an investment in the company is considered at the high end of the risk scale.

KEY POINTS

Named Patient Program (NPP) Sales: The company has produced a number of batches of Bisantrene for use under the Named Patient Program (NPP). The company is seeking to make the drug available in Europe, UK and South Korea for the treatment of AML. The company was seeking to commence sales in France in 4Q'CY17, however, is yet to achieve any sales of Bisantrene under the NPP. The company continues its endeavour to commence sales with the extension of the target market into the UK and other countries, however, it is difficult to forecast when sales will commence. Sales under the NPP will provide for some short-term revenue while the company seeks to obtain FDA approval.

Rare Paediatric Disease (RPD) Designation provides opportunity for Priority Review Voucher (PRV) : In July 2018, the company announced that the FDA has granted Bisantrene RPD designation for the treatment of childhood AML. The RPD designation means that Bisantrene has the opportunity to be awarded a PRV at the time of marketing approval. A PRV holds significant value in the secondary market with PRVs being sold from anywhere to US$68m to US$350m and therefore would be a valuable asset to RAC. In light of the RPD designation, the company will run clinical trials for the use of Bisantrene in childhood AML in parallel to the trials for adult AML. The trials required for the childhood AML will require significantly less subjects than the adult trials and as such are expected to be completed at a negligible additional cost.

Key Appointments: Over the last 12 months, the company has made two key appointments: (1) Dr. Samar Al-Behaisi as the Chief Medical Officer and Vice President (VP) Medical Affairs. Dr. Al-Bahaisi is an oncologist and medical affairs expert with over 20 years industry experience, including experience in oncology NPPs in Europe; and (2) Dr. John Cullity was appointed to the board as a non-executive director. Dr. Cullity is a physician with expertise in haematology-oncology, including AML. Dr. Cullity was formerly a senior executive at Sanofi-Aventis in the US during which time he was a leader of the AML taskforce, and a Principal at Torreya Partners where he was involved in a number of corporate transactions.

Capital Position: At 30 June 2018, the company had $3.7m in cash. The company raised $3.6m in March 2018 through an oversubscribed share placement. The company issued 11.4m shares at $0.32 per share to professional and sophisticated shareholders. The share price represented a discount to the previous closing price. The company has sufficient cash reserves to cover four quarters of operation based on the cash burn for the June 2018 quarter. The company will be required to raise additional capital to complete the clinical trials and pivotal study required for FDA approval, which is expected to cost approximately ~$18m.

Investment Case & Valuation: Our base case valuation for RAC has been reduced from $0.44 in our last report released in September 2017 to **$0.40** per share. Our valuation is based on a fully diluted basis. The reduction in the valuation is primarily a result of the increase in the discount rate from 12.4% to 17.4%, driven primarily by an increase to the beta from 1.1 to 1.5. The company now has three key value drivers: (1) NPP Sales; (2) FDA approval of Bisantrene; and (3) RPD designation and PRV. We have assumed the company will be awarded a PRV and will sell the PRV for an amount equal to the last sale of a PRV (US$81m). We note that the receipt of a PRV will depend on the results of the childhood clinical trials and be subject to the FDA awarding the PRV. The company will have to raise capital to fund the clinical trials and achieve FDA approval for Bisantrene. Given the development stage of the drug and the capital position of the company there remains significant risk with an investment in the company, however, there is significant upside potential in the event the company can achieve FDA approval.

PROFIT & LOSS ($M)				
Y/E June	2016A	2017A	2018A	2019F
Revenue	0.2	0.0	0.0	0.2
EBITDA	-0.3	-3.9	-6.1	-3.5
Depreciation & Amortisation	0.0	-0.3	-0.3	-0.3
Interest	0.0	0.0	0.0	0.0
Profit Before Tax	-0.3	-4.2	-6.3	-3.8
Tax Expense	0.0	0.0	0.0	0.0
Net Profit After Tax	-0.3	-4.2	-6.3	-3.8

BALANCE SHEET ($M)				
Y/E June	2016A	2017A	2018A	2019F
Cash	4.3	1.7	3.7	2.6
Receivables	0.0	0.0	0.0	0.0
Other Current Assets	0.1	0.1	0.0	0.0
Total Current Assets	4.5	1.8	3.7	2.6
Property Plant & Equipment	0.0	0.0	0.0	0.0
Intangible Assets	0.0	4.3	4.5	4.2
Investments	0.0	0.0	0.0	0.0
Deferred Tax Assets	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Total Non-Current Assets	0.0	4.3	4.5	4.2
Total Assets	4.5	6.0	8.2	6.8
Trade and other payables	0.4	0.4	0.3	0.3
Borrowings	0.0	0.0	0.0	0.0
Current tax liabilities	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0
Other liabilities	0.0	0.0	0.0	0.0
Current Liabilities	0.4	0.4	0.3	0.3
Trade and other payables	0.0	0.0	0.0	0.0
Borrowings	0.0	0.0	0.0	0.0
Deferred tax	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0
Non-Current Liabilities	0.0	0.0	0.0	0.0
Total Liabilities	0.4	0.4	0.3	0.3
Net Assets	4.1	5.7	7.9	6.5
Shareholders Equity	4.1	5.6	7.9	6.5

CASHFLOW ($M)				
Y/E June	2016A	2017A	2018A	2019F
PAT	-0.3	-4.2	-6.3	-3.8
Adjustments for non-cash items	-0.5	1.5	2.5	-0.3
Change in Working Capital	0.2	0.2	0.0	0.0
Net Cash from Operation Activities	-0.3	-2.5	-3.9	-4.0
Payments for entities and businesses, net of cash acquired	0.0	0.0	0.0	0.0
Payments for property, plant and equipment	0.0	0.0	0.0	0.0
Payments for intangible assets	0.0	0.0	0.0	0.0
Payments for other assets	0.0	0.0	0.0	0.0
Payments for acquisition of associates and other investments	0.0	0.0	0.0	0.0
Proceeds on disposal of businesses and property, plant and equipment	0.0	0.0	0.0	0.0
Loans to third party/franchisee	0.0	0.1	0.0	0.0
Dividends from associates	0.0	0.0	0.0	0.0
Others	0.0	0.0	0.0	0.0
Net Cash from Investing	0.0	0.1	0.0	0.0
Proceeds from borrowings	0.0	0.0	0.0	0.0
Repayments of borrowings	0.0	0.0	0.0	0.0
IPO costs	0.0	-0.3	0.0	0.0
Dividends paid to ordinary shareholders	0.0	0.0	0.0	0.0
Dividends paid to non-controlling interests	0.0	0.0	0.0	0.0
Proceeds from share issue	4.6	0.0	5.9	2.9
Proceeds from related party loan	0.0	0.0	0.0	0.0
Net Cash from Financing	4.6	-0.3	5.9	2.9
Cash at Beginning of the Year	0.0	4.3	1.7	3.7
FX Effect	0.0	0.0	0.0	0.0
Net Change in Cash	4.3	-2.6	2.0	-1.1
Cash at End	4.3	1.7	3.7	2.6

Key Valuation Assumptions	
AUD/USD	0.73
Probability of FDA Aprroval	60%
WACC	17.4%
Cost of Pivotal Study	$18m
Market Penetration:	
Europe	12%-19%
US	19%-29%
Gross Margin	85%
Distribution Cost:	
Europe	25%
US	15%

COMPANY UPDATE

Since our last report published in September 2017, the company has gone through a tumultuous time with both positive and negative news flow.

Let's get the negatives out of the way first. The share price has declined significantly since our last report with the share price declining 73.1% from its high of $0.52 in January 2018 to 14.0 cents per share at 5 October 2018. The key drivers of the share price decline were (1) delays to the NPP sales; (2) dilution from the capital raising at a discount to the share price and release of 27.34m shares from voluntary escrow; and (3) exit of legacy shareholders.

1) Delays to NPP Sales

The company was expected to commence sales of Bisantrene under the NPP to France in the 4Q'CY17, before expanding sales to other countries in Europe and South Korea over the proceeding two years. The company has experienced delays in their efforts to commence sales under the NPP in these countries. Sales were expected to generate revenue to support the development of Bisantrene in the company's quest to gain FDA approval. Without the revenue the company has had to rein in its costs and raise additional capital to continue its operations.

Despite the delays, the company has made progress with potential NPP sales including expansion of sales plans to the UK and other countries. See below for detailed information regarding NPP sales.

2) Dilution Impact

The company completed a capital raising in March 2018, raising $3.6m which was a significant positive for the company with the offer oversubscribed. However, the capital was raised at a 13.5% discount to the share price at the time which had a dilutionary impact on the share price.

In July 2018, 27.34m shares were released from escrow. This increased the number of shares available for trade by 54.8%. Further to this, 10m performance shares were issued to Update Pharma in June 2018.

3) Exit of Legacy Shareholders

Legacy shareholders sought to exit the company since our last report. This coupled with low liquidity and the dilution to the share price pushed the share price lower. While this has kept the negative trend of the share price, those seeking to exit the company have been 'cleared out', which we envisage will allow the company to reverse the share price trend.

Now to the positives..... Despite the delays to the NPP sales, the company has expanded the program to the UK. We explore this further in the NPP Activities section below. The company has also made a number of key additions to the team with the appointments of Dr. Samar Al-Behaisi as Chief Medical Officer and Dr. John Cullity as a non-executive director.

One the key positives for the company was the FDA granted Bisantrene a Rare Paediatric Disease (RPD) designation for the treatment of AML in children. The RPD designation means that Bisantrene has the opportunity to be awarded a Priority Review Voucher (PRV) at the time of marketing approval for paediatric AML. If awarded, the PRV can be sold and historical sales suggest the PRV has significant value.

The company continues to take steps to progress to the clinical trials to complete the pivotal study required to obtain FDA approval. In May 2018, the company signed an agreement with Novotech, an Asia-Pacific based Contract Clinical Research Organisation (CRO) to manage the clinical trial. The use of an Asia-Pacific based CRO entitles the company to receive a rebate of up to 43.5% on eligible research and development expenditure. The company has also signed an agreement with NSF Health Sciences (NSF) to facilitate the IND filing. NSF are a US based company and in addition to preparing the IND application will act as the US agent for RAC with the FDA, whereby NSF will be the intermediary regarding FDA correspondence, IND amendments, protocol amendments, pharmacovigilance and other reporting. Acceptance of the IND filing by the FDA will allow RAC to conduct the pivotal trial. Approval of the IND application will be a significant milestone for the company. The company will be seeking to commence the registration trial in the 2H'CY19. To achieve this the IND application will need to be filed by March-end 2019. Once the IND application has been accepted by the FDA, the company can submit a clinical trial protocol to conduct the childhood AML trials under the RPD designation.

KEY APPOINTMENTS

- In May 2018, the company appointed Dr. Samar Al-Behaisi as the Chief Medical Officer and Vice President (VP) Medical Affairs. Dr. Al-Bahaisi is an oncologist and medical affairs expert with over 20 years industry experience, including experience in oncology NPPs in Europe. Dr. Al-Bahaisi is based in Switzerland and will be responsible for the effective execution of the clinical registration trial and for progressing NPP activities. The appointment of Dr. Al-Bahaisi has replaced the agreement with CarthaGenetics, who were responsible for the market development and awareness of Bisantrene in Europe. This agreement was terminated with the appointment of Dr. Al-Bahaisi.
- In April 2018, the company announced the appointment of Dr. John Cullity to the board as a non-executive director. Dr. Cullity is a physician with expertise in haematology-oncology, including AML. Dr. Cullity was formerly a senior executive at Sanofi-Aventis in the US during which time he was a leader of the AML taskforce, and a Principal at Torreya Partners where he was involved in a number of corporate transactions. Dr. Cullity is a welcome addition to the board. Dr. Cullty replaced Dr. Brendan Dekauwe who resigned from the board.
- In addition to the key appointments, there were a number of exits from the team during the last 12 months. Dr. John Rothman stepped down as the full time Chief Scientific Officer in August 2018. Dr. Rothman has played a significant part in the company with Dr. Rothman being involved with the company from the start. Dr. Rothman will continue as a part-time consultant. The consulting agreement with Gordon Beck (VP Business Development) has also been terminated after the appointment of Dr. Al-Bahaisi.

RARE PAEDIATRIC DISEASE (RPD) DESIGNATION

In July 2018, the company announced that the FDA has granted Bisantrene RPD designation for the treatment of childhood AML. The RPD designation means that Bisantrene has the opportunity to be awarded a PRV at the time of marketing approval.

To be awarded the PRV, the company will need to conduct a clinical trial in childhood AML under a US Investigational New Drug (IND) application. Upon approval of Bisantrene for the designated indication, the PRV may be awarded.

The company intends to run the clinical trials for childhood AML in parallel with the adult trials and if awarded the PRV intends to sell it.

The RPD designation was awarded on the back of lobbying by RAC, who argued that childhood AML can be considered a substantively different disease to adult AML based on genetic markers disproportionately found in childhood AML and it therefore constitutes a rare paediatric disease. The FDA agreed with this argument.

What is a Priority Review Voucher (PRV)?

The PRV was introduced as law in the US in 2007 in an effort to provide an incentive to develop treatments for rare diseases. Under the law, a developer of a treatment for a neglected or rare paediatric disease can receive a PRV from the FDA to be used with a product of its choice or sold to another pharmaceutical company.

A PRV grants the holder an accelerated six month review of a drug application by the FDA and as such holds significant value, providing companies the ability to accelerate the review of commercial drugs with significant market potential.

The PRV program for rare paediatric diseases will expire in October 2020 although a drug designated as a rare paediatric disease can still receive a PRV if the drug is approved by October 2022. The program can be renewed with the Congress already renewing the program several times. We would expect the program to be renewed from the current expiration date of 2020.

PRVs can be transferred to other companies and as such there is a secondary market. The value of PRVs is determined by supply and demand. Since the law was passed, PRVs have sold for a range of US$68m to US$350m. The most recent PRV sale in 2018 was for US$80.6m.

Given the value of the PRV on the secondary market and assuming the program is renewed for paediatric rare diseases, the PRV would hold significant value to RAC. If we were to assume a sales price of US$81m, in line with the last PRV sale, this would equate to a NPV of US$28.3m (AUD$38.8m based on an AUD/USD of 0.73) if we assumed the PRV was sold in FY24 and assumed the capital outlay was the additional cost associated with conducting the childhood trials ($3m). Based on the fully diluted shares on issue at the date of this report and assuming a discount rate of 17.4%, the value of the PRV alone is greater than the current share price. We note that the receipt of the PRV is contingent on the approval of Bisantrene for the designated indication and there is no guarantee the PRV will be awarded.

NAMED PATIENT PROGRAM (NPP) ACTIVITIES

- Over the last 12 months the company has successfully manufactured two batches of Bisantrene with the company currently having treatments for 100 patients in stock, which will be dedicated to the NPP. The company will continue to manufacture the drug in preparation for the clinical trials and NPP treatment.
- With the appointment of Dr. Samar Al-Behaisi as the Chief Medical Officer and Vice President (VP) Medical Affairs, the company terminated the marketing agreement of CarthaGenetics.
- The company has experienced delays with the commencement of sales through the NPP throughout Europe. The company continues to market its product, however, it is unknown when sales will occur.
- In April 2018, the company signed an agreement with Durbin PLC for the global distribution of Bisantrene. Durbin is a UK based distributor of pharmaceutical and healthcare products. The agreement facilitated the expansion of the NPP activities into the UK and throughout the European Economic Area. Under the agreement, Durbin will be responsible for all the warehousing, invoicing, customer service and distribution of Bisantrene throughout a number of countries. The agreement has an initial term of three years, during which time the agreement can be terminated by either party with six months notice. RAC will supply Durbin with Bisantrene viles on a consignment basis and there is no minimum purchase order requirements.
- The company expanded the NPP program to the UK with the company announcing in June 2018, that approval had been received from the Medicines and Healthcare Products Regulatory Agency (MHRA), allowing the supply of unlicensed medicines in the UK in response to requests from doctors for treating patients with unmet medical needs. The initial approval is for 75 courses of treatment (1,050 viles at 14 viles per course of treatment).
- The company has undertaken a number of group and individual meetings with haematological oncologists and pharmacists to talk about the use and benefits of Bisantrene. The company has also presented at conferences in the US and Europe.

INVESTMENT CASE & VALUATION

- We have reduced our base case valuation of RAC from $0.44 in our report released in September 2017 to **$0.40 per share**. The valuation is based on the three key value drivers of the company: (1) NPP Sales; (2) FDA approval of Bisantrene; and (3) RPD designation and PRV.
- Despite the fall in the share price the underlying investment thematic in the company has not changed. While we have paired back our NPP sales assumptions, the assumptions regarding the AML market remain unchanged and the company has added value through the potential PRV. The reduction in the valuation is driven by an increase in the discount rate from 12.4% to 17.4%, which is primarily due to an increase in the beta from 1.1 to 1.5.
- We have added the UK to our NPP sales, however, have significantly paired back the NPP sales assumptions with no sales expected in FY19 and a small ramp up beginning in FY'20. We have assumed the company will be awarded with a PRV and will sell it for an amount equal to the last PRV sale (US$81m). We have assumed this will occur in FY'24. The PRV is value accretive to the company.

- We have retained a 60% probability of the Bisantrene receiving FDA approval and maintained the conservative market penetration assumptions in the US and Europe. The ability of the company to achieve levels above the assumed penetration levels will represent upside value for the company.
- We have not allocated any value for the potential use of Bisantrene in the treatment of cancers other than AML. The use of Bisantrene in the treatment of other cancers significantly expands the value potential.
- The company will have to raise additional capital to complete the pivotal study with the pivotal study (including the childhood study) expected to cost approximately $18m. This compares to the cash position of $3.7m at 30 June 2018. Assuming the IND filing is completed by 1Q'CY2019, the company is expected to commence the clinical trials in FY'20. As such an investment in the company entails the risks associated with raising capital, including dilution risk in the event the company raises the capital at a discount to the share price.
- The company has experienced significant downside pressure on the share price since our previous report as detailed in the report. We view there to be significant upside value in the company, particularly at the current share price, however, note there are also significant risks. We expect a re-rating of the stock to occur with the achievement of key milestones for the company. These milestones will include achieving the first sale under the NPP, filing of the IND in the 1Q'CY19, commencement of the clinical trials and ultimately achieving FDA approval.

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