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RESEARCH
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Race Oncology Limited (ASX: RAC)

Update

September 2017

INDEPENDENT
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INDEPENDENT INVESTMENT RESEARCH

Race Oncology Limited (ASX: RAC)

Update - September 2017

Investment Profile	
Share price ($) as at 15 September 2017	0.35
Base Case Value ($) per share	**0.44**
Issued capital:	
Ordinary shares (M)	65.3
Options (M)	31.0
Performance Rights (M)	10.0
Fully Diluted (M)	106.3
Fully Diluted Market capitalisation ($M)	37.2
12-month Share Price Low/High ($)	0.165/0.43

Board and Management

Directors:

Dr Bill Garner (Chairman)

Peter Molloy (CEO)

Brendan De Kauwe

Chris Ntoumenopoulos

Management:

Dr John Rothman (Chief Scientific Officer)

Major Shareholders	%
William Garner	23.6
Peter Malloy	6.3
Freeman Road Pty Ltd	2.6
Rodney Lambert	1.8
Top 20 Shareholders	**48.4**

Source: IRESS

Share Price

BIG STRIDES MADE IN THE RE-DEVELOPMENT OF BISANTRENE

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 and South Korea under a Named Patient Program (NPP) over the next two years. The company is also seeking to gain approval by the FDA for its drug via the 505(b)(2) route. To that end preparations are underway for an IND filing ahead of a pivotal study. RAC believes that, subject to favourable performance in the pivotal study, it will be in a position to seek FDA approval for Bisantrene around 2021/22.

KEY POINTS

First Batch of Bisantrene Ready for NPP: On 12 September 2017, the company announced the completion of the production of the first commercial batch of Bisantrene. The production is completed in two phases. The first phase of production is undertaken by Sai Life Sciences Ltd, located in India, who are responsible for the production of the Bisantrene API. The API is then sent to the US, for the second and final phase of production, in which IriSys LLC, manufacture the finished product. The first batch is expected to be able to treat up to 60 patients under the NPP. A further four batches will be produced in September. Assuming the batches will be the same size, this means the company will have enough Bisantrene to treat up to 240 patients by September-end.

Named Patient Program (NPP) to Commence in 4Q of 2017: After the first batch of Bisantrene has passed the quality control checks (expected in October) the drug will be available for use under the compassionate use program that the company refers to as its "Named Patient Program" (NPP). The company is on track to make the drug available in France for the treatment of AML in Q4 of 2017, to be followed by its availability in Italy, Turkey and South Korea over the proceeding two years. Sales under the NPP will provide for some short-term revenue while the company seeks to obtain FDA approval..

FDA Confirms 505(b)(2) Pathway and Agreement Signed with the National Cancer Institute (NCI): At a pre-IND meeting with the FDA in February 2017, the FDA confirmed that Bisantrene qualified for the 505(b)(2) pathway in the US. This was a positive for the development of Bisantrene and provided a clear pathway for development. After this meeting RAC entered into an agreement with NCI that provides access and use to all the historical data and regulatory filings for Bisantrene. This agreement completes the picture for RAC and will assist with the company's IND filing.

Capital Raising Completed : The company raised $2.5m in July 2017, through the successful completion of a share placement. The company issued 12.5m new shares at $0.20 per share to professional and sophisticated investors. This price represented a discount to the share price at the time. The share placement boosted the cash reserves to $4.2m. We expect this to cover the cash requirements for FY18, however, the company will be required to raise additional capital to complete the pivotal study required for FDA approval, which is expected to cost between $15m and $20m.

Valuation: Our base case valuation for RAC remains at **$0.44** per share. Our valuation is based on a fully diluted basis. The company is expected to generate revenue over the short-term through the sale of Bisantrene under the NPP throughout the four above mentioned countries. While this revenue will contribute to cashflow, the company will have to raise additional capital to fund the pivotal study, which is expected to completed over the next three years. Given the company has no credit facility we would expect the capital to be raised through equity placements. We note that the company has 10m options on issue that expire in July 2018. If these options are exercised the company will raise $2.5m. The options are in-the-money at the current share price. In addition to the potential dilutionary impact of future capital raisings, dilution will likely result when the shares currently held in escrow are released in July 2018. These shares will increase the number of shares on issue by 72%. The company has taken significant strides towards the re-development of Bisantrene since listing in July 2016. We would expect the company reaching further milestones to result in a continued re-rating of the stock price, with the ultimate catalyst being the drug gaining approval by the FDA. We note that our valuation only incorporates the potential market for Bisantrene for the treatment of AML. The ability of the company to expand the markets of use for Bisantrene offers significant upside potential.

PROFIT & LOSS ($M)			
Y/E June	2016A	2017A	2018F
Revenue	0.2	0.0	0.5
EBITDA	-0.3	-3.9	-4.2
Depreciation & Amortisation	0.0	0.3	0.3
Interest	0.0	0.0	0.0
Profit Before Tax	-0.3	-4.2	-4.5
Tax Expense	0.0	0.0	0.0
Net Profit After Tax	-0.3	-4.2	-4.5

BALANCE SHEET ($M)			
Y/E June	2016A	2017A	2018F
Cash	4.3	1.7	2.6
Receivables	0.0	0.0	0.0
Other Current Assets	0.1	0.1	0.1
Total Current Assets	4.5	1.8	2.7
Property Plant & Equipment	0.0	0.0	0.0
Intangible Assets	0.0	4.3	5.3
Investments	0.0	0.0	0.0
Deferred Tax Assets	0.0	0.0	0.0
Other	0.0	0.0	0.0
Total Non-Current Assets	0.0	4.3	5.3
Total Assets	4.5	6.0	7.9
Trade and other payables	0.4	0.4	0.0
Borrowings	0.0	0.0	0.0
Current tax liabilities	0.0	0.0	0.0
Provisions	0.0	0.0	0.0
Other liabilities	0.0	0.0	0.0
Current Liabilities	0.4	0.4	0.0
Trade and other payables	0.0	0.0	0.0
Borrowings	0.0	0.0	0.0
Deferred tax	0.0	0.0	0.0
Provisions	0.0	0.0	0.0
Non-Current Liabilities	0.0	0.0	0.0
Total Liabilities	0.4	0.4	0.0
Net Assets	4.1	5.7	7.9
Shareholders Equity	4.1	5.6	6.2

CASHFLOW ($M)			
Y/E June	2016A	2017A	2018F
PAT	-0.3	-4.2	-4.5
Adjustments for non-cash items	-0.5	-2.7	-4.7
Change in Working Capital	0.2	0.2	-0.4
Net Cash from Operation Activities	-0.3	-2.5	-5.1
Payments for entities and businesses, net of cash acquired	0.0	0.0	0.0
Payments for property, plant and equipment	0.0	0.0	0.0
Payments for intangible assets	0.0	0.0	-1.0
Payments for other assets	0.0	0.0	0.0
Payments for acquisition of associates and other investments	0.0	0.0	0.0
Proceeds on disposal of businesses and property, plant and equipment	0.0	0.0	0.0
Loans to third party/franchisee	0.0	0.1	0.0
Dividends from associates	0.0	0.0	0.0
Others	0.0	0.0	0.0
Net Cash from Investing	0.0	0.1	-1.0
Proceeds from borrowings	0.0	0.0	0.0
Repayments of borrowings	0.0	0.0	0.0
IPO costs	0.0	-0.3	0.0
Dividends paid to ordinary shareholders	0.0	0.0	0.0
Dividends paid to non-controlling interests	0.0	0.0	0.0
Proceeds from share issue	4.6	0.0	7.0
Proceeds from related party loan	0.0	0.0	0.0
Net Cash from Financing	4.6	-0.3	7.0
Cash at Beginning of the Year	0.0	4.3	1.7
FX Effect	0.0	0.0	0.0
Net Change in Cash	4.3	-2.6	0.9
Cash at End	4.3	1.7	2.6

Key Valuation Assumptions	
AUD/USD	0.75
Probability of FDA Aprroval	60%
WACC	12.4%
Cost of Pivotal Study	$15m-20m
Market Penetration:	
Europe	12%-19%
US	19%-29%
Gross Margin	85%
Distribution Cost:	
Europe	25%
US	15%

COMPANY UPDATE

Since our Initiation of Coverage report released in July 2016, the company has taken great strides in the re-development of Bisantrene for the treatment of AML.

MANUFACTURING AGREEMENTS

- Throughout 2017, the company has secured manufacturing agreements with two companies for the two phases of production:

  (1) The company signed an agreement with Sai Life Sciences, located in India, for the manufacture of the Bisantrene API. The initial agreement is for the supply of the Bisantrene API for at least one year to support the sale of Bisantrene under the NPP in Europe. The company intends that Sai Life Sciences will become the long-term API manufacturer.

  (2) An agreement was also secured with IriSys LLC, a US based company, to complete phase two of the manufacturing process. IriSys will be responsible for the final Bisantrene formulation and production of the finished product for distribution.

PRODUCT DEVELOPMENT AND NAMED PATIENT PROGRAM (NPP)

- With the completion of the first batch of Bisantrene for commercialisation expected to be available for distribution in October, the company is on track to make the drug available for use under the NPP in France for the treatment of AML in Q4 of 2017, to be followed by its availability in Italy, Turkey and South Korea over the next two years.
- In July 2016, the company entered into an agreement with CarthaGenetics, a Swiss based company, for the distribution of Bisantrene under the NPP in Europe. CarthaGenetics will be responsible for the market development and awareness of Bisantrene and all necessary regulatory approvals to allow Bisantrene to be used in each of the target countries in Europe.
- For the sale and distribution of Bisantrene in South Korea under the NPP, the company has entered into an exclusive agreement with BL&H. BL&H will be responsible for the sale and shipment of Bisantrene to hospitals in South Korea and in turn will receive a 25% commission.
- In July 2017, the company announced that an agreement had been secured with the NCI (National Cancer Institute) in the US. Under the agreement, RAC has been granted the right to access and use all the NCI data and associated regulatory filings on Bisantrene for the purpose of developing and supporting the IND for Bisantrene by the company. The data provided under the agreement completes the picture for RAC and will be invaluable for the filing and regulatory review of RAC's IND. The agreement with NCI was entered into after the company announced it had held it's pre-IND meeting with the FDA, which defined the pathway for the development of Bisantrene. At this meeting, the FDA confirmed that the proposed development of Bisantrene qualified for the 505(b)(2) pathway in the US, which allows for the use of historical preclinical and clinical data on Bisantrene and provides a fast track for FDA approval. It was indicated at this meeting that the company could proceed directly to a pivotal study without having to conduct a phase II bridging study.
- The company has added a number of personnel since listing. These appointments include a Head of European Marketing Operations and the establishment of a Scientific Advisory Board (SAB). The SAB comprises three doctors, two of which are considered leading oncologists. The SAB in conjunction with the company will be looking to finalise the clinical trial protocol and prepare for the commencement of the pivotal study in FY18.

JV WITH TARGIMMUNE THERAPEUTICS AG

- The company has entered into a joint venture (JV) with TargImmune Therapeutics AG, a Swiss based company, to expand the markets for Bisantrene beyond AML to include its use for the treatment of other cancers. The JV is 50/50 has been named Race Immunotherapies and will focus on developing new and improved cancer therapies based on combining Bisantrene with TargImmune's targeted cancer treatment. All new intellectual property created by the JV will be equally owned by both parties.

- The JV will be independently funded with operations commencing once the funding is in place and the agreements formally executed. RAC will provide scientific support and Bisantrene drug product but no direct funding to the JV. All core development work will be conducted by TargImmune scientists.
- The TargImmune technology platform was licensed from the Hebrew University of Jerusalem. The platform encompasses a proprietary non-viral vector to target receptors that are overexpressed on cancer cells. Once at the target cell, the vector delivers an immun-modulating agent into the cell that triggers apoptosis (cell death). The technology is known as Cancer Targeted Delivery of pIC (CTPIC).
- TargImmune believes therapeutic synergies can be achieved by combining the CTPIC with Bisantrene. In turn, the anti-cancer effects of Bisantrene could be greatly enhanced by the combination with CTPIC.
- The initial focus of the JV will be on targeting the therapeutic opportunities in breast, lung, head and neck cancers. From this, the JV will explore the opportunities for the treatment of other cancers, such as prostate cancer.

CAPITAL RAISING

- Post the year-end, the company successfully completed a share purchase plan of $2.5m through the issue of 12.5m new shares at $0.20 per share. This was at a discount to the share price. Subscribers to the placement were issued a free attaching option on a 1 for 2 basis, with an exercise price of $0.30 to be exercised on or before 30 September 2018.
- The placement was issued via two tranches: (1) the first tranche of 11.25m shares was issued three trading days after the completion of the offer; (2) the second tranche of 1.25m shares and the free attaching options was conditional upon the approval of shareholders to be obtained at a General Meeting held on 30 August. The proposal was ratified at the General Meeting.

INVESTMENT CASE

- We have retained our value of **$0.44** per share from our Initiation of Coverage report published in July 2016, maintaining our range of $0.44-$1.24 per share. Our valuation is based on a probability weighted DCF of the potential sales of Bisantrene in the US and Europe. We have assigned a 60% probability of the drug receiving FDA approval.
- Our market penetration assumptions detailed in the Initiation report remain unchanged. We note that the ability of the company to achieve levels above the assumed market penetration levels will represent upside value.
- We have not allocated any value for the potential for the 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 for drug sales.
- While the company has made significant strides in the re-development of Bisantrene, there remains a number of milestones to be achieved to reach the ultimate goal of achieving FDA approval. Gaining FDA approval will be a significant catalyst for the share price. The positive response from the pre-IND meeting in February and confirmation that Bisantrene qualified for the 505(b)(2) pathway in the US was a positive step towards gaining approval.
- In addition to the development risk associated with Bisantrene, there remains dilution risk in the short-term given the significant portion of shares on issue that are currently held in escrow and are due to be released from escrow in July 2018. This combined with a total of 20m performance shares and options due to mature over the next 12-months could result in some downward pressure on the share price in the short-term. Further to this, the company will be required to raise additional capital to fund the pivotal study, which is expected to cost between $15m and $20m.

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INDEPENDENT
INVESTMENT RESEARCH

Independent Investment Research (Aust.) Pty Limited

SYDNEY OFFICE
Level 1, 350 George Street
Sydney NSW 2000
Phone: +61 2 8001 6693
Main Fax: +61 2 8072 2170
ABN 11 152 172 079

MELBOURNE OFFICE
Level 7, 20–22 Albert Road
South Melbourne VIC 3205
Phone: +61 3 8678 1766
Main Fax: +61 3 8678 1826

DENVER OFFICE
355 S Teller Street
Suite 200
Lakewood 80226
Denver Colorado USA
Phone: +1 161 412 444 724

MAILING ADDRESS
PO Box H297 Australia Square
NSW 1215