

Race Oncology

Rediscovering a lost chemotherapeutic

Race Oncology is currently focused on the development of bisantrene, which had been the subject of over 40 clinical trials in the 1980s and 1990s as part of Lederle's search for a safer anthracycline (a widely used class of chemotherapeutics that is associated with cardiotoxicity). Despite positive efficacy data across a variety of cancers, especially AML (it was even approved for the treatment of AML in France in 1990 but never commercialised), development stopped after Lederle was sold to Wyeth and then Wyeth was sold to Pfizer. Race will be developing bisantrene for relapsed/refractory AML and expects to initiate a pivotal trial for approval in the US around the end of 2018.

Efficacy indicated in relapsed/refractory AML

Bisantrene had been investigated in trials covering a plethora of different cancers and some efficacy had been indicated in leukaemias and lymphomas, as well as breast and ovarian cancer. AML in particular was especially compelling. In five studies totalling 85 heavily pretreated patients, bisantrene demonstrated a 48% complete response rate. Earlier studies also indicated that the cardiotoxicity typically seen with anthracyclines was greatly reduced with bisantrene.

Early access revenues in the near term

As part of an early access program, unapproved pharmaceuticals can in some cases be sold to hospitals or patients. In Europe, such programs are legal in France, Italy and Turkey, and the company expects to apply for such a program in France by the end of 2017 and once approved, start to generate revenues.

Orphan drug exclusivity provides 7 years' protection

While the original patents for bisantrene have expired, as AML is an orphan indication, bisantrene, if approved in the US, would be protected by seven years of orphan drug exclusivity. Race also owns two filed patents which, if approved, would provide patent protection through 2034 in the US, EU, Japan and other countries.

Valuation: EV of \$20m

With \$3.5m in net cash as of 31 July, 2017, additional financing will be necessary for the company to move forward with bisantrene development. In our view, \$20m is a modest EV given the efficacy demonstrated by previous studies of bisantrene in AML and we would expect that to change as Race builds awareness, generates early access revenues and progresses towards its pivotal study in the US.

Historical financials							
Year end	Revenue (A\$m)	PBT (A\$m)	EPS (p)	DPS (p)	P/E (x)	Yield (%)	
06/14	N/A	N/A	N/A	N/A	N/Á	N/A	
06/15	N/A	N/A	N/A	N/A	N/A	N/A	
06/16	0.0	(0.3)	(2.8)	N/A	N/A	N/A	
06/17	0.0	(4.2)	(7.9)	N/A	N/A	N/A	

Source: Race Oncology

Pharma & biotech

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Share details	
Code	RAC
Listing	ASX
Shares in issue	65.3m

Business description

Race Oncology is a development stage specialty pharmaceutical company which seeks to rescue, rediscover or repurpose overlooked drugs. Its main asset, bisantrene, is being developed for AML. In the US, the company is in the process of designing the pivotal trial. In Europe, it is on the verge of being used as part of an early access program aimed at relapsed/refractory AML.

Bull

- Bisantrene demonstrated a 48% response rate in relapsed/refractory AML patients.
- Early access sales provide the promise of nearterm revenue in certain regions.
- Relatively de-risked asset with more than 40 clinical trials behind it

Bear

- The composition of matter patent has expired, although orphan drug status should provide a minimum of seven years protection in the US.
- AML is a very competitive space with four recent approvals and promising products in the pipeline.
- Company will seek additional funding to support its proposed pivotal study for US approval.

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