Friday, 4 June 2021

RESEARCH REPORT

CORPORATE CONNECT

Antisense Therapeutics

FDA Feedback as Good As It Gets

Share Price & Estimated Future Price

Price in 12-months*	$0.48
Current Price	$0.19
Implied Increase/Dec	+152%

* Price at end FY21/beginning FY22

Antisense Therapeutics has received formal written feedback from the US Food and Drug Administration (FDA) on its development plans for ATL1102 for non-ambulant patients with Duchenne muscular dystrophy (DMD). In a phase II trial, ATL1102 performed extremely well. The regulatory path for a disease like DMD can be simplified and shortened. To achieve this outcome, though, determining the requirements of regulators is paramount.

FDA Feedback: Key points from the FDA's feedback are:

- **Phase II study results of ATL1102 are sufficient to support larger studies**,
- Higher doses of ATL1102 (above 25mg/week) could be considered given adequate justification,
- **A single, appropriately powered, randomized, double blind, placebo-controlled trial with a primary endpoint of PUL2.0 (performance of upper limb 2.0) appears acceptable to support a marketing application**,
- The secondary endpoints assessed by MyoGrip, MyoPinch and predicted forced vital capacity (FVC) appear reasonable,
- A nine-month non-human primate (NHP) study is required to support the phase II/IIb study, but it can overlap with the IIb/III study out to 6-months dosing,
- **The FDA has suggested Antisense apply for Fast Track Designation (FTD)**, and **that they review Antisense's phase IIb/III study protocol**.

CCR's View: The FDA never outwardly states that it supports the development of a particular drug, unlike some have claimed. It only advises on the sufficiency of current data and future plans. It is up to investors to determine whether the feedback is supportive of the company's plans. **Our opinion is that the FDA's feedback is as supportive of the company's plans as it could have been**.

The FDA has already granted ATL1102 Orphan Drug status (reduced fees and income maximisation (seven-year marketing exclusivity)), as well as Rare Paediatric Disease designation (provides a valuable, transferable Priority Review Voucher upon product approval). FTD is designed around maximising a drug's chances of ultimate approval. Benefits, like accelerated approval, which can get a drug on market extremely quickly, are alluring. Near term, **we believe it is the increased interactions with the agency that Antisense will benefit from the most, given the FDA's likely unique requirements for marketing approval**. The FDA is the sole arbiter for US marketing approval and knowing exactly what they want is ideal. **Antisense said that it would apply for FTD and we have no doubt that application will be successful.**

The NHP study was expected in our eyes because, historically, the FDA has generally required an NHP study to support a proposed dosing regimen and the period of dosing prior to the initiation of a human study. The FDA has made a significant concession in allowing the NHP and proposed phase IIb/III trial to overlap, Carefully designed, this study will give Antisense the important option of studying higher doses of ATL1102, if it chooses. **The NHP study will only need to be done once and it will support any other indications Antisense chooses to trial ATL1102 in**.

Antisense is due to receive feedback from the European Medicines Agency on its Paediatric Investigation Plan, which covers the whole of ATL1102's development, soon. Importantly, Antisense could use this feedback in discussions with the FDA to align the requirements of the EMA, as much as possible, with those of the FDA.

Conclusion: While Europe is Antisense's primary target, the US is the biggest. Clear feedback from the FDA justifies a small, but telling, increase in our target price. **Target price raised from by $0.05 $0.43 to $0.48**

Company Information

ASX Ticker	ANP
Shares on Issue	574m
Fully Diluted Shares on Issue	629m
Market Capitalisation	106m
ASX Vol. (Shares/Day)	1.5m

Cash Sufficiency

	$ Million
A) Last Appendix 4C	End March 2021
B) Cash & Equivalents at 4C	8.3
C) Burn[1]	-1.7
D) Quarters Cash Remaining[2]	6.2
E) Estimated Current Q Burn[3]	-1.1
F) Estimated Cash Raised Post 4C[4]	0.1
G) Estimated Current Cash[5]	**7.3**
H) Significant Estimated New Commitment(s)[6]	

1 Burn = Net Cash from/used In Operating Activities; **2** Quarters Cash Remaining = (B+F)/C+E;
3 Equals C *(# Days Since previous Q end Q4 / # Days in Current Q);
4 Equals Capital Raising(s) – Estimated Costs; **5** Equals B – E + F
6 Equals estimated maximum new significant commitments that the company has or is likely to become contractually or ethically committed to.

Key Personnel

Robert Moses	Chairman
Mr Mark Diamond	MD & CEO
Dr Charmaine Gittleson	NED
Mr William Goolsbee	NED
Dr Graeme Mitchell	NED
Dr Gary Pace	NED
Dr George Tachas	NED

Chart (Source: Iress)

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