Tuesday, 5 October 2021

RESEARCH REPORT

CORPORATE CONNECT

Antisense Therapeutics (ANP)

Paediatric Investigation Plan Almost Certain To Get the Tick and Other Notable Events

Share Price & Estimated Future Price

Price in 12-months*	$0.48
Current Price	$0.195
Implied Increase/Dec	+146%

* Price at end FY22/beginning FY23

Antisense Therapeutics reported on Friday 30 September (2021), that it had received a draft opinion recommending agreement with the company's Paediatric Investigation Plan (PIP) for the development of ATL1102 for Duchenne muscular dystrophy (DMD) from the Paediatric Committee (PDCO) for the European Medicines Agency (EMA). This is not a final decision, but we understand it is very unusual for the EMA not to adopt a recommended PIP. A PIP must be adopted by the EMA before a medicine can be approved for use in children in EU Member States. The receipt of the of the draft opinion by Antisense is a significant positive for the company.

What is a PIP? A PIP is the investigation plan for a developmental medicine for children. Its purpose is to ensure that the data required for the medicine to adequately be assessed is collected. The flip-side is that children not be put through unnecessary clinical studies. **A PIP is a highly significant document in that it must describe to the development plan up to the point of submitting a marketing authorisation application**. There would be few if any adult drugs where the company would have thought through the development of the drug in that detail due to the uncertainty inherent in development. Importantly, PIPs, can be amended.

Antisense stated in its announcement that the PIP covers not only the company's planned phase IIb trial in non-ambulant DMD children, but the entire paediatric development of ATL1102, which includes studies in ambulant boys. There are two significant points here. **The first is that Antisense has thought very broadly about ATL1102's development for DMD and the second is that they are already thinking about what is next (ambulant)**. This is exactly what you want to see from a company.

Antisense's PIP will be discussed and a decision made on adoption at an October 15th, 2021, meeting of PDCO. PDCO has asked Antisense to check the PIP for any inaccuracies, which, of course, the company has agreed to do. Once adopted, Antisense should be notified shortly thereafter. **Given the time and thought Antisense has put into the PIP, we see it is as close to certain as anything can be that it will be adopted by the EMA.**

Additional Events: At the 26th Annual Congress of the World Muscle Society, Antisense presented data demonstrating ATL1102 moved two proteins closely linked to loss of ambulation in DMD subjects in the right direction shown to slow the normal decline. Two further key markers moved significantly as predicted by ATL1102's hypothesized mechanism of action (MOA). Clinical results determine product approvals, but a well-supported MOA like this reduces clinical risk substantially.

Pfizer's Fordadistrogene movaparvovec, a DMD gene therapy, initially ran into potency assay issue with the FDA earlier this year. Now a serious safety issue has been found. Currently, Pfizer believes it effects DMD patients with mutations in certain exons and those patients are now excluded from the trial. Pfizer's issues highlight the difficulty in gene therapies development.

New Director: Antisense has announced further board renewal with Dr Gil Price to replace 6-year director Mr William Goolsbee. Dr Price's recruitment appointment significantly strengthens the board's clinical and scientific expertise, particularly in the area of DMD, as well as governance. Dr Price, as a physician, has been focussed on drug development, adverse drug reactions, drug utilization and regulation. While as a senior executive his expertise spans clinical asset investment strategy, evaluation, financing and execution. Additionally, he was a director of Sarepta Therapeutics (2007-2016), the first company to obtain a DMD drug approval.

Conclusion: Antisense intends to release a significant amount of detail about its phase IIb trial in non-ambulant DMD patients once they receive the formal PIP opinion from PDCO. Until then, **Target price maintained $0.48**

Company Information

ASX Ticker	ANP
Shares on Issue	574m
Fully Diluted Shares on Issue	629m
Market Capitalisation	112m
ASX Vol. (Shares/Day)	1.5m

Cash Sufficiency

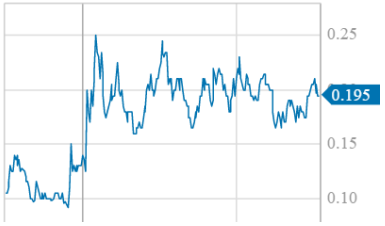
	$ Million
A) Last Appendix 4C	End June 2021
B) Cash & Equivalents at 4C	6.0
C) Burn[1]	-2.3
D) Estimated Current Q Burn[2]	-2.4
E) Estimated Cash Raised Post 4C[3]	0.1
F) Estimated Current Cash[4]	**3.57**
H) Significant Estimated New Commitment(s)[5]	None

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

Key Personnel

Dr Charmaine Gittleson	Chair
Mr Mark Diamond	MD & CEO
Mr William Goolsbee	NED
Dr Graham Mitchell	NED
Mr Bob Moses	NED
Dr Gary Pace	NED
Dr Gil Price	NED
Dr George Tachas	Director Drug Discovery
Nuket Desem	Director Clinical & Regulatory Affairs

Chart (Source: Iress)



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