WILSONS

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Theme Alert

Sector Healthcare

Company

Antisense Therapeutics (ANP)

Getting the FDA monkey off their back

Recommendation OVERWEIGHT

12-mth target price (AUD) $0.36

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Announcement Highlights

Antisense have announced formal commencement and commitment to a US monkey toxicology study, as per the request of the FDA in relation to advancement of ATL1102 in Duchenne Muscular Dystrophy. As we have previously outlined, completion of a successful 9-month non-human primate toxicology study (to supplement their successful 6-month studies) to demonstrate long-term safety of dosing ATL1102, enables lifting of the US IND partial hold for ATL1102 as well as re-opening the door for ANP to re-submit for Fast Track (or Breakthrough Therapy) designations. We of course await initiation of the Phase IIb trial in Europe as the next catalyst, noting that early 2024 data readout will be most important pivotal catalyst for the stock in the coming ~12-18 months.

Wilsons' View

Initial analysis

Commitment to ATL1102 program; investing to expand strategic interest. Lifting of the partial hold on the US IND is key to opening dialogue with the FDA around future ATL1102 registration pathways. Having one key market "locked" for ATL1102's advancement was holding back investor interest in our view. This is an important advancement for the ATL1102 DMD program, in that it demonstrates ANP are investing in ensuring this asset has the broadest and most strategically attractive path forward, as they head into their European Phase IIb. Whilst Europe is a more immediate available market, the recent program change to a Phase IIb (followed by Phase III) does re-open the possibility of a harmonized global (EU + US) Phase III program following the 1Q24 data readout – with this US toxicology step important in enabling this path optionality.

Toxicology study low risk in our view. As we have previously summarised, we assess the level of incremental risk associated with this 9-month toxicology study as limited, given the existing 6-month studies conducted, as well as understanding the safety profile of the broader class of antisense oligonucleotide drugs (of which ATL1102 is one). In this sense we view this toxicology study requirement as more of a (frustrating) check-box exercise to satisfy regulators as opposed to a risk-associated program which could affect future US trial proceedings.

Earnings implications

None.

Investment view

We maintain our OVERWEIGHT rating and $0.36/sh risked PT on Antisense, noting that today's announcement does bring more positivity on the stock and the decisions being made to realise the full value of ATL1102.

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Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/disclosures.

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