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Antisense Therapeutics (ANP)

Start of DMD pivotal trial nears, but extra funds needed

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Speculative Investment

Recommendation: Outperform

Our View

ANP has announced a 1 for 20 bonus offer of New Options to eligible shareholders for nil consideration, exercisable at 48c. These options will make up for the options that were not issued last December due to the shortfall in the capital raise. The New Options could raise $36m to help fund the continuation of the upcoming pivotal trial of ATL1102 in non-ambulant DMD beyond the planned futility analysis, if exercised in full. However, the company still faces a shortfall of ~$14m in the funding for the first stage of the Phase IIb/III trial and is considering a range of funding options. With $23.5m cash at 31 December, ANP has sufficient funds to initiate the pivotal trial, but is likely to need additional funds later in the year. With the pivotal trial expected to commence mid-year our undiluted valuation is unchanged at $0.27/sh, while our fully diluted valuation declines slightly to $0.25/sh, allowing for a potential $14m capital raise.

Key Points

Preparations for the Phase IIb/III DMD trial well advanced
ANP almost completed site selection for the Phase IIb/III European trial. Submission of clinical trial applications to national authorities in the 9 participating countries will commence next month. Patient recruitment will commence once trial approvals are received. The double blind, pivotal trial will recruit 114 non-ambulant DMD patients who will be randomised 1:1:1 to receive weekly doses of placebo, 25mg or 50mg of ATL1102 for 52 weeks. The primary endpoint will be the change in the Performance of Upper Limb Module for DMD 2.0 (PUL 2.0) vs placebo. A futility analysis will be conducted when ~48 patients have completed the week 24 interim PUL 2.0 assessment (mid CY23), leading to a go/no go decision whether to continue the treatment groups or the study itself. The primary endpoint is expected to read out in mid-CY24.

Investigating options to address $14m funding shortfall
ANP raised $20m in a placement at $0.24/sh in November, but the associated entitlement offer only raised $2.6m out of the target of $16.8m. This leaves a shortfall of ~$14m in the estimated cost of funding the pivotal trial to the futility analysis in mid CY23. The company is continuing discussions with third parties regarding options to source the additional funds, including via equity, debt via a loan or a convertible instrument, partnering, collaboration, or a mix thereof.

Positive FDA feedback on US regulatory plans for ATL1102 in DMD
ANP has received positive feedback from the FDA regarding the protocol for the proposed 9-month monkey toxicology study to support dosing of patients with ATL1102 beyond 6 months in the US. The FDA has previously advised that the tox study could be run in parallel with the initial stages of a clinical trial, as long as it was completed before patients were dosed beyond 6 months. Separately, the company considers there may be an option to take the EU Phase IIb/III data to the FDA to support an application for approval of ATL1102 for DMD without further trials, should the trial results be sufficiently strong to warrant it.

ATL1102 showed promise in Phase IIa DMD trial
In a Phase IIa trial in 9 non-ambulant DMD patients, subjects treated with 25mg ATL1102 per week for 24 weeks showed an improvement in PUL 2.0 scores, whereas PUL 2.0 scores declined in all 6 other studies of DMD patients that we examined. ATL1102 shows promise as a treatment to reduce inflammation and resultant muscle damage in DMD, which will be investigated in the upcoming pivotal trial at up to twice the dose used in the Phase IIa trial.

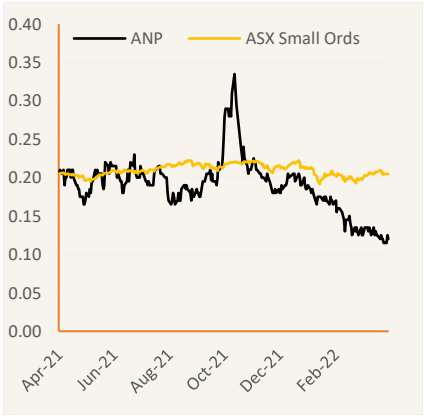
A Trial of ATL1102 in an animal model of an undisclosed inflammatory muscle disease, under a collaboration with the Murdoch Children's Research Institute, is due to report initial data in Q2 CY22. The disease has no effective treatments.

Our conflicts of interest are disclosed on the last page of this report.

Summary (AUD)

Market Capitalisation	**$80m**
Share price	**$0.12**
52 week low	$0.115
52 week high	$0.35
Cash as at 31 December 2021	$23.5m

Share price graph (AUD)



Key Financials (AUDm)

	FY21A	FY22F	FY23F
Revenue	0.6	2.1	5.0
R&D	(4.9)	(7.4)	(19.4)
SG&A	(3.7)	(1.6)	(1.3)
EBITDA	(8.0)	(7.0)	(15.7)
Reported NPAT	(8.0)	(7.0)	(15.4)
NPAT Adj.	(8.0)	(7.0)	(15.4)
EPS Adj. (c)	(1.5)	(1.0)	(2.0)
PE ratio (x)	n/a	n/a	n/a
DPS (c)	0.0	0.0	0.0
EV/Sales	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a
ROE	n/a	n/a	n/a

Antisense Therapeutics - Summary of Forecasts — ANP $ 0.12

PROFIT & LOSS SUMMARY (A$m)

Year end June	FY20A	FY21A	FY22F	FY23F
Sales, royalties, milestones	0.0	0.0	0.0	0.0
Other (includes R&D tax rebate	0.7	0.6	2.1	5.0
Total Revenue	**0.7**	**0.6**	**2.1**	**5.0**
Growth (pcp)	26.3%	-14.6%	228.8%	138.5%
R&D Expenses	(2.2)	(4.9)	(7.4)	(19.4)
CoGS + SG&A expenses	(4.3)	(3.7)	(1.6)	(1.3)
EBITDA	**(5.8)**	**(8.0)**	**(7.0)**	**(15.7)**
Dep'n/Other Amort'n	(0.1)	(0.1)	(0.1)	(0.1)
EBIT	**(5.9)**	**(8.1)**	**(7.0)**	**(15.8)**
Net Interest	0.0	(0.0)	0.1	0.3
Pre-Tax Profit	**(5.9)**	**(8.1)**	**(7.0)**	**(15.4)**
Tax Expense	0.0	0.0	0.0	0.0
Minorities	0.0	0.0	0.0	0.0
NPAT	**(5.9)**	**(8.0)**	**(7.0)**	**(15.4)**
Growth (pcp)	-	-	-	-
Adjustments	0.0	0.0	0.0	0.0
NPAT Reported	(5.9)	(8.0)	(7.0)	(15.4)

PER SHARE DATA*

Year end June	FY20A	FY21A	FY22F	FY23F
EPS (c) - Reported	**(1.3)**	**(1.5)**	**(1.0)**	**(2.0)**
Growth (pcp)	n/a	14.2%	-30.9%	91.6%
EPS (c) - Adjusted	(1.3)	(1.5)	(1.0)	(2.0)
Growth (pcp)	n/a	14.2%	-30.9%	91.6%
Gross CF per share (c)	(0.9)	(1.1)	(1.2)	(2.3)
NTA per share (c)	0.9	1.0	4.3	2.4
Dividend (c)	0.0	0.0	0.0	0.0
Franking	0.0	0.0	0.0	0.0

KEY RATIOS

Year end June	FY20A	FY21A	FY22F	FY23F
Current ratio (x)	6.5	6.4	33.5	19.1
Net Debt : Equity (%)	-86.6%	-99.8%	-95.9%	-77.5%
Net Debt: EBITDA (x)	0.7	0.7	4.7	0.9
ROE (%)	n/a	n/a	n/a	n/a
ROIC (%)	n/a	n/a	n/a	n/a
Dividend Payout Ratio (%)	n/a	n/a	n/a	n/a

VALUATION MULTIPLES

Year end June	FY20A	FY21A	FY22F	FY23F
Reported PE Ratio (x)	**n/a**	**n/a**	**n/a**	**n/a**
Adjusted PE Ratio (x)	**n/a**	**n/a**	**n/a**	**n/a**
Dividend Yield (%)	0.0%	0.0%	0.0%	0.0%
EV/Sales (x)	n/a	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a	n/a
EV/EBIT (x)	n/a	n/a	n/a	n/a

CAPITAL RAISING ASSUMPTIONS

Year end June	FY20A	FY21A	FY22F	FY23F
Shares Issued (m)	68.7	85.0	212.7	0.0
Issue Price (A$)	0.08	0.100	0.17	0.12
Gross Cash Raised (A$m)	5.5	8.5	36.8	0.0

BALANCE SHEET SUMMARY

Year end June	FY20A	FY21A	FY22F	FY23F
Cash + Cash Equivalents	4.1	6.0	32.9	15.0
Receivables	0.7	0.6	2.0	0.0
Inventories	0.0	0.0	0.0	0.0
Other	0.5	0.1	0.1	5.0
Total Current Assets	5.2	6.7	35.1	20.0
Inventories	0.0	0.0	0.0	0.0
PP&E	0.0	0.3	0.3	0.2
Intangibles	0.0	0.0	0.0	0.0
Other	0.1	0.0	0.0	0.0
Total Non-Current Assets	0.1	0.3	0.3	0.2
TOTAL ASSETS	**5.4**	**7.0**	**35.3**	**20.2**
Accounts Payable	0.3	0.5	0.5	0.0
Borrowings	0.1	0.1	0.1	0.1
Provisions	0.4	0.5	0.5	0.5
Other	0.0	0.0	0.0	0.5
Total Current Liabilities	0.8	1.0	1.0	1.0
Borrowings	0.0	0.2	0.2	0.2
Provisions	0.0	0.0	0.0	0.0
Other	0.0	0.5	0.5	0.5
Total Non-Current Liabilities	0.0	0.2	0.2	0.2
TOTAL LIABILITIES	**0.8**	**1.3**	**1.3**	**1.3**
TOTAL EQUITY	**4.5**	**5.7**	**34.0**	**18.9**

CASH FLOW SUMMARY

Year end June	FY20A	FY21A	FY22F	FY23F
EBIT (excl Abs/Extr)	**(5.9)**	**(8.1)**	**(7.0)**	**(15.8)**
Add: Dep'n & Amort'n	0.1	0.1	0.1	0.1
Other non-cash items	(2.0)	(2.4)	2.3	(0.3)
Less: Tax paid	0.0	(0.1)	0.0	0.0
Net Interest	0.0	(0.0)	0.1	0.3
Change in Rec.	(0.1)	0.1	(1.4)	2.0
Change in Inv.	0.0	0.0	0.0	0.0
Gross Cashflows	(3.9)	(5.8)	(8.0)	(17.9)
Capex	(0.0)	(0.0)	(0.0)	(0.0)
Free Cashflows	(4.0)	(5.8)	(8.0)	(17.9)
Share Issue Proceeds	5.2	7.9	35.0	0.0
Other	(0.1)	(0.1)	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0
Net Cash Flow	**1.2**	**2.0**	**26.9**	**(17.9)**
FX Effect on Cash	0.0	0.0	0.0	0.0

ANP valuation summary

	Probability (%)	Valuation (A$m)	Valuation A$/share
ATL1102 RoW non-ambulant DMD	30%	73.7	0.11
ATL1102 US non-ambulant DMD	20%	44.4	0.07
ATL1102 Ambulant DMD	20%	39.2	0.06
RPD Priority Review Voucher	10%	11.1	0.02
SG&A	-	(9.5)	(0.01)
Portfolio total	-	158.9	0.24
Cash 31Dec 2021	-	23.5	0.04
Total Valuation	-	183.4	0.27

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