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Antisense Therapeutics (ANP)

Positive FDA feedback on pivotal trial design

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Speculative Investment

Recommendation: Outperform

Our View

ANP has received formal minutes from the type C meeting with the FDA held on 19 April. The FDA feedback noted that the design of the proposed Phase IIb/III trial of ATL1102 in non-ambulant DMD patients (including the PUL 2.0 primary endpoint) appears to be acceptable and that it would consider the exploration of higher doses subject to adequate justification. The FDA expects the company to conduct a 9-month monkey toxicology study to support dosing for 12 months vs 6 months in the earlier Phase IIa trial, but in a positive surprise would allow the Phase IIb/III trial to commence before the monkey study is completed. While the FDA feedback is positive for the US development plans for ATL1102, ANP's main focus continues to be on the planned European Phase IIb trial, which aims to commence recruitment in Q421. The company expects to receive feedback from European Medicines Agency (EMA) on its Paediatric Investigation Plan (PIP) for ATL1102 in the coming weeks, which will allow it to finalise the trial design. Our valuation is unchanged at $154m, $0.27/sh (undiluted), or $0.25/sh fully diluted for a potential capital raise to fund the est. $25m European trial.

Key Points

Proposed US Phase IIb/III trial design appears acceptable. The FDA feedback confirmed that the findings from 24 weeks dosing with ATL1102 at 25mg/week in the Phase IIa trial at Royal Children's Hospital, Melbourne were adequate to support larger studies. It also noted that the proposal for a single, randomised, double blind, placebo controlled Phase IIb/III study in non-ambulant boys of 52 weeks duration was acceptable, as were the PUL 2.0 primary endpoint and suggested secondary endpoints. The FDA said it could consider higher doses of ATL1102 beyond 25mg/week, subject to adequate justification.

PIP feedback from EMA next key milestone. A key upcoming milestone for ANP is the receipt of feedback on the design of the proposed European Phase IIb trial, as part of feedback on the overall PIP submitted to the Paediatric Committee (PDCO) of the EMA in January. After it has received the feedback from PDCO, ANP will finalise the design of the Europe-based, randomised Phase IIb trial of ATL1102 in non-ambulant boys with DMD. It aims to initiate recruitment of the Phase IIb trial in Q421.

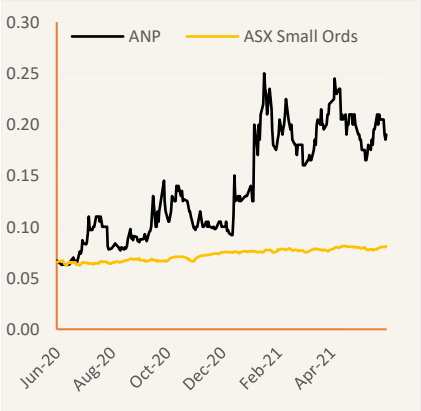
Regulators' expectations appear to be aligned. While final feedback from the EMA is still pending, the feedback that ANP has received to date indicates that the FDA and EMA both have similar expectations regarding the key features that should be included in the design of a pivotal trial of ATL1102 in non-ambulant DMD patients, including the patient population, treatment duration and primary endpoint. The key difference appears to be the FDA's requirement for a 9-month animal toxicology study (est. cost $1-2m).

A range of development options for ATL1102. While the company is yet to confirm its path forward, given the high cost of pivotal trials we currently model ANP deferring initiation of the US based Phase IIb/III trial until after the efficacy of ATL1102 has been confirmed in the European Phase IIb trial. The fact that the FDA would allow dosing of patients to commence before the 9-month monkey study is complete (providing a draft study report is submitted before the duration of dosing exceeds 6 months) may allow the initiation of the monkey study to also be deferred until after the topline data readout; given that by then safety data would be available from 12-month dosing of human study subjects it is possible the monkey study may no longer be required (subject to FDA feedback). If the results of the European Phase IIb trial are positive, ANP might consider applying for US approval based on the European trial data without conducting a separate US pivotal trial, subject to the feasibility of such a route.

Summary (AUD)

Market Capitalisation	**$123.5m**
Share price	**$0.215**
52 week low	$0.27
52 week high	$0.06
Cash as at 31 March 2021	$8.3m

Share price graph (AUD)



Key Financials (AUDm)

	FY20A	FY21E	FY22F
Revenue	0.7	1.5	2.2
R&D	(2.2)	(3.8)	(7.4)
SG&A	(4.3)	(1.6)	(1.6)
EBITDA	(5.8)	(3.9)	(6.9)
Reported NPAT	(5.9)	(3.9)	(6.8)
NPAT Adj.	(5.9)	(3.9)	(6.8)
EPS Adj. (c)	(1.3)	(0.7)	(1.1)
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 $0.215

PROFIT & LOSS SUMMARY (A$m)

Year end June	FY19A	FY20A	FY21E	FY22F
Sales, royalties, milestones	0.0	0.0	0.0	0.0
Other (includes R&D tax rebate	0.6	0.7	1.5	2.2
Total Revenue	**0.6**	**0.7**	**1.5**	**2.2**
Growth (pcp)	n/a	26.3%	97.8%	49.3%
R&D Expenses	(1.8)	(2.2)	(3.8)	(7.4)
CoGS + SG&A expenses	(1.8)	(4.3)	(1.6)	(1.6)
EBITDA	**(3.0)**	**(5.8)**	**(3.9)**	**(6.9)**
Dep'n/Other Amort'n	(0.0)	(0.1)	(0.0)	(0.0)
EBIT	**(3.0)**	**(5.9)**	**(3.9)**	**(6.9)**
Net Interest	0.1	0.0	0.0	0.1
Pre-Tax Profit	**(2.9)**	**(5.9)**	**(3.9)**	**(6.8)**
Tax Expense	0.0	0.0	0.0	0.0
Minorities	0.0	0.0	0.0	0.0
NPAT	**(2.9)**	**(5.9)**	**(3.9)**	**(6.8)**
Growth (pcp)	-	-	-	-
Adjustments	0.0	0.0	0.0	0.0
NPAT Reported	(2.9)	(5.9)	(3.9)	(6.8)

PER SHARE DATA*

Year end June	FY19A	FY20A	FY21E	FY22F
EPS (c) - Reported	**(0.8)**	**(1.3)**	**(0.7)**	**(1.1)**
Growth (pcp)	n/a	n/a	n/a	n/a
EPS (c) - Adjusted	(0.8)	(1.3)	(0.7)	(1.1)
Growth (pcp)	n/a	n/a	n/a	n/a
Gross CF per share (c)	(0.8)	(0.9)	(0.9)	(1.2)
NTA per share (c)	0.7	0.9	1.5	3.2
Dividend (c)	0.0	0.0	0.0	0.0
Franking	0.0	0.0	0.0	0.0

KEY RATIOS

Year end June	FY19A	FY20A	FY21E	FY22F
Current ratio (x)	4.2	6.5	18.2	42.9
Net Debt : Equity (%)	n/a	-86.6%	-81.6%	-89.0%
Net Debt: EBITDA (x)	1.0	0.7	1.8	2.8
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	FY19A	FY20A	FY21E	FY22F
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	FY19A	FY20A	FY21E	FY22F
Shares Issued (m)	48.5	68.7	85.0	100.0
Issue Price (A$)	0.00	0.08	0.100	0.20
Gross Cash Raised (A$m)	1.6	5.5	8.5	20.0

BALANCE SHEET SUMMARY

Year end June	FY19A	FY20A	FY21E	FY22F
Cash + Cash Equivalents	2.9	4.1	7.4	19.2
Receivables	0.6	0.7	1.4	2.1
Inventories	0.0	0.0	0.0	0.0
Other	0.2	0.5	0.5	0.5
Total Current Assets	3.7	5.2	9.2	21.8
Inventories	0.0	0.0	0.0	0.0
PP&E	0.0	0.0	0.0	0.0
Intangibles	0.0	0.0	0.0	0.0
Other	0.0	0.1	0.1	0.1
Total Non-Current Assets	0.0	0.1	0.1	0.2
TOTAL ASSETS	**3.7**	**5.4**	**9.4**	**21.9**
Accounts Payable	0.6	0.3	0.0	0.0
Borrowings	0.0	0.1	0.1	0.1
Provisions	0.3	0.4	0.4	0.4
Other	0.0	0.0	0.0	0.0
Total Current Liabilities	0.9	0.8	0.5	0.5
Borrowings	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Total Non-Current Liabilities	0.0	0.0	0.0	0.0
TOTAL LIABILITIES	**0.9**	**0.8**	**0.5**	**0.5**
TOTAL EQUITY	**2.8**	**4.5**	**8.8**	**21.4**

CASH FLOW SUMMARY

Year end June	FY19A	FY20A	FY21E	FY22F
EBIT (excl Abs/Extr)	**(3.0)**	**(5.9)**	**(3.9)**	**(6.9)**
Add: Dep'n & Amort'n	0.0	0.1	0.0	0.0
Other non-cash items	0.4	(2.0)	1.3	1.0
Less: Tax paid	0.0	0.0	0.0	0.0
Net Interest	0.1	0.0	0.0	0.1
Change in Rec.	(0.6)	(0.1)	(0.7)	(0.7)
Change in Inv.	0.0	0.0	0.0	0.0
Gross Cashflows	(2.9)	(3.9)	(4.6)	(7.2)
Capex	2.4	(0.0)	(0.0)	(0.0)
Free Cashflows	(2.9)	(4.0)	(4.6)	(7.2)
Share Issue Proceeds	1.5	5.2	7.9	19.0
Other	2.4	(0.1)	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0
Net Cash Flow	**1.0**	**1.2**	**3.3**	**11.8**
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	25%	6.2	0.11
ATL1102 US non-ambulant DMD	20%	4.7.6	0.08
ATL1102 Ambulant DMD	20%	35.4	0.06
SG&A to 2024	-	1.7	0.00
Portfolio total	-	145.9	0.25
Cash end FY21	-	7.4	0.01
Total Valuation	-	154.2	0.27

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