

Not so Fast Track

We maintain our OVERWEIGHT recommendation on Antisense Therapeutics (ANP) and risked PT of \$0.63 per share. Antisense announced their application for Fast Track Designation (FTD) cannot be processed until the FDA's partial 'clinical hold' on their drug's IND is lifted. Submissions to that effect are planned. Whilst this is a small set-back, the key point remains that FDA is at the table and open to the idea of approving ATL1102 on the basis of a single Phase IIb/III trial. That remains the objective in Europe, where regulatory interactions are far more progressed. ANP are still on track for a CY21 start for their pivotal EU Phase IIb study. We expect to hear regarding final PIP approval toward end of 3Q'CY21 with all EU preparatory trial plans rolling full steam ahead. This is the key catalyst for the market in the near term. EU prospects are the primary driver of our valuation.

Key points

FTD mix up. We now understand that FTD requests are unable to be considered with outstanding on-hold INDs, which was not made clear to ANP at the time of their FTD submission. ANP's FTD application is able to be reconsidered once the IND hold is resolved (via submission and acceptance of their clinical trial and monkey toxicology protocols). FTD refusal here is not based on any clinical evidence review – it is administrative. We still view FTD as possible at a later date, noting that their existing Rare Paediatric Disease (RPD) designation from FDA comes with expedited review optionality.

Europe should be investors focus. Whilst the US market is an important opportunity it has never been the driver of ANP valuation in our view (75% of PT is EU). Not only is ANP primed for a registration trial in Europe which would set it up for first potential marketing approvals, it is also a larger market opportunity (TAM \$1.7B vs \$0.9B) with less competitors (i.e. no exon-skipping), a larger addressable DMD cohort (2-3x), and a market where ANP have strong relationships with trial clinicians that are highly beneficial to eventual market entry and clinical adoption. These are still being built in the US market.

Toxicology study commitment positive. ANP's comment they are preparing to submit their protocol outline for a 9-month toxicology study to the FDA solidifies our confidence that ANP are committed to confirming the longer-term safety of ATL1102 and working with regulators. There is a known class effect of antisense oligonucleotides (of which ATL1102 belongs) in non-human primates where they have been seen to induce vasculitis, however thus far this has not translated to humans. This study will confirm no new AEs arise following 9 months of dosing which have not already been seen at 6 months. Importantly Antisense can leverage this safety study data for future indications with ATL1102.

Valuation. We maintain our real options SOTP valuation for Antisense of \$0.63 per share comprising \$0.48 for European ATL1102 DMD prospects and \$0.15 for US ATL1102 DMD prospects. Our unrisksed valuation is \$1.43 per share.

Risks and catalysts on page 2 of this report

Earnings forecasts					
Year-end June (AUD)	FY19A	FY20A	FY21F	FY22F	FY23F
NPAT rep (\$m)	-2.9	-5.9	-9.7	-13.3	-2.5
NPAT norm (\$m)	-2.9	-5.9	-9.7	-13.3	-2.5
Consensus NPAT (\$m)			-7.1	-14.3	-5.1
EPS norm (cps)	-0.8	-1.3	-2.5	-2.0	-0.3
EPS growth (%)	36.7	-71.1	-90.6	18.3	83.1
P/E norm (x)	-22.4	-13.1	-6.9	-8.4	-49.6
EV/EBITDA (x)	-30.6	-15.4	-9.2	-6.7	-31.4
FCF yield (%)	-3.0	-4.0	-9.4	-10.3	2.2
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Franking (%)	0	0	0	0	0

Source: Company data, Wilsons estimates, Refinitiv

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Analyst(s) who own shares in the Company: n/a

Recommendation	OVERWEIGHT
12-mth target price (AUD)	\$0.63
Share price @ 13-Aug-21 (AUD)	\$0.17
Forecast 12-mth capital return	270.6%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	270.6%
Market cap	\$98m
Enterprise value	\$89m
Shares on issue	574m
Sold short	
ASX 300 weight	n/a
Median turnover/day	\$0.2m

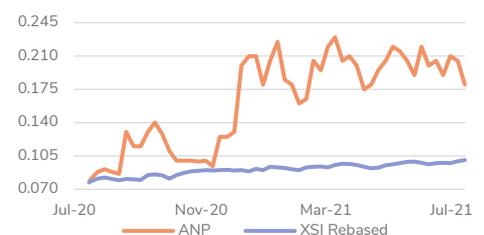
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12-mth price performance (\$)

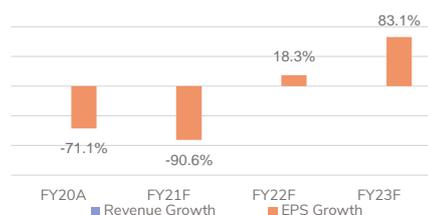


	1-mth	6-mth	12-mth
Abs return (%)	-16.3	-20.0	133.8
Rel return (%)	-19.8	-28.2	103.3

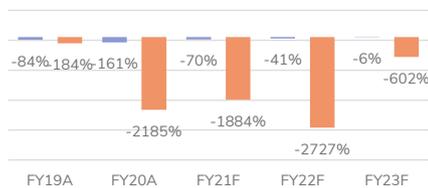
Key changes

		29-Jun	After	Var %
NPAT:	FY21F	-9.7	-9.7	0.0%
norm	FY22F	-13.3	-13.3	0.0%
	(\$m) FY23F	-2.5	-2.5	0.0%
EPS:	FY21F	-2.5	-2.5	0.0%
norm	FY22F	-2.0	-2.0	0.0%
	(cps) FY23F	-0.3	-0.3	0.0%
DPS:	FY21F	0.0	0.0	0.0%
	(cps) FY22F	0.0	0.0	0.0%
	FY23F	0.0	0.0	0.0%
Pricetarget:		0.63	0.63	0.0%
Rating:		O/W	O/W	

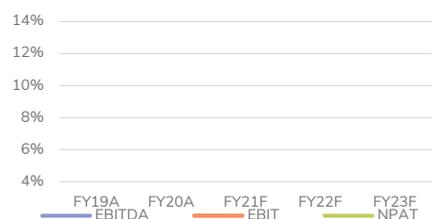
Growth rates



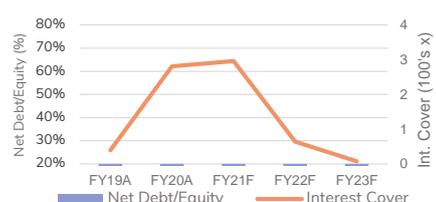
Returns



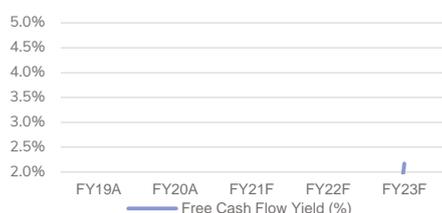
Margin trends



Solvency



Free cash flow yield



Interims (\$m)

	1H20A	2H20A	1H21A	2H21E
Sales revenue	0.0	0.0	0.0	0.0
EBITDA	-4.3	-1.5	-2.1	-7.7
EBIT	-4.3	-1.6	-2.0	-7.7
Net profit	-4.3	-1.6	-2.0	-7.7
Norm EPS	-1.0	-0.3	0.4	-1.3
EBIT/sales (%)				
Dividend (c)	0.0	0.0	0.0	0.0
Franking (%)	0.0	0.0	0.0	0.0
Payout ratio (%)	0.0	0.0	0.0	0.0
Adj payout (%)	0.0	0.0	0.0	0.0

Key assumptions

	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F	FY24F
Revenue Growth (%)	-0.6	-0.4	1.2	0.2	-0.2	4.8	0.3	-0.6
EBIT Growth (%)	0.1	-0.2	0.3	1.0	0.7	0.4	-0.8	6.8
NPAT Growth (%)	0.1	-0.2	0.3	1.0	0.6	0.4	-0.8	7.9
EPS Growth (%)	0.2	-0.3	-0.4	0.7	0.4	0.1	-0.8	7.9
Tax Rate (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
R&D Expenditure	-1.1	-1.0	-1.8	-1.9	-10.0	-13.0	-5.0	-22.0

Financial ratios

	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F	FY24F
PE (x)	-10.5	-15.0	-23.7	-13.8	-7.3	-8.9	-52.5	-5.9
EV/EBITDA (x)	-32.6	-38.6	-30.6	-15.4	-9.2	-6.7	-31.4	-3.9
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-3.0	-2.4	-3.0	-4.0	-9.4	-10.3	2.2	-21.8
Payout ratio (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Adj payout (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Profit and loss (\$m)

	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F	FY24F
Sales revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	-2.7	-2.3	-2.9	-5.8	-9.8	-13.4	-2.9	-22.9
Depn & amort	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1
EBIT	-2.7	-2.3	-2.9	-5.9	-9.7	-13.5	-3.0	-23.0
Net interest expense	-0.1	0.0	-0.1	0.0	0.0	-0.2	-0.4	-0.4
Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minorities/pref divs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Equity accounted NPAT	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (pre-sig items)	-2.8	-2.3	-2.9	-5.9	-9.7	-13.3	-2.5	-22.6
Abns/exts/signif	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Reported net profit	-2.8	-2.3	-2.9	-5.9	-9.7	-13.3	-2.5	-22.6

Cash flow (\$m)

	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F	FY24F
EBITDA	-2.7	-2.3	-2.9	-5.8	-9.8	-13.4	-2.9	-22.9
Interest & tax	-0.1	0.0	-0.1	0.0	0.1	0.2	0.4	0.4
Working cap/other	-0.1	0.0	0.1	1.9	0.5	3.1	4.6	1.2
Operating cash flow	-2.9	-2.3	-2.9	-3.9	-9.2	-10.0	2.1	-21.3
Maintenance capex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Free cash flow	-2.9	-2.3	-2.9	-3.9	-9.2	-10.0	2.1	-21.3
Dividends paid	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Growth capex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Invest/disposals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Oth investing/finance flows	-0.1	-2.7	2.3	-0.4	-2.0	-1.8	0.0	0.0
Cash flow pre-financing	-3.0	-5.0	-0.6	-4.3	-11.2	-11.8	2.1	-21.3
Funded by equity	0.1	5.0	1.6	5.5	33.5	30.0	0.0	0.0
Funded by debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Funded by cash	2.9	0.0	-1.0	-1.2	-22.3	-18.2	-2.1	21.3

Balance sheet summary (\$m)

	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F	FY24F
Cash	1.9	1.9	2.9	4.1	23.0	41.1	43.3	22.0
Current receivables	0.4	0.3	0.6	0.7	0.5	0.8	0.8	1.1
Current inventories	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net PPE	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Intangibles/capitalised	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	2.5	4.8	3.7	5.4	24.2	42.7	44.8	23.8
Current payables	0.4	0.3	0.6	0.3	0.4	0.5	0.7	0.6
Total debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total liabilities	0.7	0.6	0.9	0.8	0.9	1.1	1.3	1.2
Shareholder equity	1.9	4.2	2.8	4.5	23.2	41.6	43.5	22.6
Total funds employed	1.9	4.2	2.8	4.5	23.2	41.6	43.5	22.6



Antisense Therapeutics Limited (ANP)

Business description

Antisense Therapeutics is a clinical stage biopharmaceutical company focused on development of antisense oligonucleotides targeting rare diseases. Their primary asset, ATL1102, is currently in Phase II trials for the treatment of Duchenne Muscular Dystrophy (DMD) with positive results thus far in the more advanced, non-ambulant disease population. Antisense have also conducted some advanced clinical work on ATL1102 as a treatment for multiple sclerosis (MS) and with another asset ATL1103, for the growth disorder, Acromegaly.

Investment thesis

We maintain our OVERWEIGHT recommendation on Antisense Therapeutics (ANP) and risked PT of \$0.63 per share. Antisense announced their application for Fast Track Designation (FTD) cannot be processed until the FDA's partial 'clinical hold' on their drug's IND is lifted. Submissions to that effect are planned. Whilst this is a small set-back, the key point remains that FDA is at the table and open to the idea of approving ATL1102 on the basis of a single Phase IIb/III trial. That remains the objective in Europe, where regulatory interactions are far more progressed. ANP are still on track for a CY21 start for their pivotal EU Phase IIb study. We expect to hear regarding final PIP approval toward end of 3Q'CY21 with all EU preparatory trial plans rolling full steam ahead. This is the key catalyst for the market in the near term. EU prospects are the primary driver of our valuation.

Revenue drivers

Underlying growth in DMD market driven by greater diagnosis rates
Partnering transactions related to ATL1103 or ATL1102 assets with upfront payments/milestones and royalties

Margin drivers

- Not applicable.

Key issues/catalysts

Clinical trial results
Regulatory interactions with EMA and FDA including CTA and/or IND approval of Phase IIb/III trials
Competitor development progress in DMD market
Partnering opportunities

Risk to view

Failure of ATL1102 to show adequate efficacy in DMD to achieve regulatory approvals
Development of superior disease modifying/curative drugs by competitors
Availability of capital to fund intensive period of R&D in near term with limited catalysts
Ability of management to deliver on commercialisation outcomes

Balance sheet

- Cash of \$6.02M as at 30 June 2021.

Board

- Robert Moses (Chairman)
- Mark Diamond (Managing Director)
- William Goolsbee (Non-executive Director)
- Dr Charmaine Gittleson (Non-executive Director)
- Dr Graham Mitchell (Non-executive Director)
- Dr Gary Pace (Non-executive Director)

Management

Mark Diamond (Chief Executive Officer)
Dr George Tachas (Director – Drug Discovery & Patents)
Phillip Hains (Chief Financial Officer)
Nuket Desem (Director of Clinical & Regulatory Affairs)
Dr Gil Price (Consultant Medical Director)
Alicia Mellors (Company Secretary)

Contact details

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Definitions at wilsonsadvisory.com.au/disclosures.

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