

## Europe a go!

We maintain our OVERWEIGHT recommendation on Antisense Therapeutics (ANP) and moderate our risked PT to \$0.57 per share owing to equity dilution. Antisense have now received a final positive opinion from EMA on their Phase IIb/III trial in non-ambulant DMD with ATL1102 and have their Clinical Trial Applications currently under review by the relevant European competent authorities to get the trial underway. This trial is the only remaining hurdle to European market access for ATL1102 (WILSe: FY26 EU launch, \$630M peak sales). There continue to be plans to harmonise EU and US market access with a single trial, which we view as a possibility given the high unmet clinical need in DMD, positive efficacy data thus far, and FDA precedents in other rare indications (i.e. Radicava® in ALS). Antisense now have capital to get their pivotal EU study underway.

### Key points

**EU regulator confirms Phase IIb/III; allows trial to proceed.** Both EU (EMA) and UK (MHRA) regulators have given positive final opinions on ANP's pivotal Phase IIb/III trial in DMD. This was a major hurdle in progressing closer to market authorisation/s. We now anticipate recruitment start by end FY22 (~6months delay) with readout from futility analysis due 2H23. Assuming significant outcomes, ANP is on track for FY26e EU approval & launch.

**Higher dose confirmed.** One third of patients will receive 50mg ATL1102 in upcoming EU trial - double the Phase II dose (25mg/week). We view this as potential upside for ATL1102's efficacy magnitude given the weight range of DMD patients being recruited.

**Capital secured to partially support Phase IIb/III trial.** The recent November \$20M placement will support initiation of their European Phase IIb/III trial, however Antisense may require additional funds to support study completion.

**US development underway: monkeys next.** Harmonisation of EU and US clinical data packages is paramount to additional value creation for ANP. As ANP await feedback on their recently submitted monkey toxicology protocol (per FDA requirements) we note regular FDA interactions regarding trial harmonisation are planned throughout CY22.

**CY21 board updates.** ANP have streamlined their board appointing Dr Charmaine Gittleston (ex-CSL rare diseases) as Chair in addition to Dr Gil Price (CMO, ex-Sarepta) joining the board as NED, with three long time members stepping down making way for the next stage of ANP's progress as a company.

**Valuation.** Our \$0.57 per share risked SOTP valuation is adjusted for recent equity dilution. Our PT is weighted toward the European DMD opportunity (\$0.43/sh) versus US DMD opportunity for ATL1102 (\$0.14/sh). Our unrisked PT is \$1.30 per share.

### Risks and catalysts on p.5 of this report

Earnings forecasts					
Year-end June (AUD)	FY20A	FY21A	FY22F	FY23F	FY24F
NPAT rep (\$m)	-5.9	-8.1	-15.5	-2.7	-24.9
NPAT norm (\$m)	-5.9	-8.1	-15.5	-2.7	-24.9
Consensus NPAT (\$m)			-10.5	-14.4	-22.6
EPS norm (cps)	-1.3	-1.5	-2.4	-0.4	-3.4
EPS growth (%)	-71.1	-15.0	-58.7	84.7	-830.5
P/E norm (x)	-13.8	-12.0	-7.6	-49.6	-5.3
EV/EBITDA (x)	-16.8	-11.9	-6.2	-34.1	-3.8
FCF yield (%)	-3.3	-4.8	-11.8	1.7	-19.6
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)	\$0.57
Share price @ 17-Jan-22 (AUD)	\$0.18
Forecast 12-mth capital return	216.7%
Forecast 12-mth dividend yield	0.0%
<b>12-mth total shareholder return</b>	<b>216.7%</b>
Market cap	\$120m
Enterprise value	\$97m
Shares on issue	669m
Sold short	
ASX 300 weight	n/a
Median turnover/day	\$0.2m

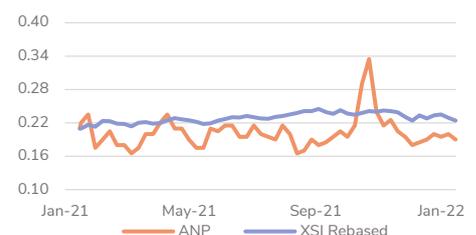
### Dr Melissa Benson

melissa.benson@wilsonsadvisory.com.au  
Tel. +61 2 8247 6639

### Dr Shane Storey

shane.storey@wilsonsadvisory.com.au  
Tel. +61 7 3212 1351

### 12-mth price performance (\$)



	1-mth	6-mth	12-mth
Abs return (%)	2.7	-7.3	-9.5
Rel return (%)	5.5	-4.7	-16.2

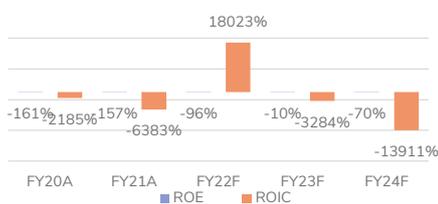
### Key changes

		30-Sep	After	Var %
NPAT:	FY22F	-13.3	-15.5	N/A
norm	FY23F	-2.5	-2.7	N/A
(\$m)	FY24F	-22.6	-24.9	N/A
EPS:	FY22F	-2.0	-2.4	N/A
norm	FY23F	-0.3	-0.4	N/A
(cps)	FY24F	-3.1	-3.4	N/A
DPS:	FY22F	0.0	0.0	0.0%
(cps)	FY23F	0.0	0.0	0.0%
	FY24F	0.0	0.0	0.0%
Pricetarget:		0.63	0.57	-9.5%
Rating:		O/W	O/W	

### Growth rates



### Returns



### Margin trends



### Solvency



### Free cash flow yield



### Interims (\$m)

	1H21A	2H21A	1H22E	2H22E
Sales revenue	0.0	0.0	0.0	0.0
EBITDA	-2.1	-6.1	-7.8	-7.7
EBIT	-2.0	-6.0	-7.9	-7.8
Net profit	-2.0	-6.0	-7.9	-7.7
Norm EPS	-0.4	-1.1	-1.4	-1.0
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	FY21A	FY22F	FY23F	FY24F
Revenue Growth (%)	-0.6	-0.4	1.2	0.2	-0.2	1.7	1.6	-0.6
EBIT Growth (%)	0.0	-0.2	0.3	1.0	0.4	0.9	-0.8	7.6
NPAT Growth (%)	0.1	-0.2	0.3	1.0	0.4	0.9	-0.8	8.3
EPS Growth (%)	0.2	-0.3	-0.4	0.7	0.1	0.6	-0.8	8.3
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	-4.9	-13.0	-5.0	-22.0

### Financial ratios

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
PE (x)	-11.1	-15.8	-25.0	-14.6	-12.7	-8.0	-52.4	-5.6
EV/EBITDA (x)	-35.4	-42.0	-33.2	-16.8	-11.9	-6.2	-34.1	-3.8
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-2.4	-1.9	-2.4	-3.3	-4.8	-11.8	1.7	-19.6
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	FY21A	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	-8.1	-15.6	-2.9	-25.3
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	-8.0	-15.7	-3.0	-25.4
Net interest expense	-0.1	0.0	-0.1	0.0	0.0	-0.1	-0.3	-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	-8.1	-15.5	-2.7	-24.9
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	-8.1	-15.5	-2.7	-24.9

### Cash flow (\$m)

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
EBITDA	-2.7	-2.3	-2.9	-5.8	-8.1	-15.6	-2.9	-25.3
Interest & tax	-0.1	0.0	-0.1	0.0	0.0	0.1	0.3	0.4
Working cap/other	-0.1	0.0	0.1	1.9	2.3	1.3	4.6	1.2
Operating cash flow	-2.9	-2.3	-2.9	-3.9	-5.8	-14.1	2.0	-23.6
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	-5.8	-14.1	2.0	-23.6
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	-0.7	-2.2	0.0	-2.4
Cash flow pre-financing	-3.0	-5.0	-0.6	-4.3	-6.5	-16.4	2.0	-26.0
Funded by equity	0.1	5.0	1.6	5.5	8.5	36.8	0.0	40.0
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	-2.0	-20.4	-2.0	-14.0

### Balance sheet summary (\$m)

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
Cash	1.9	1.9	2.9	4.1	6.0	26.5	28.5	42.4
Current receivables	0.4	0.3	0.6	0.7	0.6	0.9	0.9	1.2
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	2.6	4.8	3.7	5.4	7.0	27.8	29.7	44.0
Current payables	0.4	0.3	0.6	0.3	0.5	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	1.3	1.1	1.3	1.3
Shareholder equity	1.9	4.2	2.8	4.5	5.7	26.6	28.4	42.7
Total funds employed	1.9	4.2	2.8	4.5	5.7	26.6	28.4	42.7

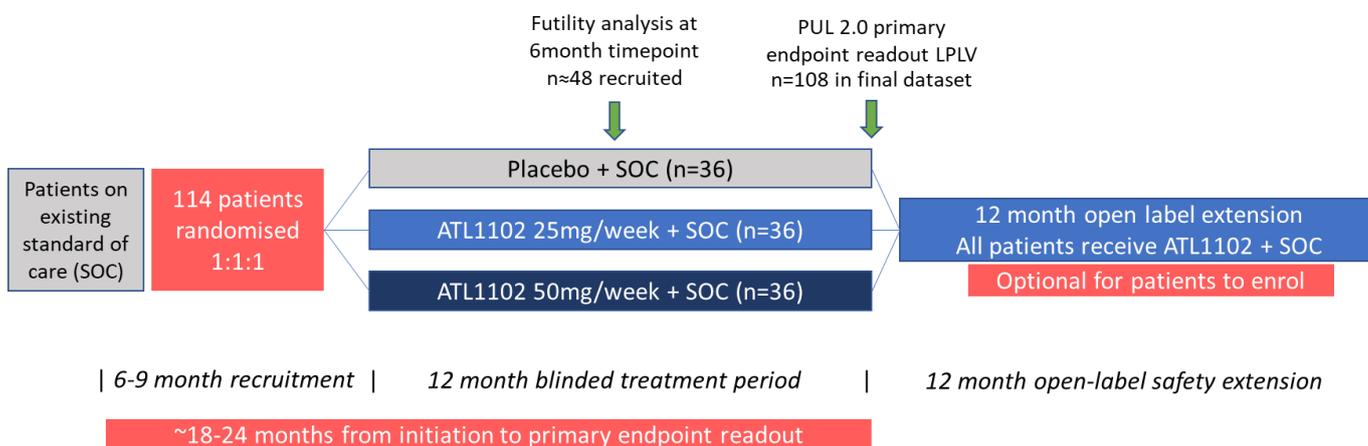


## Pivotal European trial overview

### Key points:

- Study design: Parallel, double-blind, randomised, placebo-controlled trial (see **Figure 1**).
- Sample size: 108 non-ambulant boys with DMD (114 randomised accounting for dropout).
- **Primary endpoint:** Relative change in PUL2.0 score over 12-month period (ATL1102 vs placebo). A reminder, Phase II data showed benefit of ATL1102 over 6-month timeframe.
- Secondary endpoints: Safety & tolerability, Quality of Life, respiratory function, PK.
- Drug dosing timeframe: 12 months (with follow-on 12-month open-label extension phase).
- Treatment groups: Three (Placebo, ATL1102 25mg/week, ATL1102 50mg/week).
- Planned analyses: An interim futility analysis (blinding maintained) at 6-month timepoint to dictate trial continuation (n=16 per arm included).
- Study sites: 30 sites across EU (~7 countries), UK and Australia.

**Figure 1. Finalised European Phase IIb/III pivotal clinical trial of ATL1102 in DMD**



SOC: Standard of care, i.e. corticosteroids. LPLV: Last patient last visit.

Source: Antisense, Wilsons.

## Competitive landscape update

### Non-ambulant DMD

**CAP-1002.** As summarised extensively in our [previous note](#), the final Phase IIb readout (n=6) from Capricor's (NASDAQ:CAPR) cell therapy CAP-1002 asset showed less significant improvements in PUL2.0 score vs. ATL1102 in a similar patient population, albeit at an extended 12-month timepoint but smaller sample ( $\Delta 1.8$ pt CAP-1002 vs  $\Delta 2.9$ pt ATL1102). The ability for Capricor to progress CAP-1002 into a Phase III study is premised on them finding a development partner.

**Pamrevlumab.** FibroGen's (NASDAQ:FGEN) Phase III trial of pamrevlumab in non-ambulant DMD (LELANTOS) is due to report top-line trial results 1H 2023 with the study still recruiting its 90-patient target across 53 global sites. To date we have not had PUL2.0 data to compare to ATL1102.

### DMD gene therapies

**At this point in time, gene therapies are not the silver bullet in DMD that was once thought.** Whilst correction of the lack of dystrophin is disease modifying in DMD, current gene therapy approaches within the pipeline are unable to address this completely. Pipeline gene therapies are generating micro-dystrophin, which is correcting some DMD progression but does not correct the disease fully (i.e. cardiomyopathy & inflammation still present) with some serious safety events. Data thus far suggests waning of efficacy 3-5 years post treatment owing to transgene dilution, meaning repeat treatments are required. Complementary therapies to manage disease symptoms (i.e. fibrosis, inflammation) are needed.



**Pfizer program on hold after non-ambulant patient fatality.** Pfizer's Phase Ib study of their gene therapy PF-06939926 was placed on clinical hold by FDA in late Dec 2021 following the death of a trial participant. The study aimed to recruit 35 patients of both ambulatory and non-ambulatory status. The recent participant death was a non-ambulatory patient. Previously reported adverse events (causing prior holds/revisions) with this therapy in DMD showed associations with muscle weakness and myocarditis (inflammation of the heart tissue) which required high dose corticosteroids to ablate. It is unclear what the fate of this program will be as Pfizer conducts its investigation into this recent patient death. A data readout is now not expected until Q1 2023 (delayed from CY22).

**Sarepta initiates pivotal trial; ambulant only.** At the 2022 JP Morgan Healthcare conference (Jan 2022) Sarepta noted a potential CY23 submission for approval of their gene therapy, SRP-9001, in DMD. SRP-9001 is currently being evaluated in a pivotal 120 patient Phase III trial (EMBARK<sup>1</sup>) in partnership with Roche which will recruit ambulant DMD patients only. This study is a 24-month crossover design. To date, SRP-9001 is only being evaluated in non-ambulant patients in a subset of the current Phase 1b ENDEAVOUR study (<10 patients). This study is yet to report data from the non-ambulant cohort.

### Corticosteroid therapy

**Lack of innovation; tolerability continues to be major issue.** Despite being the only approved therapies for management of DMD, corticosteroids (Emflaza/deflazacort, prednisolone, prednisone) continue to be poorly tolerated by many patients and by the time patients have lost the ability to walk (non-ambulant) they have often ceased steroids or manage with the worsening/compounding side effects of long-term use (eg. weight gain, neurological problems, bone fractures).

High-dose corticosteroids are likely to remain the backbone DMD therapy until the advent of new, improved anti-inflammatory treatments (such as ATL1102).

### US progress update

**Monkey toxicology study outstanding; progress made.** Antisense submitted their protocol to FDA for the required 9-month non-human primate toxicology study in early December. They are currently awaiting FDA feedback on this study protocol before being able to proceed (expected 1Q'22). As we have [previously noted](#), we do not assess a significant risk attributed to this longer duration study given the past results of ATL1102 in prior 6-month toxicology studies and the past behaviour of other antisense oligonucleotide drugs (of which ATL1102 is one) in these extended length studies.

**Harmonisation still on table; key focus.** Use of the data from the EU Phase IIb/III trial to support a US market approval is a key focus of ANP. This approach clearly has time and cost benefits, but also allows for an expedited development pathway potentially supporting faster access to efficacious drugs for long-suffering DMD patients. The FDA's willingness to engage on this harmonisation prospect, with interactions and discussions planned over CY22 suggests they are open to this prospect. We expect this to be a key priority for ANP management throughout CY22, once their EU study is underway and recruiting.

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<sup>1</sup> <https://www.parentprojectmd.org/drug-development-pipeline/srp-9001-micro-dystrophin-gene-transfer/>



## 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 moderate our risked PT to \$0.57 per share owing to equity dilution. Antisense have now received a final positive opinion from EMA on their Phase IIb/III trial in non-ambulant DMD with ATL1102 and have their Clinical Trial Applications currently under review by the relevant European competent authorities to get the trial underway. This trial is the only remaining hurdle to European market access for ATL1102 (WILSe: FY26 EU launch, \$630M peak sales). There continue to be plans to harmonise EU and US market access with a single trial, which we view as a possibility given the high unmet clinical need in DMD, positive efficacy data thus far, and FDA precedents in other rare indications (i.e. Radicava® in ALS). Antisense now have capital to get their pivotal EU study underway.

### 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 ~\$24M as at 31 Dec 2021.

### Board

Dr Charmaine Gittleson (Chairman)  
Mark Diamond (Managing Director)  
Dr Gary Pace (Non-executive Director)  
Dr Gil Price (Non-executive Director)

### Management

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

### Contact details

Antisense Therapeutics Limited  
Level 1, 14 Wallace Avenue  
Toorak, VIC 3142 Australia  
antisense.com.au



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