WILSONS
Equity Research

Date
08 September 2021

Theme
Company Update

Company
Antisense Therapeutics Limited (ANP)

Monkey business

Recommendation	OVERWEIGHT
12-mth target price (AUD)	$0.63
Share price @ 07-Sep-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	$92m
Shares on issue	574m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.2m

We maintain our OVERWEIGHT recommendation on Antisense Therapeutics (ANP) and risked PT of $0.63 per share. Earlier this year, Antisense received feedback from the FDA requiring a 9-month, non-clinical toxicology study in order to support a Phase IIb/III 12-month dosing trial of ATL1102 in DMD boys. This is a routine requirement for the drug class that ATL1102 belongs to (antisense oligonucleotides or ASOs). The new study also helps align the company's US and European regulatory strategies. In this note, we provide a brief overview of the non-clinical toxicology data to date for ATL1102 in comparison with data from approved ASOs. After discussions with regulatory consultants we conclude that the extended 9-month toxicology study that Antisense are about to embark upon is a low risk exercise that adds much value to the ATL1102 program in DMD. As we continue to highlight, the US market is secondary to our positive investment thesis, with European market progress the primary focus. PIP feedback/acceptance within the coming months, ahead of 4Q21 trial start continues to be the most near-term catalyst.

Key points

FDA consistent on toxicology requirements for this drug class. All FDA approved antisense oligonucleotide drugs (ASOs) for DMD (Sarepta's 3 exon skipping drugs) completed 9-month non-clinical toxicology studies to support their development/subsequent approval. FDA decision making is consistent with their treatment of other ASO drugs.

Vasculitis issue thus far restricted to primates. The major ASO-related AE of interest to regulators is vasculitis which has been seen in monkey safety studies of ASOs, including ATL1102 when studied at doses ≥3 mg/kg. This is a known class effect of ASOs which has not translated to humans. Changes to monkey availability with the Chinese export ban on the US could delay start of this study by up to ~8months. We do not model a US Phase IIb/III trial start until ~2023 in our base case scenario.

Existing data highlights all expected AEs. We understand that within the two completed 6-month toxicology studies of ATL1102 all expected drug-class related adverse events (AEs) have been observed, consistent with other ASOs. The risk a new AE arises in a 9-month study is low, with a more likely outcome being changes to known AE frequencies or severity, that is unlikely to affect clinical trial plans. Review of data from FDA approved ASO drugs concludes the same, de-risking this upcoming monkey study in our view.

Valuation. Our sum-of-the-parts $0.63/sh risked PT comprises a) $0.48/share for European DMD opportunity & $0.15/share for US DMD opportunity. Unrisked PT is $1.43.

Risks and catalysts

Risks: a) unfavourable clinical trial results; b) lack of capital to support expenses; c) share dilution; d) competitor development of DMD therapies **Catalysts:** a) EMA trial approval; b) FDA engagement & IND approval; c) board renewal; d) partnering opportunities.

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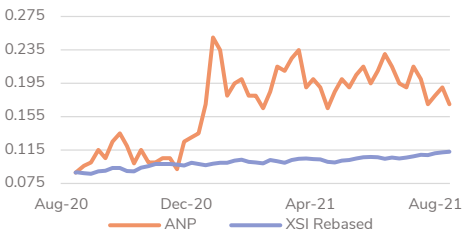
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	-17.1	6.2	93.2
Rel return (%)	-21.3	-9.0	64.9

Earnings forecasts

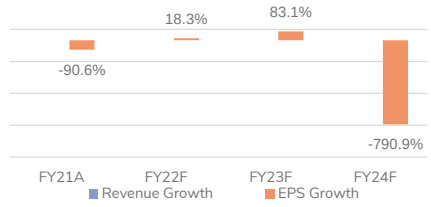
Year-end June (AUD)	FY20A	FY21A	FY22F	FY23F	FY24F
NPAT rep ($m)	-5.9	-8.1	-13.3	-2.5	-22.6
NPAT norm ($m)	-5.9	-9.7	-13.3	-2.5	-22.6
Consensus NPAT ($m)			-14.3	-5.4	-0.8
EPS norm (cps)	-1.3	-2.5	-2.0	-0.3	-3.1
EPS growth (%)	-71.1	-90.6	18.3	83.1	-790.9
P/E norm (x)	-13.1	-6.9	-8.4	-49.6	-5.6
EV/EBITDA (x)	-15.8	-11.2	-6.8	-32.2	-4.0
FCF yield (%)	-4.0	-6.0	-10.3	2.2	-21.8
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

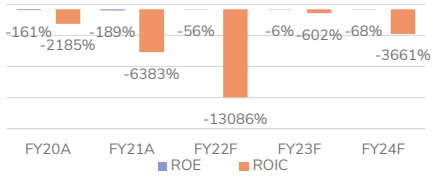
Key changes

		16-Aug	After	Var %
NPAT: norm ($m)	FY22F	-13.3	-13.3	0.0%
	FY23F	-2.5	-2.5	0.0%
	FY24F	-22.6	-22.6	0.0%
EPS: norm (cps)	FY22F	-2.0	-2.0	0.0%
	FY23F	-0.3	-0.3	0.0%
	FY24F	-3.1	-3.1	0.0%
DPS: (cps)	FY22F	0.0	0.0	0.0%
	FY23F	0.0	0.0	0.0%
	FY24F	0.0	0.0	0.0%
Price target:		0.63	0.63	0.0%
Rating:		O/W	O/W	

Growth rates

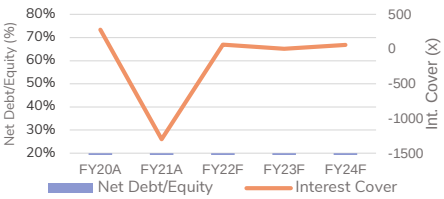


Returns

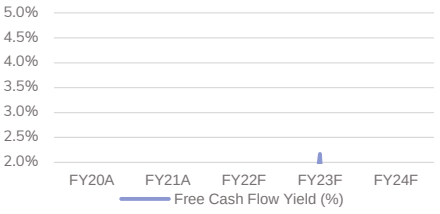


Margin trends

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	-5.7	-7.6
EBIT	-2.0	-6.0	-5.8	-7.7
Net profit	**-2.0**	**-7.7**	**-5.7**	**-7.6**
Norm EPS	**-0.4**	**-1.1**	**-1.0**	**-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	4.5	0.3	-0.6
EBIT Growth (%)	0.0	-0.2	0.3	1.0	0.4	0.7	-0.8	6.8
NPAT Growth (%)	0.1	-0.2	0.3	1.0	0.4	0.6	-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	FY21A	FY22F	FY23F	FY24F
PE (x)	-9.9	-14.2	-22.4	-13.1	-6.9	-8.4	-49.6	-5.6
EV/EBITDA (x)	-33.4	-39.6	-31.3	-15.8	-11.2	-6.8	-32.2	-4.0
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	-6.0	-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	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	-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**	**-8.0**	**-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**	**-8.1**	**-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**	**-8.1**	**-13.3**	**-2.5**	**-22.6**

Cash flow ($m)

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
EBITDA	-2.7	-2.3	-2.9	-5.8	-8.1	-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	2.3	3.1	4.6	1.2
Operating cash flow	**-2.9**	**-2.3**	**-2.9**	**-3.9**	**-5.8**	**-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**	**-5.8**	**-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	-0.7	-1.8	0.0	0.0
Cash flow pre-financing	**-3.0**	**-5.0**	**-0.6**	**-4.3**	**-6.5**	**-11.8**	**2.1**	**-21.3**
Funded by equity	0.1	5.0	1.6	5.5	8.5	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	-2.0	-18.2	-2.1	21.3

Balance sheet summary ($m)

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
Cash	1.9	1.9	2.9	4.1	6.0	41.1	43.3	22.0
Current receivables	0.4	0.3	0.6	0.7	0.6	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	**2.6**	**4.8**	**3.7**	**5.4**	**7.0**	**42.7**	**44.8**	**23.8**
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**	**1.2**
Shareholder equity	**1.9**	**4.2**	**2.8**	**4.5**	**5.7**	**41.6**	**43.5**	**22.6**
Total funds employed	**1.9**	**4.2**	**2.8**	**4.5**	**5.7**	**41.6**	**43.5**	**22.6**

Non-clinical toxicology simplified

Non-human primate data requirement in drug development

FDA guidance. Current industry guidance documents recommend that 9-month non-clinical toxicology data from non-rodents is required to support paediatric dosing of a drug beyond 6 months[1] (**Table 1**).

Chronic and repeated dosing of non-human primates (i.e. monkeys) with an investigational drug is used to determine if there are any toxicities that develop (i.e. renal, liver etc) as a result of prolonged drug exposure, which is relevant for drugs to treat chronic conditions. Monkeys are used in such cases given their similarity to humans in terms of drug metabolism and organ function, there are however instances where effects seen in monkeys do not translate to effects in humans. Non-clinical toxicity studies are a key safety component of drug development.

Antisense have thus far completed two 6-month monkey toxicology studies. These are adequate to support a 12-month Phase IIb in Europe however the FDA has a higher non-clinical toxicology mandate.

Table 1. Recommended Duration of Repeated-Dose Toxicity Studies to Support the Conduct of Clinical trials

Maximum Duration of Clinical Trial	Rodents	Non-rodents (i.e. monkey)
Up to 2 weeks	2 weeks	2 weeks
Between 2 weeks and 6 months	Same as clinical trial length	Same as clinical trial length
Longer than 6 months	6 months	**9 months**

Source: Adapted from FDA Industry Guidance M3(R2) Revision 1.

NOAEL. The No Observed Adverse Effect Level (NOAEL) is the lowest dose of a drug at which no adverse drug effects are seen in test animals. This level is typically used to determine the margin of safety for a clinical dose range in human trials. A 3-fold margin is a typical starting point. Antisense have previously noted that their preclinical/clinical experience to date should allow future dosing at or above a 1.5mg/kg dose level[2]. Based on this we assess a potential NOAEL for ATL1102 of ≈1.5mg/kg, which is 3-fold higher than the currently evaluated Phase II ATL1102 dose in non-ambulant DMD boys (25mg ~ 0.5mg/kg based on median recruited body weight). This gives 2- to 4-fold headroom with respect to increasing the dose in future Phase IIb/III trials (i.e. 50-100mg), which aligns with the higher dose range guided by Antisense for the anticipated EU Phase IIb.

Recent FDA feedback

As we outlined in our prior research, the FDA feedback received by Antisense, with regards to proceeding with ATL1102 in a chronic (12 month) DMD trial, was met with a requirement to complete an additional 9-month non-clinical toxicology study. This was our base case expectation.

No luck on 9-month exception, but a win on timing. As a reminder, Antisense appealed for an exception to the 9-month study requirement earlier this year, allowing them to continue in a 12-month clinical trial using 6-month non-human primate study data to support them (which the EU regulator, EMA, allows). Despite not being able to provide a strong clinical rationale the FDA rejected this proposal. They did however provide a concession, in that Antisense can begin a Phase IIb/III clinical trial whilst the 9-month toxicology study runs in parallel. This is a significant benefit for Antisense given the lag time to start clinical work is reduced by ~6months.

Not setting a new precedent for DMD studies. A likely reason for FDA rejecting ANP's appeal could simply be a preference to remain consistent with their industry guidance documents and not be seen as playing favourites. Our understanding is that all of the existing FDA-approved DMD drugs (which are also ASOs) (**Table 2**) undertook 9-month toxicology studies to support their clinical development/marketing authorisation. An exception from guidance would set a new precedent the regulator was unlikely to do.

[1] US Food & Drug Administration. 2010. Guidance for Industry: M3(R2) Nonclinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m3r2-nonclinical-safety-studies-conduct-human-clinical-trials-and-marketing-authorization

[2] ANP ASX announcement. 1 April 2014. https://www.prnewswire.com/news-releases/atl1102-for-ms---toxicology-study-main-findings-253366821.html

Known class effects of Antisense Oligonucleotides (ASOs)

Checklist of target organ effects from ASOs in non-human primate studies.

Antisense oligonucleotide (ASO) drugs have been shown to have a broadly consistent "checklist" of adverse events which are observed in almost all non-clinical toxicology studies. Some of these have been shown to translate reliably to patients treated with ASOs, however not all, and not to the same extent. These adverse events are associated with the structure of ASOs and their required ability to accumulate within tissues (including tissues that are not the target) as well as their interactions with off-target proteins within the body. Clinically, approved ASO drugs are used to treat significant and often life-threatening medical conditions (i.e. DMD, **Table 2**) where the benefits of the drug significantly outweigh the associated off-target side effects.

Typical side effects of antisense oligonucleotides (ASOs) include[3]:

- Thrombocytopenia (low platelet count affecting blood clotting ability);
- Proinflammatory effects including vasculitis (inflammation of blood vessels) and inflammatory infiltrate production causing injection site reactions and/or flu-like symptoms;
- Glomerulonephritis (impairment of kidneys);
- Hepatoxicity (liver impairment) including single-cell necrosis.

Vasculitis the key effect for consideration. The development of vasculitis is a key side effect of ASOs which has thus far been prevalent in nonclinical studies but extremely rare in clinical trials. Monitoring for any vasculitis-associated symptoms is required in all ASO trials, including for ATL1102. Encouragingly, there is mounting clinical evidence to show that vasculitis appears to be a monkey-specific issue as they are more sensitive to ASO-mediated complement activation which is thought to be the root cause[2]. Clinical manifestation of ASO-related inflammation in humans appears more in the form of injection site reactions (ISRs) and flu-like symptoms. ISRs were seen in the prior DMD Phase II of ATL1102[4].

Table 2. Existing antisense oligonucleotides (ASOs) approved by the FDA.

Drug	Company	Year approved	Indication
Mipomersen	Kastle Therapeutics	2013^	Homozygous Familial Hypercholesterolemia
Nusinersen	Biogen	2016	Spinal Muscular Atrophy
Inotersen	Ionis Therapeutics	2018	Familial Amyloid Neuropathies
Eteplirsen	Sarepta Therapeutics	2016	**Duchenne Muscular Dystrophy**
Golodirsen	Sarepta Therapeutics	2019	**Duchenne Muscular Dystrophy**
Casimersen	Sarepta Therapeutics	2021	**Duchenne Muscular Dystrophy**

^ *Since discontinued by sponsor.*

Source: Dhuri et al. 2020[5] , Bachem, FDA.

Data from existing approved ASOs highlights lack of significant change between 6- and 9-month timepoints. Our understanding is that all of the expected class-related side effects of ASOs (as listed above) are relevant to ATL1102, and have been observed in the prior 6-month nonclinical toxicology studies, including vasculitis events[6]. The key takeaway here being, there are no new adverse events expected to arise (based on ASO profile) within the 6-9month timeframe that haven't already been observed. The risk therefore, associated with the longer 9-month toxicology study is significantly reduced in our view. Potential outcomes of this 3-month extension could include a) increased frequency of an adverse event or b) increased severity of a known adverse event, both of which are unlikely to change any clinical trial plans in our assessment.

Review of existing approved ASO (**Table 2**) non-clinical toxicology data from public FDA dossiers highlights this also. There is an absence of new adverse events arising between 6- and 9-month timepoints in these FDA approved ASO cases. Relevant adverse events were identified by the 6-month timepoint.

[3] Frazier, KS. 2015. Antisense Oligonucleotide Therapies: The Promise and the Challenges from a Toxicologic Pathologist's Perspective. *Toxicologic Pathology*, 43: 78-89.
[4] ANP ASX Announcement. 18 November 2019. https://www.asx.com.au/asxpdf/20191118/pdf/44bnq0q2zb6v0x.pdf
[5] Dhuri et al. 2004. Antisense Oligonucleotides: An Emerging Area in Drug Discovery and Development. *J Clin Med.* 9. doi:10.3390/jcm9062004
[6] ANP AGM Presentation. November 2017. http://www.antisense.com.au/wp-content/uploads/2017/11/ASX-17_29-Nov_AGM-Presentation.pdf

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. Earlier this year, Antisense received feedback from the FDA requiring a 9-month, non-clinical toxicology study in order to support a Phase IIb/III 12-month dosing trial of ATL1102 in DMD boys. This is a routine requirement for the drug class that ATL1102 belongs to (antisense oligonucleotides or ASOs). The new study also helps align the company's US and European regulatory strategies. In this note, we provide a brief overview of the non-clinical toxicology data to date for ATL1102 in comparison with data from approved ASOs. After discussions with regulatory consultants we conclude that the extended 9-month toxicology study that Antisense are about to embark upon is a low risk exercise that adds much value to the ATL1102 program in DMD. As we continue to highlight, the US market is secondary to our positive investment thesis, with European market progress the primary focus. PIP feedback/acceptance within the coming months, ahead of 4Q21 trial start continues to be the most near-term catalyst.

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

Balance sheet

- Cash of ~$6M as at 30 June 2021.

Margin drivers

- Not applicable.

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)

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

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)

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

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Disclaimers and Disclosures

Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/disclosures.

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