WILSONS
Equity Research

Date
21 April 2021

Theme
Company Update

Company

Antisense Therapeutics Limited (ANP)

European access: a pivotal proposal

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	**$0.57**
Share price @ 20-Apr-21 (AUD)	$0.19
Forecast 12-mth capital return	200.0%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**200.0%**
Market cap	$109m
Enterprise value	$100m
Shares on issue	574m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.3m

We maintain our OVERWEIGHT recommendation on Antisense Therapeutics (ANP) and risked $0.57 per share price target. Having realised a >200% capital return increase since our December initiation we take the opportunity to remind investors of the further potential upside within the next 12 months for Antisense, specifically in relation to their European Phase IIb trial campaign in Duchenne Muscular Dystrophy (DMD). Last month we provided an update on the competitive landscape in DMD, with several notable CY21 setbacks within the sector (SRP-9001, SGT-001, Translarna), as well as a new US market entrant in Sarepta's casimersen. We continue to view Antisense's ATL1102 as well placed within the competitive pipeline given the few players actively targeting non-ambulant, wheelchair bound, DMD patients (which comprise 50% of the DMD population). Here we provide a summary of the expected near-term catalysts and their impact on valuation.

Key points

Awaiting PIP feedback. Feedback on the Paediatric Investigational Plan (PIP) submitted in late February is crucial to confirm the Phase IIb trial design, including its pivotal status and higher drug dosing arm. We still anticipate a Clinical Trial Application filing in FY21.

Pivotal status. Pivotal status would mean that ATL1102 may be considered for marketing authorisation following this upcoming EU Phase IIb trial, as opposed to requiring a follow-on Phase III. There is precedent in rare diseases for single Phase IIb pivotal studies.

EU treatment well-coordinated for DMD. Large coordinated neuromuscular centres and academic networks (with KOLs) manage patient treatment in EU and are targets for trial recruitment (e.g. Germany, France (Sorbonne), UK (UCL) and the Netherlands). This coordinated approach simplifies the marketing effort to the point independent EU commercialisation is achievable for Antisense.

First FDA engagement. Antisense had their first engagement with the FDA this week. The focus of this meeting being the acceptability of the existing safety data for ATL1102 to support 12-month dosing in a US Phase II/III clinical trial. We expect formal meeting minutes within 30 days. We also note recent increased US engagement by Antisense at several rare disease conferences increasing awareness with key advocacy groups.

Valuation & catalysts. We maintain our $0.57/sh SOTP valuation, noting that positive FDA feedback regarding safety package acceptability (outcome expected within a month) potentially de-risks our valuation to $0.61/sh. We view confirmation of the pivotal status of EU Phase IIb as a catalyst to drive positive SP momentum ahead of CTA filing approval.

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 approval for trial commencement; b) FDA engagement; c) board renewal; d) partnering opportunities.

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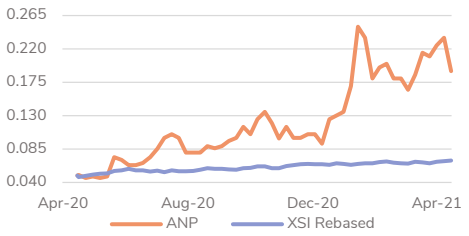
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	-7.3	40.7	287.8
Rel return (%)	-10.8	27.8	245.8

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)			-7.4	-15.5	-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)	-25.0	-14.6	-7.7	-9.4	-55.4
EV/EBITDA (x)	-34.2	-17.3	-10.3	-7.5	-35.1
FCF yield (%)	-2.7	-3.6	-8.4	-9.2	1.9
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

		18-Mar	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%
Price target:		0.57	0.57	0.0%
Rating:		O/W	O/W	

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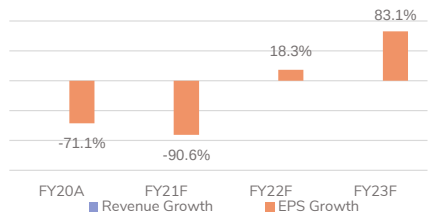
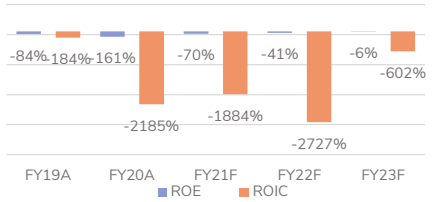
Regulatory disclosures

Growth rates

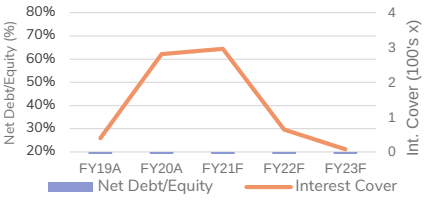


Returns

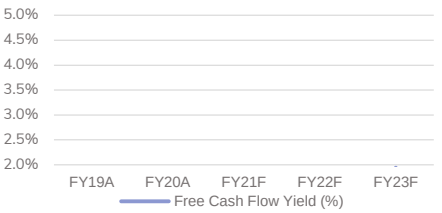


Margin trends

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)	-11.1	-15.8	-25.0	-14.6	-7.7	-9.4	-55.4	-6.2
EV/EBITDA (x)	-36.5	-43.2	-34.2	-17.3	-10.3	-7.5	-35.1	-4.4
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-2.7	-2.1	-2.7	-3.6	-8.4	-9.2	1.9	-19.5
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**

ANP opportunity refresh

The opportunity

DMD: a rare disease market with limited options. Briefly, Antisense's ATL1102 is an antisense RNA oligonucleotide that blocks CD49d, which plays an important role in inflammatory responses, and has been shown to be a biomarker associated with DMD disease severity (i.e. it is correlated positively to disease progression).

Antisense's ATL1102 asset has shown promising efficacy in Phase IIa with a European (potentially pivotal) Phase IIb trial the next major clinical step toward major market access. When viewed through a safety and tolerability lens, ATL1102, in comparison to existing anti-inflammatory options (prednisolone, Emflaza), appears to be superior, of course noting long term dosing (>6 months) is yet to be evaluated in DMD patients.

We assess approximately ~10,000 patients in the US and another ~25,000 patients in Europe requiring treatment, half of whom are wheelchair bound and represent the patient population being evaluated in Antisense's clinical DMD program. Despite these being small patient numbers, given the rare nature of DMD, we assess a potential revenue opportunity of >A$500m from EU market alone. Rare disease markets necessitate high average selling prices (ASP). We model ATL1102's potential ASP as A$140,250 – $220,000 (for EU vs US markets) which is ~80% lower than the existing approved DMD specific drug alternatives (which are limited to <30% patients in total due to genetic applicability).

Limited R&D players in non-ambulant patient population. We continue to view ATL1102 as well positioned within the competitive landscape. The Antisense approach to DMD to provide a potentially safer and more specific way of treating the immune-mediated inflammation that attends and exacerbates DMD. If approved, ATL1102 will compete with high-dose, chronic corticosteroids.

Other developers in the space are attempting 'disease modifying' approaches that target the disease's genetic basis (micro-dystrophin/ exon skipping). A slew of recent failures (Sarepta's SRP-9001; Translarna's repeated and continued FDA rejections; Catabasis' edasalonexent demise) highlights that these potential therapies for DMD are likely further afield than first anticipated.

The broader applicability of an anti-inflammatory approach, as opposed to exon skipping drugs (each limited to 1-8% market), provides a larger addressable market opportunity for ATL1102.

Opportunity to independently commercialise in key EU market. Given the relatively small addressable market (by patient number) we assess a realistic opportunity for Antisense to independently commercialise ATL1102 for DMD at the relevant time. We draw parallels between Antisense and another Australian biopharma, Clinuvel Pharmaceuticals, who have successfully completed independent commercialisation of their drug asset, SCENESSE, for a rare disease, Erythropoietic protoporphyria (EPP), in the European market with US launch underway.

As a reminder, we forecast potential FY24 launch of ATL1102 in Europe with possible peak revenues ~$600m. We assess TAMs of $1.7b (€1.1b) in EU market and $900m (US$600m) in US market. As a reference point, within three years of Sarepta's US launch of its exon 51 skipping drug, Exondys 51, it has achieved in excess of $350m annual revenues.

Phase IIb European trial. The next step in advancing ATL1102 is a Phase IIb trial in Europe. As a reminder we anticipate this to be a blinded, placebo-controlled, parallel, three-arm study including ~108 patients (n=36 per arm) with DMD (non-ambulatory status). We anticipate each arm will evaluate placebo vs 25mg ATL1102 vs a higher dose of ATL1102 (~50-100mg) over a 12-month dosing period, with a further 12-month open-label observational period. We factor in ~$27m in associated R&D costs for this trial. We understand drug manufacture is near complete as is appointment of a CRO that will manage the trial.

The next regulatory catalysts

There are two important near-term catalysts related to regulatory progress of ATL1102 in both major jurisdictions (EU, US).

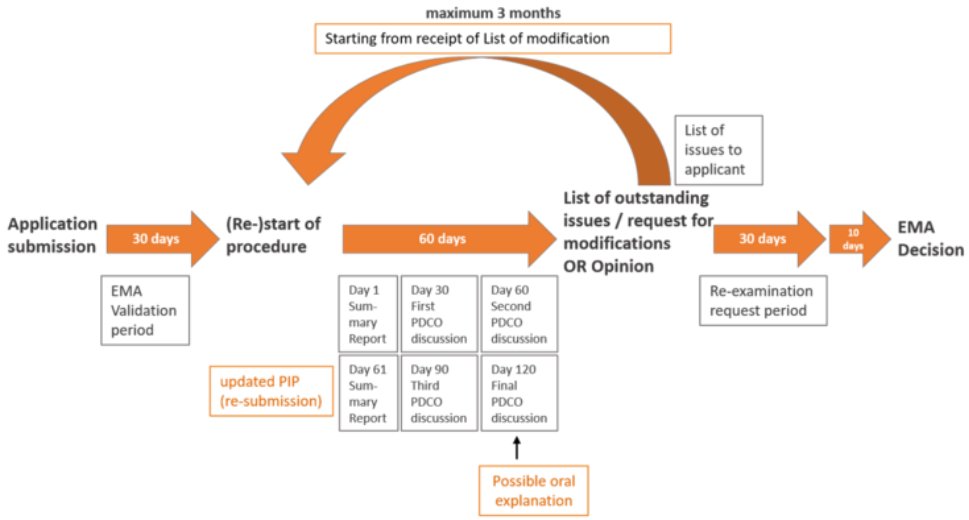
PIP feedback from EMA (EU). Paediatric Investigational Plans (PIPs) are used to ensure that necessary data are obtained to support authorisation of medicines for use in children. The PIP evaluation pathway is the precursor to a Clinical Trial Application (CTA) which, once approved, allows for clinical trial start.

Key information that the PIP will confirm (i.e. EMA agreement on these trial facets);

- Pivotal status of trial (aka whether this standalone trial can serve as the basis for a marketing authorisation application)
- Dose of third trial arm (>25mg existing Phase IIa dose)
- Number of patients required

Decision timelines. Antisense submitted the PIP on ~Feb 25th (market announcement date) with the Day 60 summary report due around ~26th April. Pending no request for modifications, we would expect an EMA decision early June. Following a PIP decision would be the CTA application/s for the Phase IIb trial, with an evaluation period of ~60 days (however this varies by national authority). This brings CTA decision timelines to ~late July (noting that approval in some national jurisdictions could be earlier/within 2Q21). This pushes a potential trial start to 2H CY21 (4Q21) as guided by ANP at the time of submission.

Figure 1. Paediatric Investigational Plan (PIP) review timeline



Source: BioPharma Excellence[1]

We anticipate Antisense are currently nearing receipt of the 60-day summary report based on a 25th Feb PIP submission date.

FDA Type C meeting feedback from FDA (US). The Type C meeting held yesterday (April 19th ET) with the FDA marks the first official engagement with the US regulator specific to ATL1102 for DMD. Prior engagements have been had regarding this molecule with regards to their Multiple Sclerosis program back in 2016/17. Confirmation that the existing clinical and pre-clinical safety and toxicity data for ATL1102 is sufficient to support extended dosing (12 month) in paediatric populations was the key agenda item of this meeting. We expect more clarity on the outcome of this within the next 30 days when official FDA meeting minutes are due. This meeting will provide clarity on next steps for ATL1102 in US trials. See overleaf for the risk we associate with this event in our valuation model and the potential upside it unlocks.

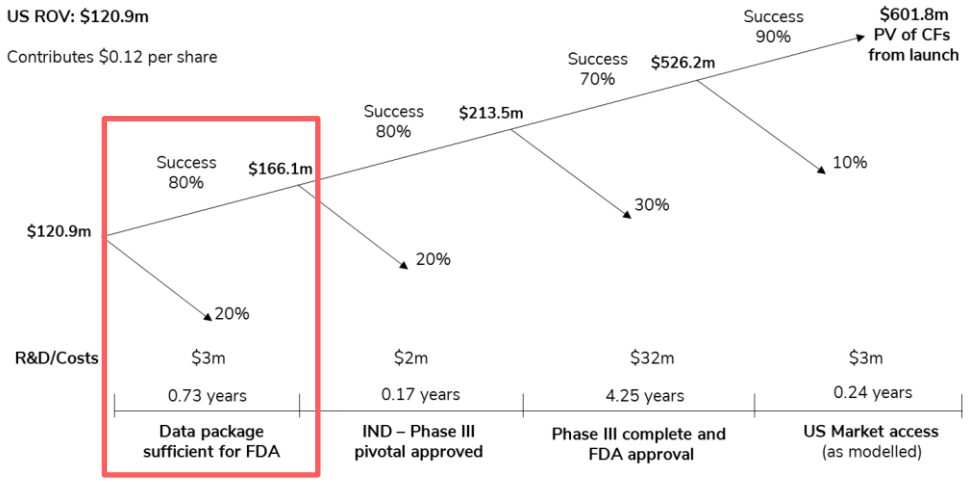
[1] Reavie, L. Opportunities to improve the PIP outcome during the PIP submission process. BioPharma Excellence. Oct 31, 2019. Online; accessed 15 April 2021.

Potential valuation de-risking event on the horizon

Within our SOTP valuation we value the US and EU market opportunities for ATL1102 in the treatment of DMD. Within our US real options valuation (ROV) model we attribute an 80% estimated probability of success to the FDA accepting the existing Antisense data package to support a US 12-month dosing study. In the event further work is required to support the extended 12-month dosing (from the current 6-month) we anticipate a potential $3m R&D investment. We expect information on this particular de-risking event within the next month from Antisense having now had the FDA meeting on this topic.

It is important to note that lack of acceptance of the existing data package does not preclude US clinical trials; rather it adds a further step (R&D $3m, ~12months) to gather additional data before filing of a US IND can be considered. As a reminder, we do not anticipate a US pivotal study to complete until 1H 2026 (conservatively) and therefore there is time redundancy built into our modelling.

Figure 2. Real Options DCF decision tree for US market ATL1102 opportunity



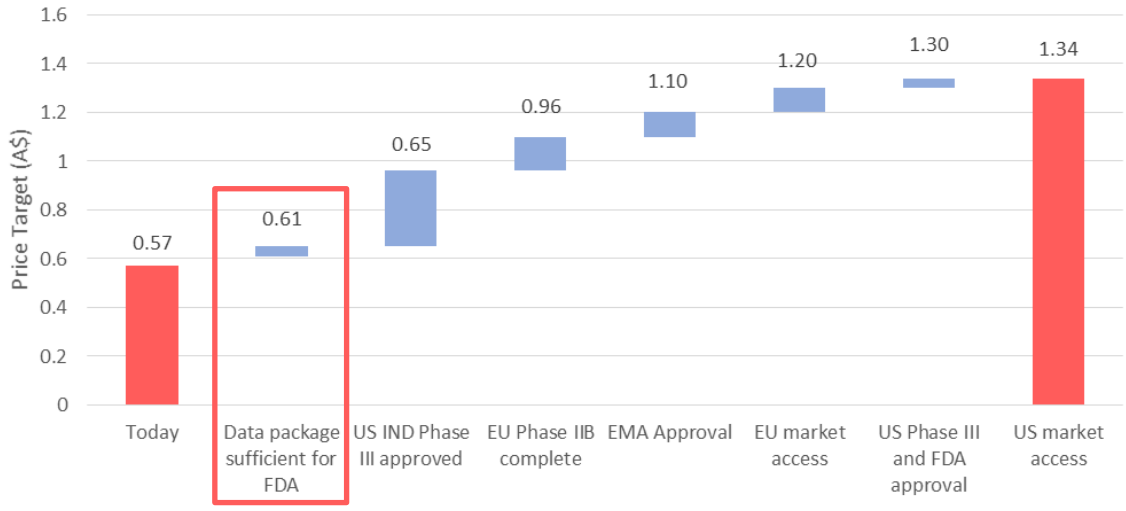
Source: *Wilsons*

Sum of the parts valuation summary		
	Valuation	PT
WACC (%)	10.0	
EU Market		
NPV FCF FY26 ($m)	1544.3	
Unrisked ROV ($m)	972.7	
Probability success	46%	
Risk-adj ROV ($m)	431.9	
Unrisked val ($/sh)		1.01
Risk-adj val ($/sh)		**0.45**
US Market		
NPV FCF FY27 ($m)	601.8	
Unrisked ROV ($m)	323.7	
Probability success	40%	
Risk-adj ROV ($m)	120.9	
Unrisked val ($/sh)		0.33
Risk-adj val ($/sh)		**0.12**
SOTP val (unrisked)		$1.34
SOTP val (risked)		**$0.57**

Source: *Wilsons*

News of a positive outcome from the most recent FDA meeting (allowing for 12-month dosing with the existing data package) supports ROV de-risking and an associated increase in our risked PT to $0.61 per share (Figure 2 & 3).

Figure 3. Price target build over time with model de-risking events (3-5 year time horizon)



Source: *Wilsons*

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 $0.57 per share price target. Having realised a >250% capital return increase since our December initiation we take the opportunity to remind the market of the further potential upside within the next 12 months for Antisense, specifically in relation to their European Phase IIb trial campaign in Duchenne Muscular Dystrophy (DMD). Last month we provided an update on the competitive landscape in DMD, with several notable CY21 setbacks within the sector (SRP-9001, SGT-001, Translarna), as well as a new US market entrant in Sarepta's casimersen. We continue to view Antisense's ATL1102 as well placed within the competitive pipeline given the few players actively targeting non-ambulant, wheelchair bound, DMD patients (which comprise 50% of the DMD population). Here we provide a summary of the expected near-term catalysts and their impact on our valuation model.

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

- Net cash of ~$9M as at Dec 2020.

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

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 & Secretary)

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

Contact details

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Disclaimers and disclosures

Recommendation structure and other definitions

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