WILSONS
Equity Research

Date
29 June 2021

Theme
Company Update

Company
Antisense Therapeutics Limited (ANP)

Harmony on the table

We maintain our OVERWEIGHT recommendation on Antisense Therapeutics and increase our risked PT to $0.63 per share. Recent regulator interactions have provided clarity around the pathway to major market access for ATL1102 in Duchenne muscular dystrophy (DMD). Emboldened by feedback from an FDA Type C meeting, ANP has applied for Fast Track Designation for ATL1102 in DMD. If granted, it provides them with increased FDA engagement and a faster review. Importantly Antisense also reported EMA feedback on their EU Phase IIb trial design – we are now looking to see a CTA submission in 3Q'21 with trial commencement still on track for CY21. Of focus is the possibility of a single pivotal Phase IIb trial to harmonise access to both major markets (US, EU) with existing predicates to support this option.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	**$0.63**
Share price @ 25-Jun-21 (AUD)	$0.19
Forecast 12-mth capital return	231.6%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**231.6%**
Market cap	$109m
Enterprise value	$101m
Shares on issue	574m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.3m

Key points

Initial FDA meeting outcomes positive. We view the FDA feedback as positive, in that there is a clear path to a pivotal, registration-directed clinical trial for ATL1102 in US patients (confirmation of acceptability of a single Phase IIb/III study). The need for parallel non-human primate toxicology was expected; the positive being it does not preclude trial initiation. In principal, FDA agreement on proposed trial design and endpoints (i.e. PUL2.0) in line with EU design is a positive step on the path to US access, which prior to CY21 was not established.

PIP feedback received. EMA feedback on the Paediatric Investigation Plan (PIP) to allow EU Phase IIb clinical trial application (CTA) submission has been received. Ahead of this, ANP have completed drug manufacture for the trial and proceed with trial preparations (including CRO finalisation and site scouting). We understand feedback on some key points regarding design is being prepared for PDCO with 4Q'21 trial approvals still expected to allow for trial initiation in late CY21.

Harmonisation potential. Regulator feedback has highlighted the potential option of a single harmonized pivotal Phase IIb study to support marketing authorisation in both EU and US markets. A single registration study would bring significant cost savings and time benefits leading to a shorter path to monetise their asset, ATL1102. In this note we discuss optionality of this approach and precedents for FDA approval of drugs from data generated ex-US that supports this as a strategy for ANP to evaluate.

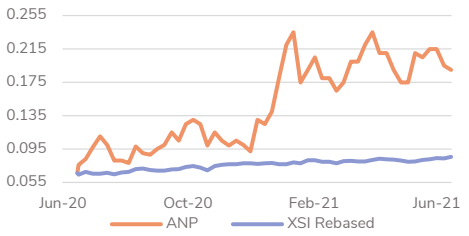
Valuation. Our SOTP valuation comprises: a) real options valuation (ROV) for EU market ($0.47/sh risked) and b) ROV for US market ($0.12/sh risked). We de-risk one step in our US ROV model given that FDA feedback suggests a Phase IIb/III trial application can proceed, noting that additional toxicology is still required in parallel (therefore we have retained the associated costs). This increases our US ROV contribution to $0.16/share, and PT to $0.63/sh (+10.5%). Our unrisked valuation is maintained at $1.40/sh.

Risks and catalysts on page 6.

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

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

12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	-7.3	52.0	187.9
Rel return (%)	-11.4	42.4	158.6

Earnings forecasts

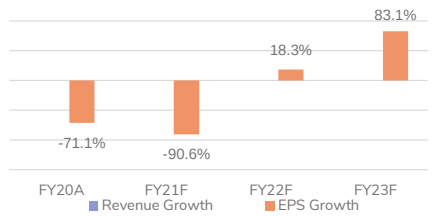
Year-end June (AUD)	FY19A	FY20A	FY21F	FY22F	FY23F
NPAT rep ($m)	-2.9	-5.9	-9.7	-13.3	-2.5
NPAT norm ($m)	-2.9	-5.9	-9.7	-13.3	-2.5
Consensus NPAT ($m)			-7.1	-14.3	-5.1
EPS norm (cps)	-0.8	-1.3	-2.5	-2.0	-0.3
EPS growth (%)	36.7	-71.1	-90.6	18.3	83.1
P/E norm (x)	-25.0	-14.6	-7.7	-9.4	-55.4
EV/EBITDA (x)	-34.5	-17.4	-10.3	-7.5	-35.4
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

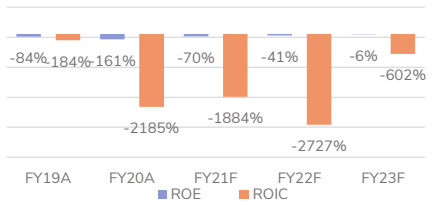
Key changes

		21-Apr	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	0.63	10.5%
Rating:		O/W	O/W	

Growth rates

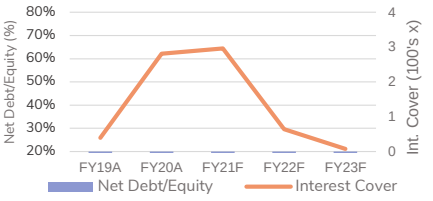


Returns

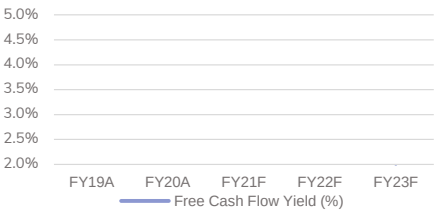


Margin trends

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)	-11.1	-15.8	-25.0	-14.6	-7.7	-9.4	-55.4	-6.2
EV/EBITDA (x)	-36.8	-43.5	-34.5	-17.4	-10.3	-7.5	-35.4	-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**

Harmony on the table?

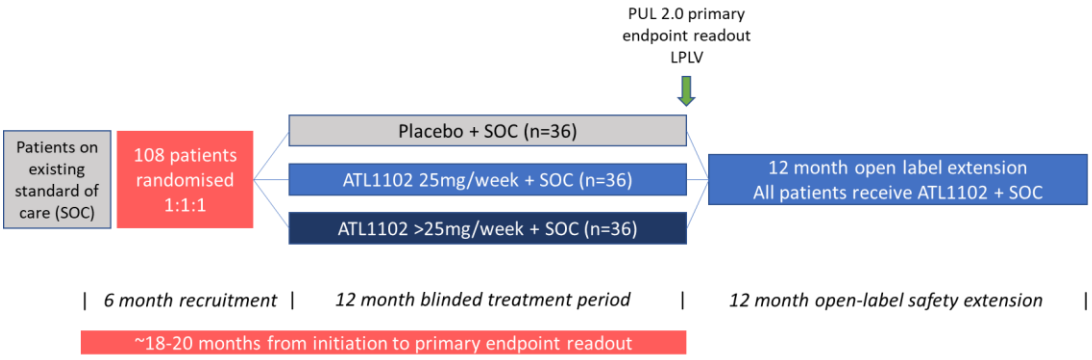
EMA feedback

PIP feedback places EU Phase IIb timeline a quarter later than anticipated. We were anticipating a CTA submission this quarter however we now understand this is more likely toward late 3Q'21, however encouragingly Antisense are still understood to be on track for a CY21 EU trial start in line with forecasts.

Trial design. As a reminder, we understand the European Phase IIb trial to be a double-blinded, placebo-controlled, parallel arm, randomised trial of non-ambulant DMD boys. We understand Antisense will look to randomise 108 patients (n=36 per arm) to either placebo, ATL1102 25mg/week and ATL1102 >25mg/week (i.e. 50mg/week) on top of their existing standard of care (i.e. corticosteroids). In terms of trial sites, we understand there is a potential to include both European and Australian study sites including those that participated in the prior Phase II study (RCH, Melbourne) with ~20 sites total to be included (see **Figure 1** below). We have previously flagged potential site locations (DE, FR, GB, NL). Antisense have proposed a 6-month recruitment window which requires them to recruit at a run rate of 18 patients per month (~1 per trial site). Given the dearth of clinical trial activity in non-ambulant DMD patients we do not assess this as unrealistic however implies trial sites must be well prepared.

We do not expect confirmation on EU Phase IIb design now until ~3Q'21; these are our best estimates.

Figure 1. Our best estimates of Antisense's Phase IIb trial design



SOC: Standard of care therapy; LPLV; Last patient last visit
Source: Wilsons

PIP feedback; points of focus. We understand ANP are currently working to address queries from PDCO in response to their PIP submitted in February. The details of what was queried has not yet been made available to the market. Below we outline key trial design points likely to be up for discussion with EMA.

PIP: Paediatric Investigational Plan. PDCO: Paediatric Committee of European Medicines Agency

Key trial design points we assess as critical:

Choice of ATL1102 dose for third trial arm. The dose for the third trial arm is not yet confirmed; we understand it will fall within ~26-100mg/week dose range. Further, there are still questions surrounding the 12-month open label extension and what ATL1102 dose patients will transition to from relevant study arms. We estimate patients could continue on their existing randomised dose with placebo patients being divided up 1:1.

Randomisation criteria. We have recently been reminded of the consequences of poorly stratified trial groups, with Sarepta's Phase II DMD trial of SPR-9001 failing to achieve its primary endpoint, due to imbalances between placebo and drug groups at baseline, earlier this year. We expect a) patient weight, b) entry PUL2.0 score and c) backbone corticosteroid therapy, to be key randomisation criteria for the study. We of course keep in mind that baseline PUL2.0 does predict trajectory of patients to some extent and therefore is an important stratification criterion to ensure groups are equal for comparisons[1].

[1] Pane et al. (2018) Upper limb function in Duchenne muscular dystrophy: 24 month longitudinal data. *PLoS ONE*, 13 (6): e0199223.

Patient inclusion criteria. The selection of DMD patients for the trial is another key point that may be part of feedback communications. The two key things that come to mind are ambulatory status of patients (i.e. if EMA were wanting broadened patient inclusion criteria outside of non-ambulatory boys) and allowable/defined standard of care (SOC) treatment backbone. We do not assess that the Phase IIb on the table now is likely to include ambulatory patients but we keep in mind that a PIP includes commentary around all potential studies Antisense may complete with ATL1102 in children, and therefore scope to explore ambulatory DMD patients in future trials is a likely discussion point given that expansion into non-ambulatory patients is a likely future direction should efficacy be shown in non-ambulant cohorts. Understanding safety in a broader DMD population is also likely of interest to the EMA given the potential for future off-label use.

Safety monitoring plan. How patient safety is to be monitored is always a key feature of trial design and often a common discussion point with regulators. In this case, Antisense are being diligent in ensuring the EU Phase IIb design includes safety monitoring requirements that the FDA proposed during their Type C meeting, specific to vasculitis that has been identified as a potential adverse event from the antisense oligonucleotide class of drugs (of which ATL1102 belongs) from non-human primate toxicology studies. Ensuring this monitoring is in place for the European trial, despite the EMA not requiring this explicitly further contributes to the harmonisation of the two regulators and opens up optionality in strategy.

A single pivotal study to enter both markets? The idea of a single pivotal trial to allow for dual market authorisation submissions has been floated by Antisense following feedback from both regulatory agencies in the past month. We assess there are three potential paths to market access for Antisense with ATL1102 in DMD with differing clinical trial necessities;

1. **Two pivotal studies** including a European pivotal Phase IIb + a US pivotal Phase IIb/III (our current base case assumption);
2. **One larger pivotal study** including addition of US sites to EU pivotal Phase IIb;
3. **A single EU pivotal Phase IIb** trial that is used to support an FDA approval based on existing market predicates (e.g. Radicava).

We understand Antisense are evaluating the options with their regulatory experts at present, however have emphasised that getting a European trial started is still a key priority for them.

ALS drug provides predicate for non-US data to support FDA approval.

Predicate drug approval highlights single trial potential. The 2017 FDA approval of Radicava (edaravone) by Mitsubishi Tanabe Pharma to treat ALS is a predicate for a rare disease drug being granted US marketing authorisation based on data that did not include US patients. The clinical evidence to support Radicava's approval was generated in Japanese patients which was then used to support Japanese, South Korean, European and US regulatory marketing approvals. Efficacy for Radicava was established in a single 6-month pivotal RCT (n= 137 patients) conducted in Japan. This provides a predicate for ANP should they look at use a single pivotal EU Phase IIb trial to seek US market approval for ATL1102.

Trial cost optionality exercise. In **Table 1** below we have outlined differences in cost estimates and impacts on timelines for each of the above options versus our current base case assumptions which assume a pivotal EU Phase IIb (FY23 completion, $25M) and US Phase IIb/III (FY25 completion, $32M).

Table 1. Estimated cost & time differences with trial strategy options

	Trials	Cost impact	Timeline impact
Option 1 (base case)	EU Phase IIb + US Phase IIb/III	As modelled ($60M total)	None – as modelled. FY24 EU & FY26 US approvals
Option 2	EU Phase IIb + US sites	Only $10M of US budget ($38M total)	Moves up US approval potential to FY24-25 vs FY26
Option 3	EU Phase IIb only	$32M less than modelled	Moves up US approval potential to FY24 from FY26

Source: Wilsons

$3M for preclinical tox is included in all Option budgets.

In all scenarios will still factor in R&D costs for the non-human primate 9-month toxicology data the FDA has requested ($3M budgeted which is conservative – could be 50% of this), including in Option 3 where Antisense use a single EU pivotal study to apply for US marketing authorisation. We view the preclinical tox request by the FDA as a necessity to complete just from a regulatory compliance perspective and would not want to see something like this prevent US market access down the line should it be raised by the FDA.

US valuation de-risked

FDA feedback

Phase IIb/III proposed trial design amendable to FDA. The FDA feedback confirmed that the existing Phase II data from the Australian trial of ATL1102 in DMD is adequate to support larger US trials, initially with the prior 25mg/week dose. We understand that the likelihood to include a higher dose arm, akin to the EU Phase IIb, is also under consideration by the FDA should relevant safety-monitoring recommendations be adopted within the trial design (i.e. vasculitis specific).

The FDA are amendable to the trial design proposed by Antisense (in line with EU Phase IIb) that would support a single pivotal Phase IIb/III trial and potential US NDA down the track (see **Figure 1**).

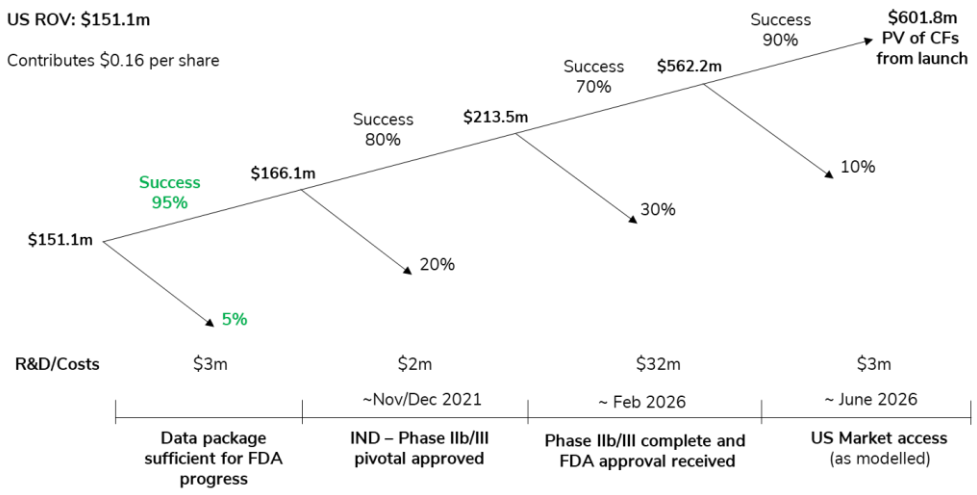
Additional toxicology data still required, however in parallel. The FDA have still noted the requirement to complete additional 9-month toxicology data in monkeys to support the extended (12-month) dosing timeframe for a Phase IIb/III US trial. As a result, we retain the additional R&D costs and time associated with completion of this preclinical tox study ($3.0M) however note that it does not preclude start of a US trial, so long as the data is submitted and accepted prior to the 6-month dosing timeframe in US patients (which is the currently allowed dosing maximum). This places the need to initiate preclinical work ~6 months ahead of a US trial start. We are conservative on our US Phase IIb/III timing, with trial IND approval ~end of CY21 and trial completion currently modelled as early 2025. As noted earlier, we assess there is an opportunity to evaluate US patients earlier (as part of a global multi-centre or within a US standalone Phase IIb/III trial). At this stage we retain a conservative timeframe for possible US market approval/entry (~mid 2026) assuming a US standalone pivotal Phase IIb/III study is still required.

Potential to bring US timelines forward.

ROV model risk adjusted. We reduce our risk associated with FDA data acceptance to support Phase IIb/III trial progression to 95% from 80% in our US ROV model. This accounts for the fact that a US trial start will not be prevented, and that we are confident supporting additional toxicology data will be generated to support extended dosing. This is based on prior understanding of how ATL1102 behaves in non-human primates at higher doses, and that the EMA has indicated a 12-month dosing timeframe is possible from evaluation of the same data. We also flag the fact that there could be the potential for the FDA to access safety data from the EU Phase IIb trial as it is generated, however this is unconfirmed.

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

De-risking the FDA engagement step to 95% elevates the current US ROV to $151.1M (+25%).



Source: Wilsons

Fast Track Designation requested. This designation gives ANP benefits of faster review and more FDA engagement during the trial planning process. Antisense will hear back on the success of this application within 60 days. Of course, noting that they already have Orphan Drug Designation (ODD) from the FDA and are eligible for a rare paediatric disease Priority Review Voucher (PRV) which has sale optionality potential. We model a potential sale of their PRV in FY25 for ~$100M.

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 increase our risked PT to $0.63 per share. Recent regulator interactions have provided clarity around the pathway to major market access for ATL1102 in Duchenne muscular dystrophy (DMD). Emboldened by feedback from an FDA Type C meeting, ANP has applied for Fast Track Designation for ATL1102 in DMD. If granted, it provides them with increased FDA engagement and a faster review. Importantly Antisense also reported EMA feedback on their EU Phase IIb trial design – we are now looking to see a CTA submission in 3Q'21 with trial commencement still on track for CY21. Of focus is the possibility of a single pivotal Phase IIb trial to harmonise access to both major markets (US, EU) with existing predicates to support this option.

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 $8.3M as at 31 March 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

Contact details

Antisense Therapeutics Limited
6 Wallace Avenue
Toorak, VIC 3142 Australia
antisense.com.au

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Recommendation structure and other definitions

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Wilsons contact

For more information please phone: 1300 655 015 or email: publications@wilsonsadvisory.com.au