WILSONS
Equity Research

Date
18 March 2021

Theme
Company Update

Company
Antisense Therapeutics Limited (ANP)

DMD around the grounds: symptoms persist

In the past week we have seen DMD program updates from Antisense's peers and as such thought this a timely opportunity to summarise changes to the competitive landscape in DMD over the past 3 months, including updates from Sarepta, Solid Biosciences and PTC. We continue to view Antisense's ATL1102 as well positioned in the DMD R&D landscape when viewing through a lens of safety and tolerability, particularly when reminded of Solid Bio's Phase I/II trial experiences as well as the accepted, yet undesirable side effect profile of existing steroid treatments (e.g. PTC's Emflaza, prednisolone). This being a reminder of the persistent need for DMD therapies with improved tolerability profiles, and confirming a market opportunity gap for therapies such as ATL1102. Progress on ATL1102's European program is gradual whilst US progress initiates with first FDA engagement in April. We maintain our O/W recommendation on Antisense Therapeutics and risked $0.57/sh PT.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	**$0.57**
Share price @ 17-Mar-21 (AUD)	$0.18
Forecast 12-mth capital return	216.7%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**216.7%**
Market cap	$103m
Enterprise value	$94m
Shares on issue	574m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.3m

Key points

Antisense update. Antisense have submitted their Paediatric Investigational Plan (PIP) to EMA for review and feedback regarding their ATL1102 Phase IIb trial design, with plans to initiate the trial in 2H 2021. They also await their first FDA engagement on ATL1102 for DMD with a meeting set for April 19th. We keenly await clarity on next steps re US trials.

Symptomatic treatments win on efficacy front but have side effect drawbacks. Disease modifying strategies (i.e. boosting dystrophin) continue to have a very modest success, as evidenced by some recent gene therapy trials, whilst symptomatic treatments carry challenging safety issues for a paediatric population (i.e. chronic steroids associated with glaucoma, behavioural changes, hyperglycaemia, osteoporosis and developmental delay to name a few).

Peers report updates on competitive programs. In the past 3 months we have seen; a) Sarepta's gene therapy, SRP-9001, fail to reach its primary efficacy endpoint due to poor trial design; b) FDA approval of Sarepta's casimersen for exon 45 amendable patients; c) PTC's real-world analysis showing their steroid Emflaza is superior to prednisolone despite carrying similar side effects, and d) Solid Bioscience's gene therapy, SGT-001, fall short in interim Phase I/II analysis in terms of magnitude of effect after a history of safety holds.

Valuation. Our risked $0.57 per share valuation of Antisense is based on a SOTP approach using ROV methodology comprising: a) EU market opportunities ($0.45) and b) US market opportunities ($0.12) for ATL1102 in DMD. Unrisked PT is $1.34 per share.

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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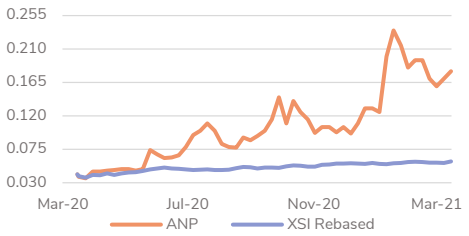
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	-7.7	56.5	339.0
Rel return (%)	-8.7	39.2	296.4

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)			-10.3	-13.2	-6.3
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)	-23.7	-13.8	-7.3	-8.9	-52.5
EV/EBITDA (x)	-32.2	-16.3	-9.7	-7.0	-33.1
FCF yield (%)	-2.8	-3.8	-8.9	-9.7	2.1
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

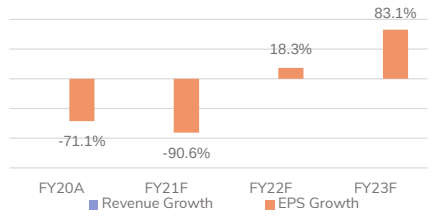
Source: Company data, Wilsons estimates, Refinitiv

Key changes

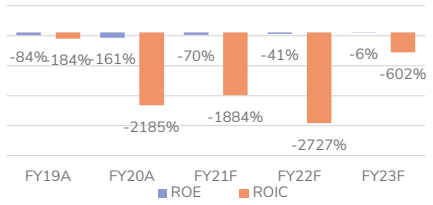
		25-Feb	After	Var %
NPAT:	FY21F	-9.7	-9.7	0.0%
norm	FY22F	-13.3	-13.3	0.0%
($m)	FY23F	-2.5	-2.5	0.0%
EPS:	FY21F	-2.5	-2.5	0.0%
norm	FY22F	-2.0	-2.0	0.0%
(cps)	FY23F	-0.3	-0.3	0.0%
DPS:	FY21F	0.0	0.0	0.0%
(cps)	FY22F	0.0	0.0	0.0%
	FY23F	0.0	0.0	0.0%
Price target:		0.57	0.57	0.0%
Rating:		O/W	O/W	

Wilsons Equity Research
Regulatory disclosures

Growth rates

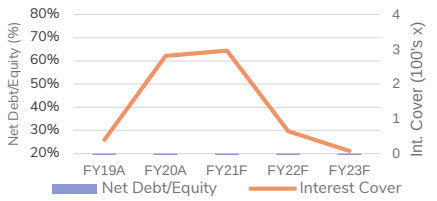


Returns

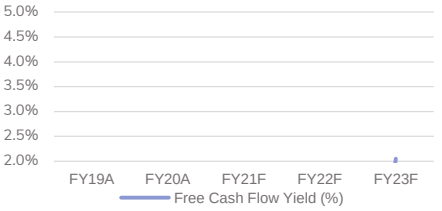


Margin trends

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)	-10.5	-15.0	-23.7	-13.8	-7.3	-8.9	-52.5	-5.9
EV/EBITDA (x)	-34.4	-40.7	-32.2	-16.3	-9.7	-7.0	-33.1	-4.1
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-2.8	-2.2	-2.8	-3.8	-8.9	-9.7	2.1	-20.6
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	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**

Recent competitive landscape changes in DMD

We have witnessed several changes to the competitive Duchenne muscular dystrophy (DMD) landscape since our initiation on Antisense Therapeutics (ANP:ASX) in mid-December. Here we summarise and evaluate these changes in terms of what they mean for the DMD landscape in which Antisense finds itself with ATL1102.

The most notable changes include:

January 7th. Sarepta's (SRPT:NASDAQ) gene therapy, SRP-9001, failed to reach its primary functional endpoint with a non-significant difference from placebo in NSAA test.

February 25th. Sarepta's AMONDYS 45 (casimersen) approved by FDA for treatment of DMD patients with exon 45 mutations amenable to exon skipping.

March 15th. PTC's (PTCT:NASDAQ) Emflaza shown in real world study to be superior to prednisolone, albeit with high side effect burden.

March 15th. Solid Biosciences (SLDB:NASDAQ) report dull interim data from SGT-001 Phase I/II trial following lift of FDA hold in October 2020.

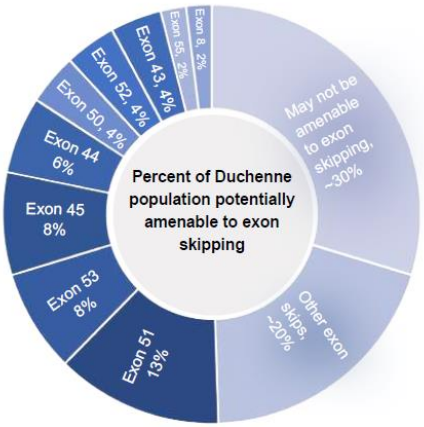
Sarepta's SRP-9001 shows biological efficacy albeit missing primary functional endpoint in Phase II trial. Highlights importance of trial design and stratification methods.

A single shot of SRP-9001, delivering a micro-dystrophin encoding gene, has shown it can significantly boost dystrophin levels measured in the skeletal muscle in ambulatory DMD patients (n=20) by ~28% ($p<0.0001$) within 12 weeks post-treatment. SRP-9001 also increased total NSAA (North Star Ambulatory Assessment) score by 48 weeks post-treatment compared to baseline, however not in a statistically significant manner ($p=0.37$) vs placebo (+1.7 points vs baseline). The lack of significance appears to rest in study group imbalances in the 6-7 year old patient group, whereby the placebo 6-7yo cohort and the 6-7yo drug cohort had differing NSAA scores at baseline meaning the drug treatment group experienced a ceiling treatment effect (as they were milder cases upon study entry). This example highlights the importance of study design and correct randomisation criteria upon treatment assignment. As a reminder, no subsequent analyses are allowed in trials that can be used for registration consideration – and therefore despite Sarepta being able to show significant effects of SRP-9001 in other age DMD patient groups, the total overall group is what counts. This study is ongoing and patients have now entered a crossover phase where they will complete an additional 48 weeks of follow up before the study closes in late 2021/early 2022. The key takeaway here is a reiterated focus on the importance of good trial design. Surely this will be a timely reminder to Antisense and others with impending trial designs to be confirmed.

Sarepta's AMONDYS 45 approval limited to 8% of US DMD population.

The approval of Sarepta's third exon skipping drug AMONDYS targeting exon 45 mutations (alongside their exon 51 and 53 offerings EXONDYS and VYONDYS) addresses at most 8% of the DMD population, given the prevalence of patients amenable to exon 45 skipping. Collectively Sarepta can now theoretically address up to 29% of the US DMD market with their three drug offering. We would however note that there continues to be ~30% of DMD patients that are unlikely to be amenable to exon skipping approaches, with a further 30% possessing more rare exon mutations that are unlikely to attract the sizable development investment needed given the small addressable market (i.e. 2% or less) (see inset).

Sarepta have had two past EMA rejections (2018) for their EXONDYS and VYONDYS assets and therefore European market entry for AMONDYS may not be a safe bet any time soon. This based on the premise that the 2018 EMA rejection of EXONDYS 51 cited a lack of observable efficacy using the surrogate endpoint of increased dystrophin production, and that future trials were required to confirm functional benefit. The AMONDYS 45 FDA approval is based on this same endpoint previously rejected by the EMA for similar assets. Ultimately this leaves a greater proportion of EU DMD patients still seeking improved treatment options (over standard corticosteroid approaches) and an opportunity for Antisense given the EU focus of their program thus far.



Source: CureDuchenne.

PTC's EMFLAZA shown to be superior to prednisolone, but reminds us it is still a corticosteroid and carries the associated heavy side effect burden.

Results of a real-world chart review were presented this week at the MDA conference showing that switching of DMD patients from prednisolone to EMFLAZA (deflazacort) was associated with a slowing or improvement in disease progression. Data from the 6 month follow up period after switching used a Clinical Global Impression (CGI) score to support the "*potential of EMFLAZA to alter the natural history of DMD, demonstrating its capability to slow progression of the disease and improve benefit-risk*"[1]. The specific data used to support this conclusion is challenging to analyse given the limited details available at in the public domain and uncertainty around the controls in place to capture comparable, quality data.

The more interesting and relevant thing this news has brought to light is the continued challenges faced with chronic corticosteroid use. Commonly reported adverse events (AEs) in this study included weight gain, central obesity, increased appetite, fluid retention and Cushingoid appearance (referred to often as "moon face") where a fatty lump between the shoulders and round face can result. On top of these we note the increased prevalence of hyperglycaemia, behavioural and mood disturbances, impaired heart/kidney function, cataracts/glaucoma, osteoporosis and stunted growth and development in children, all associated with the EMFLAZA label. With this bevy of well-established side effects, we are reminded that the risk benefit profile of drugs like EMFLAZA presents a low bar to overcome from a drug tolerability standpoint.

Solid Bioscience's interim update on their gene therapy, SGT-001, disappoints in terms of magnitude of effect, despite lift of FDA safety hold.

Solid Bioscience's single shot gene therapy for DMD, SGT-001, has had a tough run thus far. After a string of serious adverse events (SAEs) in their Phase I/II IGNITE study the FDA placed a second clinical hold on the program in late 2019, which was subsequently lifted in Oct 2020. The IGNITE trial, despite only having enrolled 6 patients, has been plagued by adverse events (AEs) including lowered red blood cell count in several patients, transient renal impairments and complement activation (an immune pathway stimulated by the body when foreign bodies are detected, which can lead to serious inflammatory consequences in some cases). After recruitment resumed in late 2020 there appears to be more positive safety news with no new drug-related SAEs reported.

Perhaps disappointingly, despite the improved safety results, the interim analysis of efficacy showed an increase in NSAA score of just +0.3 points vs baseline in the high dose and +1.0 points in the low dose SGT-001 treated groups 12 months post-treatment. This study uses a natural history cohort control which showed a 4.0 point decline over this period consistent with expected DMD decline. These effects compared to Sarepta's (SRP-9001) +1.7 NSAA total score increase vs placebo are less than thrilling, both of which are micro-dystrophin therapies (disease-modifying). Keeping in mind that the SGT-001 data are from a very small number of patients (n=6). The IGNITE study continues to recruit with top-line data expected 1H 2022.

[1] https://ir.ptcbio.com/news-releases/news-release-details/ptc-presents-results-real-world-study-steroid-switching

Wilsons' view.

Existing options either limited to niche patient cohorts or continue to have high tolerability burden.

Despite the addition of AMONDYS 45 (casimersen) to the list of approved DMD drugs in US market, there continues to be a significant portion of DMD patients inadequately treated (~60%), including those that have tried and failed current steroid options (mostly due to inability to tolerate the side effects), or those that do not have mutations amenable to existing exon skipping treatment options (45, 53, 51 only).

The currently limited treatment landscape is reiterated here where the long-term impacts of chronic corticosteroid use continue to plague clinicians especially when considering lifelong treatment of children with this drug class. Further, the limited R&D ongoing programs in non-ambulatory (wheelchair bound) DMD (~50% of all patients) continues to highlight the opportunity for Antisense's ATL1102, provided it can show adequate efficacy on upper limb function measures and good tolerability (which has been the case thus far).

Gene therapy approaches continue to face setbacks.

The lacklustre results so far from the Sarepta and Solid Biosciences gene therapy programs do not inspire confidence that a gene therapy solution for DMD is likely to be approved any time soon. Of course, there are other contenders including Pfizer's PF-06939926 which showed superior improvements in their Phase Ib trial (+3.5 NSAA score vs baseline; compared to 0.3-1.7 point improvements in Sarepta and Solid Bio's programs). Pfizer are currently enrolling their Phase III CIFFREO trial (NCT04281485) which is expected to have top-line data by 3Q22. Again, this study is conducted in ambulatory DMD boys with data absent on the effects of these gene therapies in patients that have already lost walking ability. Given that all three studies are being conducted in ambulatory patients there is not a direct comparison to be made to ATL1102 and magnitude of efficacy, as the endpoint measures are different (NSAA vs PUL2.0).

The fact remains that gene therapy studies, despite some good efficacy data, continue to be the subject of clinical holds and safety setbacks, which is not unique to the DMD field. This is seen across a host of diseases where gene therapy is being evaluated with a recent uptick observed with regards to FDA program holds of late.[2]

Continued focus on ambulatory population leaves space for ATL1102.

As highlighted in this note, none of the programs discussed are focused on wheelchair bound DMD patients. The key programs we continue to monitor in the non-ambulatory space are Capricor's cell therapy (CAP-1002) and FibroGen's pamrevlumab. The next data from either of these programs is not expected until early 2023 (Phase III pamrevlumab study), by which time we would hope to have possibly have additional Phase II ATL1002 data for comparison.

[2] Evaluate Pharma (2019). Accessed 17 March 2021. https://www.evaluate.com/vantage/articles/analysis/gene-therapy-clinical-holds-take-centre-stage

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

In the past week we have seen DMD program updates from Antisense's peers and as such thought this a timely opportunity to summarise changes to the competitive landscape in DMD over the past 3 months, including updates from Sarepta, Solid Biosciences and PTC. We continue to view Antisense's ATL1102 as well positioned in the DMD R&D landscape when viewing through a lens of safety and tolerability, particularly when reminded of Solid Bio's Phase I/II trial experiences as well as the accepted, yet undesirable side effect profile of existing steroid treatments (e.g. PTC's Emflaza, prednisolone). This being a reminder of the persistent need for DMD therapies with improved tolerability profiles, and confirming a market opportunity gap for therapies such as ATL1102. Progress on ATL1102's European program is gradual whilst US progress initiates with first FDA engagement in April. We maintain our O/W recommendation on Antisense Therapeutics and risked $0.57/sh PT.

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 Graham Mitchell (Independent 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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antisense.com.au

Disclaimers and disclosures

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