



# antisense

## THERAPEUTICS

ASX:ANP | OTC:ATHJY

AGM Presentation

December 2020



## Forward Looking Statements

This presentation contains forward-looking statements regarding the Company's business & the therapeutic & commercial potential of its technologies & products in development. Any statement describing the Company's goals, expectations, intentions or beliefs is a forward-looking statement & should be considered an at-risk statement. Such statements are subject to certain risks & uncertainties, particularly those risks or uncertainties inherent in the process of developing technology & in the process of discovering, developing & commercializing drugs that can be proven to be safe & effective for use as human therapeutics, & in the endeavor of building a business around such products & services. Actual results could differ materially from those discussed in this presentation. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the Antisense Therapeutics Limited Annual Report for the year ended 30 June 2020, which is available from the Company or at [www.antisense.com.au](http://www.antisense.com.au).

# Corporate Overview

## KEY FINANCIALS

|                                       |                   |
|---------------------------------------|-------------------|
| Market Capitalisation (at \$0.15)     | A\$86M            |
| Shares on issue                       | 574.M             |
| 52-week low/high                      | \$0.029 - \$0.160 |
| Cash reported as at 30 September 2020 | \$3.1M            |
| Capital Raising November 2020         | \$8.5M            |
| R&D Tax Credit Received               | \$0.65M           |
| Top 50 Shareholders                   | 48%               |





# Research Analyst Reports

**WILSONS**

Equity Research

Date  
16 December 2020

Theme  
Initiating Coverage  
Company  
Antisense Therapeutics Limited (ANP)

## Initiating at O/W: Sensing a Large Opportunity

We initiate coverage on Antisense Therapeutics with an OVERWEIGHT rating and a risk rated 12 month price target of \$0.57 per share. Antisense is a clinical stage biopharmaceutical company focused on antisense drugs for rare diseases. Their primary asset, ATL1102, is being developed for the treatment of Duchenne muscular dystrophy (DMD), a debilitating genetic disease affecting boys causing severe muscle wastage, leading to premature death. Antisense also have a secondary asset in development, ATL1103, as a novel treatment for acromegaly. Antisense are planning an EU pivotal Phase IB study in DMD with ATL1102 in H21. Success could lead to an early approval and independent product launch in Europe (TAM A\$1.7B). Unithed valuation is \$1.34 per share assuming independent commercialisation in major markets.

### Key points

Interesting Phase II asset with data to support proof of concept. ATL1102 is an antisense drug that blocks an inflammatory marker, CD40d, shown to be correlated to DMD disease progression. This anti-inflammatory hypothesis is supported by data from their recent Phase II trial in non-ambulatory patients that showed reduced inflammation and stabilisation of muscle fat fractions in boys treated for 6 months with ATL1102, in addition to important subsequent changes in upper body strength. Their impending Phase IIB trial will be seeking to confirm this efficacy to support a potential EMA marketing authorisation.

**Independent commercialisation strategy.** We are modelling Antisense assuming independent commercialisation of ATL1102 in both major markets (EU/US) which is supported by market predicates and recent successes in other rare diseases. We believe they are well placed to execute this strategy, which is aided by their receipt of Orphan Drug Designations (ODD) and other benefits (i.e. PRV in the US) from both regulatory agencies.

**Valuation.** We have used a sum of the parts approach to evaluate Antisense based on their EU and US market prospects in DMD. We initiate at a 12 month price target of \$0.57 per share comprised of \$0.45 for EU market assumptions and \$0.12 for US market expectations. We have made certain assumptions about future financing which are included in our target price. The key sensitivities are: a) clinical risk; b) major market sales forecasts; c) transactional parameters (milestone payments, royalty rates); and d) extensions into indications outside DMD. Our unithed price target 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.

| Earnings forecasts   |       |       |        |       |       |
|----------------------|-------|-------|--------|-------|-------|
| Year-end June (AUD)  | FY19A | FY20A | FY21F  | FY22F | FY23F |
| NPAT rev (\$m)       | -2.9  | -5.9  | -18.4  | -6.5  | -4.3  |
| NPAT norm (\$m)      | -2.9  | -5.9  | -18.4  | -6.5  | -4.3  |
| Consensus NPAT (\$m) |       |       | -4.6   | -10.4 |       |
| EPS norm (cps)       | -0.8  | -1.3  | -3.4   | -1.0  | -0.6  |
| EPS growth (%)       | 36.7  | -71.1 | -161.9 | 70.7  | 42.3  |
| PE norm (x)          | -2.1  | -7.1  | -2.7   | -9.2  | -16.0 |
| EV/EBITDA (x)        | -15.7 | -7.9  | -2.5   | -6.9  | -10.0 |
| FCF yield (%)        | -5.5  | -7.5  | -33.3  | -2.9  | -2.6  |
| DPS (cps)            | 0.0   | 0.0   | 0.0    | 0.0   | 0.0   |
| Dividend yield (%)   | 0.0   | 0.0   | 0.0    | 0.0   | 0.0   |
| Payouting (%)        | 0     | 0     | 0      | 0     | 0     |

Source: Company data, Wilsons estimates, Refinitiv

### Wilson's Equity Research

Regulatory disclosures

Wilson's restricts research analysts from trading in securities for which they write research. Other Wilson's employees may hold interests in the company, but none of these interests are material. Wilson's further advises that at the date of this report, neither Wilson's Advisory and Stockbroking Limited or Wilson's Corporate Finance Limited have any material interests in the company.

## Wilson's Equity Research

Analyst: Shane Storey, Melissa Benson

12 month Price Target - \$0.57

| Recommendation                  | OVERWEIGHT |
|---------------------------------|------------|
| 12-mth target price (AUD)       | \$0.57     |
| Share price @ 15-Dec-20 (AUD)   | \$0.09     |
| Forecast 12-mth capital return  | 523.4%     |
| Forecast 12-mth dividend yield  | 0.0%       |
| 12-mth total shareholder return | 523.4%     |
| Market cap                      | \$53m      |
| Enterprise value                | \$46m      |
| Shares on issue                 | 174m       |
| Sold short                      |            |
| ASX 300 weight                  | n/a        |
| Median turnover/day             | \$0.1m     |

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## Antisense Therapeutics (ANP)

### Promising treatment for a devastating disease

#### Our View

Antisense (ANP) reported very encouraging signs of efficacy from a small Phase II study of the fatal inherited muscle wasting disease Duchenne muscular dystrophy (DMD). Patients treated with lead drug ATL1102 for 6 months showed improvement in upper limb function and preservation of muscle mass, in marked contrast to the progressive deterioration that is the hallmark of the disease. The company plans to initiate a randomised Phase IIB study of ATL1102 in non-ambulant (wheelchair bound) DMD patients in Europe in H121. ANP has received positive feedback from European regulators regarding key aspects of the study, including that the study could potentially support an application for marketing approval in Europe if the results are positive. The company is also working to determine the appropriate clinical development and regulatory path in the US. We initiate coverage with an Outperform recommendation and a valuation of \$134m, \$0.27/sh (undiluted), or \$0.23/sh fully diluted for a potential capital raise to fund the est. \$20m European Phase IIB trial.

#### Key Points

**ATL1102 stops the VLA-4 integrin connection** that allows inflammatory cells to survive, proliferate and migrate across the vessel walls into the muscle tissue where they attack damaged and non-damaged muscle fibres. Its efficacy in reducing inflammation was confirmed in a previous randomised trial in multiple sclerosis, where it significantly reduced inflammation and disease progression.

**Improved muscle function in DMD patients treated with ATL1102** – in a recent Phase IIA study that treated 9 boys with advanced DMD with ATL1102 for 24 weeks, the boys showed improvement or stabilisation in measures of upper limb strength and function. The most impressive result, in our view, was the average 0.9 point improvement in the validated Performance of the Upper Limb (PUL) 2.0 scale observed in ATL1102 treated patients, compared to the ongoing deterioration in PUL scores reported for DMD patients in the 6 other studies that we examined. The impressive PUL 2.0 results were supported by improvement or stabilisation of scores for the MyoSet test set, a validated suite of tools to assess strength and endurance of the upper limb.

**Improvements in muscle structure as well** – subjects in the ATL1102 Phase II study showed an average decrease in MRI measurements of forearm fat fraction as well as preservation of muscle mass, in contrast to the increase in fat fraction reported from other DMD studies. As DMD progresses, damaged muscle fibres are progressively replaced by fat, so the reduction in fat fraction is further evidence that ATL1102 is effectively combating the disease. MRI measurement of fat fraction is an objective measure of disease progression that is independent of patient motivation or level of effort, so it is not subject to a placebo effect.

**Premium pricing for DMD products** – the DMD market is expected to be worth US\$4.1bn by 2023. As is common for rare diseases, DMD treatments command high prices. Prices in the US for the three DMD treatments approved in the past 4 years range from US\$63,000 to US\$300,000 per patient per year, with list prices reportedly as high as US\$892,000 per patient per year.

**Eligible for a valuable Rare Pediatric Disease Priority Review Voucher** – In September the FDA granted rare pediatric disease (RPD) designation for ATL1102 for the treatment of DMD. This means that if ATL1102 gains FDA approval it may be eligible for the award of a priority review voucher (PRV), which can be freely traded and which have recently sold for around US\$100m. Legislation to extend the RPD PRV program to September 2026 is now before the US Senate. ANP is in discussions with KOLs and regulatory consultants about the best path for development of ATL1102 in the US.

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27 October 2020

### Speculative Investment

**Recommendation: Outperform**

#### Summary (AUD)

|                              |         |
|------------------------------|---------|
| Market Capitalisation        | \$61.1m |
| Share price                  | \$0.125 |
| 52 week low                  | \$0.16  |
| 52 week high                 | \$0.03  |
| Cash as at 30 September 2020 | \$3.1m  |

#### Share price graph (AUD)



#### Key Financials (AUDm)

|               | FY20A | FY21E | FY22F  |
|---------------|-------|-------|--------|
| Revenue       | 0.7   | 1.8   | 3.5    |
| R&D           | (2.2) | (4.8) | (12.4) |
| SG&A          | (4.3) | (1.6) | (1.6)  |
| EBITDA        | (5.8) | (4.6) | (10.5) |
| Reported NPAT | (5.9) | (4.6) | (10.4) |
| NPAT Adj.     | (5.9) | (4.6) | (10.4) |
| EPS Adj. (c)  | (1.3) | (0.8) | (1.5)  |
| PE ratio (x)  | n/a   | n/a   | n/a    |
| DPS (c)       | 0.0   | 0.0   | 0.0    |
| EV/Sales      | n/a   | n/a   | n/a    |
| EV/EBITDA (x) | n/a   | n/a   | n/a    |
| ROE           | n/a   | n/a   | n/a    |

Friday, 16 October 2020

## RESEARCH REPORT

CORPORATE  
CONNECT

## Antisense Therapeutics (ANP) And a Door Opens Wide

Share Price  
& Estimated  
Future Price

|                  |         |
|------------------|---------|
| 12-Month Target* | \$0.305 |
| Price            | \$0.14  |
| Implied Return   | 118%    |
| *Implied Return  |         |

Antisense Therapeutics' lead drug sits at the nexus of two areas of drug development that are starting to grow dramatically in importance. One relates to its mode of action and the other to the drug very well and strong results in a trial in a horrible disease afflicting children, and you have the basis for true value creation.

**Introduction:** Antisense Therapeutics' lead compound, ATL1102, is, essentially, a highly targeted anti-inflammatory drug and, over recent years, the role of inflammation in many diseases is becoming apparent. The indication the company is using it for is a terrible disease called Duchenne muscular dystrophy (DMD), which causes the muscles of young boys to start to waste before the age of five, ultimately leading to their death in their late teens or early 20's.

ATL1102 works by knocking down gene expression, the product of which allows the cells likely responsible for much of the muscle wasting to migrate into position to cause it. Evidence supporting the clinical trialing of ATL1102 is robust, consisting of independent basic and clinical research, as well as evidence from Antisense, which includes a peer-reviewed article on a previous clinical trial of ATL1102 in MS, as well as the results of a Phase II trial of the drug in DMD. ATL1102 was safe and all of the clinical and non-clinical data pointed towards the drug materially improving the disease.

**To Market and Beyond:** Antisense is aiming for marketing approval in DMD boys who can no longer walk (non-ambulant). The indication provides for all of the regulatory designations that help to get a drug to market, including rare paediatric disease designation (RPDD). RPDD could provide USD100m to the company, via the sale of a priority review voucher, right when the company is preparing to market ATL1102. If Antisense is not bought out or licences ATL1102 first. Importantly, there are no drugs for non-ambulant DMD boys and the development landscape is barren, except for ATL1102. Once on market, the revenue ATL1102 can generate is extremely large, particularly, given the three truly novel branded drugs have list prices of USD700k/year and medication use is chronic. A medicine very similar to the generics currently used to treat DMD, and approved for the indication, has a list price in excess of USD100k per year. At these prices, with approximately 20,000 DMD patients overall in the US, the addressable market for ATL1102 is substantial.

**Further indications:** The role of inflammation in many diseases is only now being truly understood. The obvious next indications to trial ATL1102 are the other muscular dystrophies, which add another 125k patients to ATL1102's ultimate applicable market. The molecule ATL1102 targets is also implicated in other diseases, providing opportunities beyond the muscular dystrophies and, if fleshed out, an even stronger reason for larger biopharmaceutical companies to look at Antisense.

**Valuation:** We have valued Antisense based on a probability weighted discounted cash flow model that assumes revenues only from the non-ambulant DMD. Other potential indications represent unaccounted for upside. We have arrived at a 12-month price target of 30.5 cents per share, which gives the company a predicted market capitalisation of \$149 million.

The recommendations and opinions expressed in this research report accurately reflect the research analyst's personal, independent, and objective views about any and all the companies and securities that are the subject of this report discussed herein.

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## Corporate Connect

Analyst: Marc Sinatra

12 month Price Target - \$0.305

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Note: the above are the front page excerpts from the respective research reports available on ANP's website



# Frankfurt Dual Listing – Highlights / Progress & Key Objectives

## Highlights / progress

- Dual-listed on Frankfurt Stock Exchange on 23 November 2020 under code “AWY”
- DGWA, the German Institute for Asset and Equity Allocation and Valuation, ANP’s investor relations and corporate representatives headquartered in Germany have commenced investor information flow with corporate video, translated news items and investor awareness campaigns with EU investors
- ANP has commenced presentations to EU Fund Managers since listing
- Trading in Europe started to increase following the ASX Announcement of European Commission granting Orphan Drug Designation for ATL1102

## 2021 Objectives

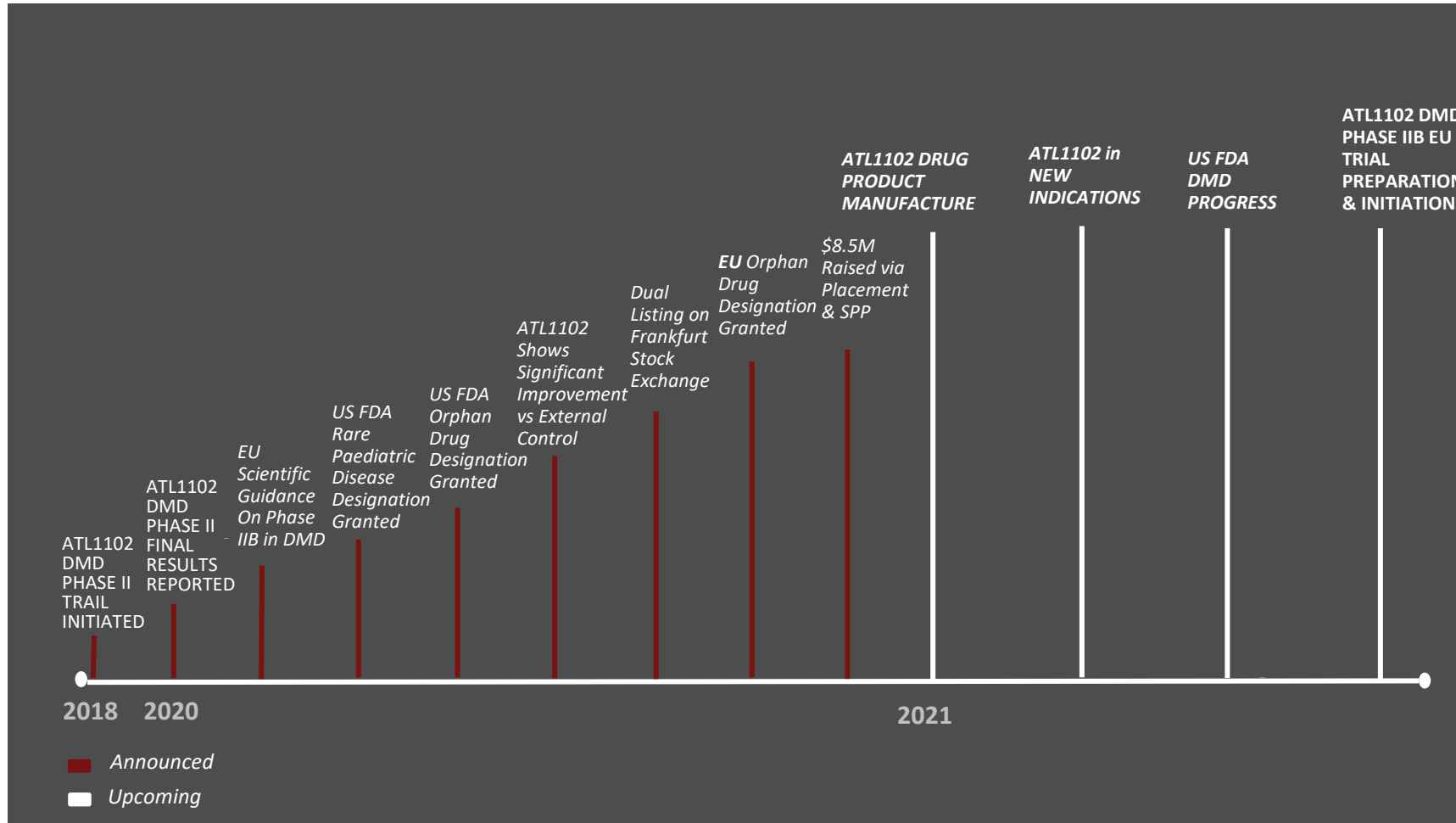
- To continue to present to EU and UK institutional investors and family offices
- Increase awareness of ANP with EU and UK potential partners and review collaboration opportunities
- Continue to increase EU shareholder base of the Company



# 2020 Major Achievements & Upcoming Key Activities

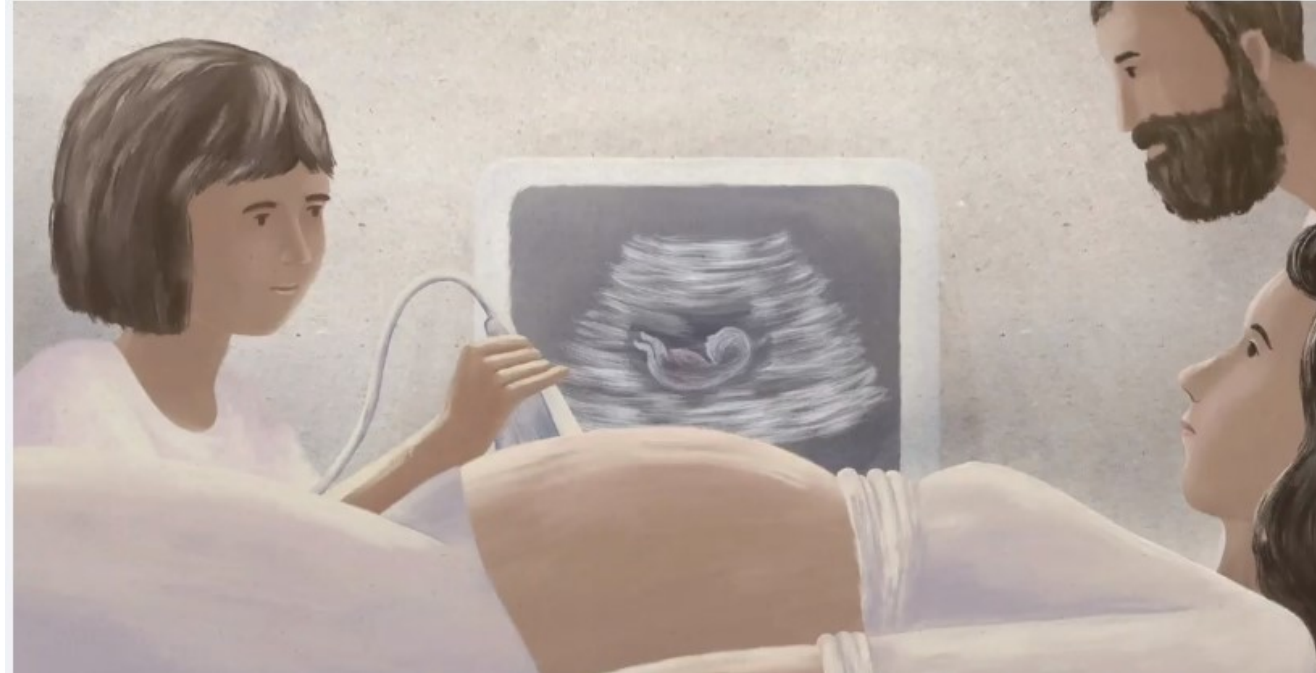
*Multiple value creation opportunities*

**Recent \$8.5M capital raising to facilitate upcoming key activities**





## Animation video about Duchenne



Please click [here](#) to view video

DISCLAIMER: Internationally acclaimed and renowned Australian film production company **Finch** have created an emotional animation about Duchenne for use by Save Our Sons when advocating to key decision-makers and influencers about the urgency of meaningful action to secure a cure. It is advised that due to the content parents and carers view the animation first and utilise their discretion as to whether their family members and loved ones view the production. Save Our Sons will use the animation for a specific target audience, and Finch have been gracious in creating this animation pro bono and also agreeing for its open use by like-minded organisations across the globe.

Film Director: Kyra Bartley See Less



## Patient Stories



### Jake

"I would ask companies considering developing a therapy for non-ambulatory patients to please do so. It could make a huge difference in the quality of life of the non-ambulatory person and their caregivers/families. Non-ambulatory individuals seem to have been forgotten in the realm of research and developing therapies. People who are non-ambulatory are still important, productive individuals with a ton of living to do and much to offer the world." - **Emily, Mother of Jake**



### Austin

"The most important things for Austin to maintain are the ability to self-feed, ability to use a keyboard, ability to lift a cell phone, ability to brush teeth, ability to adjust (put on, remove) headphones (gaming is a big deal in the Duchenne community)."- **Trina, Mother of Austin**



## ATL1102 Phase II Study

Open label Phase II trial in nine non-ambulant (wheelchair bound) boys 10-18 years of age with DMD conducted over 24 weeks of dosing.

- Primary endpoint met with confirmation of drug's safety and tolerability
- Strong effects on secondary endpoints on activity markers and disease progression
- Improvement or stabilisation across different measures of motor function & strength
- Activity on the targeted CD49d immune cells consistent with drug's proposed mechanism of action
- MRI data suggests stabilisation of percentage of fat in muscles and preservation of functional muscle mass
- International KOLs are supportive of Phase IIb plans

***“The data certainly suggests an overall ‘stabilisation’ in disease progression at the very least which of itself is a very positive clinical outcome. MRI data confirms the positive changes at a muscular/cellular level and supports the observed physical stabilisation/improvements in muscle strength and function. The consistency of positive clinically relevant effects of ATL1102 treatment across muscle measures of structure, strength and function are very pleasing and provide great encouragement for the treatment of non-ambulant patients with DMD”.***

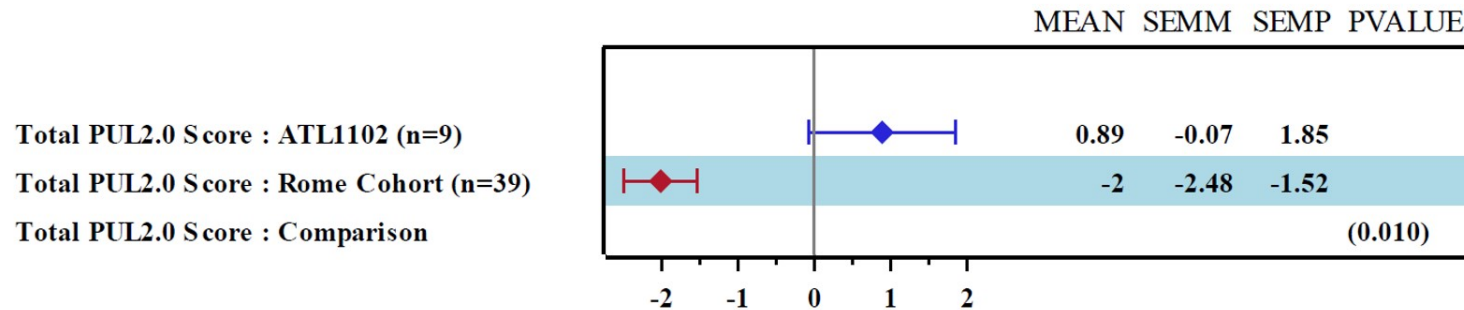
**Professor Thomas Voit MD**, Director, NIHR GOSH Biomedical Research Centre, UK



# ATL1102 Shows Statistically Significant Improvement vs Natural History Control

- New ATL1102 data presented at the 25th International Annual Congress of the World Muscle Society
- ATL1102 treated patients demonstrated a statistically significant improvement in the mean (SD) scores for the 24 week treatment compared to external control (Rome Cohort)

**Forest Plot for the Mean Change (+/- SEM) in PUL2.0 Measures from Baseline to Month 6**



“..The level of improvement achieved is very positive and clinically relevant. As Total PUL2.0 is the key efficacy endpoint for seeking drug approval in non-ambulant patients with DMD, the comparative data further indicates ATL1102’s promising potential to provide clinically meaningful benefits in the future treatment of non-ambulant DMD patients who have very limited treatment options”.

**Professor Eugenio Mercuri**, Professor of Pediatric Neurology at the Catholic University, Rome, Italy



# ATL1102 Phase IIb Clinical Study and US Regulatory Plans



- Next step to submit a Paediatric Investigational Plan (PIP) to the EMA Paediatric Committee (PDCO) and confirm the Phase IIb trial design via PIP application to be submitted in early 2021. Initial PDCO feedback is to be received ahead of submitting the Phase IIb trial application
- Activities commenced for the manufacture of clinical trial supplies of ATL1102 for the trial. Clinical supplies planned to be available in line with the receipt of PDCO feedback and the approval to commence the Phase IIb trial, anticipated in mid 2021 assuming no material changes or delays
- Ongoing interactions with US based key opinion leaders, Advocacy Groups (PPMD and MDA), and expert regulatory consultants to define clinical path and next steps for ATL1102 in DMD in the US as a priority. Currently preparing for a meeting with the FDA targeted for 1Q'21



# ATL1102 New Indications

## Overview

- ATL1102 modulates CD49d+ immune cells and disease processes in DMD and Multiple Sclerosis

## IP

- The company has continued to file new patent applications to protect the use of ATL1102 in new neuroinflammatory muscle indications with the new submission this year of International patent application PCT/AU2020/050445

## Next Steps

- Several inflammatory muscle disease indications (like DMD) have been identified which may benefit from similar CD49d cell modulation for better treatment outcomes, with animal and ex vivo studies of patient samples in the planning for 2021
- Also the broader effects of CD49d modulation by ATL1102 are to be studied by analyzing DMD patient plasma samples to identify potential additional immune modulation mechanisms that may be relevant in the treatment of other diseases with this experimental work scheduled for 1H 2021
- The funds from the recent capital raising now allow for the above work to be undertaken the results of which are anticipated to add further value to the ATL1102 asset.

- **Partnering/Corporate engagement**

As previously noted, we have received inbound interest from pharmaceutical companies and potential strategic investors in the Company and its programs. To date our approach has been to engage with these groups to explore such interest. It is important to note that such parties can often seek to undertake comprehensive due diligence ahead of any capital injection and/or collaborative commitment. Such processes can take many months to complete with no guarantee of a deal emerging from such efforts. As the Company begins to gain better definition around its clinical program in DMD following feedback from, and alignment with, expert groups including regulatory bodies, it anticipates this inbound interest to grow. The Company is well positioned and suitably experienced to manage and potentially extract value from such corporate interactions. The Company would advise the market should these interactions lead to a material transaction. Future human resourcing plans, as touched on below, will look to increase our bandwidth in managing and executing on such corporate/business development opportunities as they emerge.

- **Phase IIb timelines/funding**

As per our disclosures we are looking to submit our PIP application early next calendar year and based on initial feedback on the Phase IIb component of the PIP, look to finalise and submit our trial application for approval to conduct the study, all going well, anticipated mid-2021. The study is proposed as a 12 month dosing trial with an open label extension phase. The company expects to be able to outline additional trial details once the company has received PIP feedback and has submitted its trial protocol. The costs associated with conducting the trial will depend on the final approved design, so again the Company will be better positioned to outline these costs upon trial application submission. As reported, the recent financing has provided capital to support the preparatory work for the trial up to trial initiation, therefore the major costs associated with the conduct of the trial are not anticipated to come through until later in 2021. In the interim, the company will look at funding options for the trial while continuing with its planned corporate engagement which may present as part of the financing option.

- **Human Resourcing - Management/Board**

We are excited by the growth prospects that are presenting for the Company and recognise that this presents as an opportunity to expand the core team at ANP who to date have so competently and efficiently managed the development programs at ANP. Again the recent financing should facilitate this key initiative. Similarly the Board recognises the need to continue to evaluate its composition and skill set relevant to the stage and evolution of the Company as it is rapidly moves into late stage drug development and contemplates potential drug commercialisation.

- **ATL1103 partnering**

While our current focus is on advancing the development of ATL1102 for DMD and other potential inflammatory diseases as the key value creation driver of the business, ATL1103 does remain an asset of the Company. We continue to explore ways of monetising this asset including potential partnering. New applications of ATL1103 may also be explored via relatively low-cost animal studies with future partnering in mind. We would though expect our shareholders to regard the potential monetisation of ATL1103 as more of an upside opportunity while we look to lock in the solid value creation potential of ATL1102.



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