ASX Announcement

26 October 2022

Quarterly Activities Report & Appendix 4C

- **ATL1102 Revised Plans accelerate reporting of unblinded data**
- **Dosing commenced in DMD combination therapy study**
- **Long COVID study identifies diagnostic & therapeutic targets**

Antisense Therapeutics Limited (Antisense or Company) is pleased to provide its Appendix 4C and quarterly update for the period ended 30 September 2022.

ATL1102 for DMD: Revised Clinical Plans accelerate reporting of unblinded data

During the quarter the Company announced that it intends to conduct a double-blind, placebo controlled six-month dosing trial of ATL1102 followed by a six-month open label phase (collectively the 'Phase IIb' trial) in non-ambulant boys with Duchenne's Muscular Dystrophy (DMD). The primary endpoint of PUL2.0 will be assessed after six months of treatment

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The Phase IIb study aims to enrol and randomize 45 non-ambulant boys with DMD. Following the initial six-month regimen of either placebo, 25 mg or 50 mg once weekly, participants will be invited into a further six-month open label follow-up treatment period in which all boys will be on active treatment (25 or 50mg).

The Phase IIb trial design is modelled on the Phase IIb/III study outlined in Company's Paediatric Investigation Plan (PIP) and agreed by the European Medicines Agency (EMA) and The Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The Phase IIb/III clinical trial application submitted in Germany (BfArM) during the quarter is undergoing evaluation. With the regulatory focus now directed to submission of the Phase IIb trial applications, no additional Phase IIb/III trial submissions are currently planned.

The revised trial design now to be conducted brings forward the definitive reporting of unblinded and statistically analysed trial data following the completion of the initial randomized blinded six-month dosing period. The Company believes that if successful, positive data from a controlled trial of ATL1102 in DMD patients could add substantial value to the program and, based on previous external feedback, garner serious partnering interest at an earlier point in the development program than previously anticipated.

The revised trial design has allowed for the opportunity to incorporate Australian sites alongside key trial centres in Europe. This provides the important benefit of continuity of working with Australian investigators who were involved in the conduct of the previous successful Phase II clinical trial of ATL1102 in DMD. The addition of Australian trial sites is expected to facilitate a significantly greater proportion of the trial costs as being eligible for the R&D tax incentive cash rebate, which should have a material impact on reducing the cash requirements for the conduct of the study.

The new strategy allows the Company to confirm drug efficacy through the rigor of the placebo-controlled trial design so as to allow for discussion with regulators for potential fast tracking into registration phase or potential accelerated approval, pending trial outcomes.

The Company anticipates the first of the trial sites for the Phase IIb trial to be initiated in this calendar year**.** Based on current enrolment expectations, the last patient is projected to enter

the trial in 3Q'23 with the blinded phase of the trial to complete once the last patient has finished their six months of dosing. Reporting of the trial results would follow shortly thereafter.

Dosing commenced in DMD combination therapy study

Dosing has commenced in a muscular dystrophy (mdx) mouse model of DMD to assess the potential clinical utility of ATL1102 in combination with dystrophin restoration drugs (approved in the US for the treatment of DMD) to improve on therapeutic outcomes for patients with DMD.

Under the collaborative research agreement with the Murdoch Children's Research Institute's (MCRI), mice will be dosed with an antisense oligonucleotide designed to target CD49d (mouse equivalent of ATL1102) or control oligonucleotide or saline treatments in combination with a dystrophin restoration drug (morpholino oligonucleotide exon skipping drug of the same drug chemistry as the exon skipping treatments marketed in the US). Dosing is to be completed in November with results anticipated shortly thereafter.

Antisense inhibition of CD49d has previously demonstrated activity in an mdx mouse model as a monotherapy, reducing CD49d+ immune cells and both the CD49d target in the muscle and muscle damage. The combination study will assess the effects of antisense inhibition of CD49d in combination with a dystrophin restoration drug on markers of drug activity in the DMD mdx model including the potential of the combination to improve dystrophin expression levels beyond that achieved by the dystrophin restoration agent used alone, and thereby point to the potential utility of the combination treatment in the clinic.

Long COVID-19 study identifies diagnostic and therapeutic targets

The collaboration to study the neurological aspects of Long COVID-19 (Long Neuro COVID-19) with US based researchers led by global leader in the field, Dr Igor Koralnik, at the Northwestern Medicine Neuro-COVID clinic in Chicago, has elucidated novel blood markers as potential diagnostic and therapeutic targets in the treatment of Long COVID-19 patients.

Three (3) provisional patent applications have been filed in the US to seek protection for these new inventions. Under the collaboration, blood samples that had been collected from Long COVID-19 patients who had not been hospitalised (focused on those with neurological symptoms including brain fog, where blood immune cell changes were observed), were used to generate data on up to 7,000 proteins in the blood utilising a large-scale protein analysis known as proteomics. Industry leading proteomics group Somalogic in Boulder Colorado USA undertook the analysis, successfully testing the samples using their SomaScan® assay and then the data was statistically analysed using their Dataviz program.

The analysed data has identified a number of proteins that are significantly modulated in the blood of Long Neuro COVID-19 patients when compared to convalescent subjects who had recovered from Long COVID-19 infection with no persistent symptoms and to healthy subjects. This data has been included in recently filed patent applications as potential diagnostic and therapeutic targets for the treatment of Long COVID-19. Certain targets when combined (as few as 5) identified all 48 Neuro Covid-19 patients and the 42 of 44 subjects who were convalescent or healthy controls suggestive of these targets' diagnostic potential. A number of targets (<15) have been identified as potentially amenable to treatment by currently available drugs or other therapeutic approaches on the market. The mechanisms of action of those drugs are known to modulate the discovered target proteins, therefore the marketers/developers of those drugs have been identified as initial prospects for partnering interest. A smaller number of diagnostic markers have been detected that could assist in the identification of Neuro Long Covid patients for better designed clinical trials and potentially for earlier treatment intervention. Accordingly, the Company also plans to review its newly generated intellectual property (IP) with targeted pharmaceutical and diagnostic companies for potential commercial discussions, noting that for

these discussions to progress, the Company and potential partner companies would need to agree on licensing and/or joint development of this newly generated IP to advance as either diagnostic or therapeutic programs.

One of the aims of the proteomics analysis was to assess if Neuro Long COVID-19 patients may have been amendable to treatment with ANP's immunomodulatory drug ATL1102 which has previously demonstrated biologic activity in MS patients and the ability to reduce T cells and modulate proteins involved in the blood of DMD patients (data presented at the 2021 World Muscle Society conference WMS-ATL1102-DMD-PROTEOMICS-Poster). Encouragingly, one of the potential therapeutic markers in Long COVID-19 patients identified from this proteomics analysis is also known as having the potential to be significantly modulated by ATL1102 in DMD patients and therefore is suggestive of its therapeutic potential in Long COVID-19. The Company is looking to further explore the clinical potential of ATL1102 in this setting via applying for grant funding opportunities in collaboration with Professor Koralnik.

Of the 94.7 million people in the US diagnosed as infected and surviving COVID-19, approximately 82 million (87%) people are non-hospitalized 4, and 45% of non-hospitalized patients5 have developed some manifestation of Long COVID-19 syndrome which suggests more than 24 million people are afflicted by the condition to some extent. The main neurological symptom is brain fog (defined with the established memory tests conducted) and reported in 81% suggesting an impact on nearly 20 million people in the US.

Ongoing engagement with DMD community, investors and pharmaceutical companies

The Company continued its communication and active engagement with key opinion leaders, potential collaborators, investors and commercial partners as a key operational priority. During the quarter the Company presented and participated at the following events:

- Broker, Institutional and Sophisticated Investor presentation – Melbourne, 13 July 2022
- Australian Equities Day Webinar – Singapore, 28 July 2022
- US IR and Media engagements – August - September 2022
- Webinar overview of the ATL1102 for DMD Revised Clinical Plans announcement – 7 September 2022

Cash Flow

As at 30 September 2022 the Company reported cash of $17.9 million.

The Company is focused on deploying its existing cash reserves in the most effective manner for advancing the ATL1102 in DMD clinical development program as well as the progressing the pipeline initiatives of ATL1102 for Limb Girdle (MDR2), dystrophin restoration combination study and Long Covid-19 collaboration.

During the quarter the Company made payments to related parties of the entity and their associates as disclosed in Item 6 of the Appendix 4C amounting to $201,161. The payments related to salaries, directors' fees and consulting fees on normal commercial terms.

This announcement has been authorised for release by the Board.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Antisense Therapeutics Limited	
ABN	**Quarter ended ("current quarter")**
41 095 060 745	30 September 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development **	(613)	(613)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(48)	(48)
	(d) leased assets	(26)	(26)
	(e) staff costs	(409)	(409)
	(f) administration and corporate costs	(394)	(394)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	60	60
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	53	53
1.9	**Net cash from / (used in) operating activities**	**(1,377)**	**(1,377)**

** Includes ATL1102 drug compound manufacturing costs

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(10)	(10)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(10)**	**(10)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	-	-

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	19,233	19,233
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,377)	(1,377)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(10)	(10)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**17,846**	**17,846**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	346	817
5.2	Call deposits	17,500	18,416
5.3	Bank overdrafts		-
5.4	Other (provide details)		-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**17,846**	**19,233**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	201
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,377)
8.2	Cash and cash equivalents at quarter end (item 4.6)	17,846
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	17,846
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	13

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 26 October 2022

Authorised by: By the Board .....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.