ASX Announcement

28 April 2021

Quarterly Update & Appendix 4C

- **Type C meeting granted with US FDA to discuss ATL1102 in DMD**
- **Paediatric Investigation Plan for ATL1102 in DMD submitted to EMA**
- **Manufacture of clinical supplies in progress**
- **Dr Charmaine Gittleson appointed as a Non-Executive Director**

Antisense Therapeutics Limited [ASX:ANP | US OTC:ATHJY | FSE:AWY], (the Company) is pleased to provide its Appendix 4C and quarterly update for the period ended 31 March 2021.

Type C guidance meeting with the US Food and Drug Administration (FDA)

During the quarter the FDA has granted a Type C guidance meeting to discuss the further development of ATL1102 in Duchenne muscular dystrophy (DMD) in the US. The Company with its US based expert regulatory consultants is clarifying via the meeting the preclinical (also referred to as non-clinical) requirements to support longer term (12-month) dosing of ATL1102 in DMD patients in the US.

Subsequent to the end of the quarter, the Company reported that the meeting was held as scheduled on 19 April 2021 and that the Company will provide further details following receipt from the FDA of the official minutes of the meeting in late May 2021.

Paediatric Investigation Plan for ATL1102 in DMD submitted to European Medicines Agency

The Paediatric Investigation Plan (PIP) for the development of ATL1102 for DMD has been submitted to the European Medicines Agency (EMA) Paediatric Committee (PDCO). A paediatric investigation plan is a development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorisation of a medicine for children. The ATL1102 DMD PIP submission incorporates the planned Phase IIb clinical trial of ATL1102 in non-ambulant DMD patients to be conducted in Europe. The Company is looking to confirm the Phase IIb trial design through the PIP and initial PDCO feedback ahead of submission of the Phase IIb trial application anticipated in 2Q'21. The Company is planning to conduct a multi-centre, randomised, double-blind placebo-controlled study of ATL1102 in non-ambulant patients dosed with ATL1102 for 12 months at two dose levels to be conducted as a potentially pivotal (approvable) trial with a follow-on open label extension phase. Given that clinical trial approval in the EU is under national sovereignty, submissions will be made to the respective national authorities of the European states where the Company expects to conduct the Phase IIb trial. Approvals will likely then be staggered depending upon the approval timelines of the individual states. All going well first approvals would be anticipated in Q3'21 with site initiations commencing in Q4'21.

Clinical Supplies

The Company has commenced the manufacture of ATL1102 active ingredient for the Phase IIb trial and is planning to have this material formulated into injectable product in Q2'21.

Dr Charmaine Gittleson appointed as a Non-Executive Director

Dr Gittleson is a senior executive with extensive international experience as a pharmaceutical physician and enterprise leader in pharmaceutical drug development, governance and risk management gained during her 15-year tenure (2005-2020) with global specialty biotechnology company CSL Limited (ASX: CSL). During her time at CSL, Dr Gittleson had at various times accountability for clinical research, medical safety, medical and patient related ethics for development and on market programs, providing leadership in strategic product development, planning and implementation across multiple therapeutic and rare disease areas. At CSL Dr Gittleson held the key leadership roles of: Senior Director, Head Safety and Clinical Development (2006-2010) in Melbourne Australia; Vice President Clinical Strategy (2010-2013) and Senior Vice President Clinical Development (2013-2017) in Pennsylvania United States; and Chief Medical Officer in Melbourne from 2017 until her recent retirement from corporate roles in 2020. Dr Gittleson was Chair of the company's Global Benefit Risk Committee, overseeing overall product safety which facilitated regulatory approvals in USA, EU, Japan, South America and Asia-Pacific; Chair of CSL's Bioethics Advisory Forum, and Chair of CSL's Strategic and Technical Risk Committee, tasked with delivering development programs on time with quality and within budget, achieving five new major global product approvals and launches within a 24-month period, which included a number of rare disease therapies.

Notably in her role as Senior Vice President Clinical Development, Dr Gittleson led all clinical, safety, strategic and operational R&D functions (over 350 staff) with teams in USA, Europe, Japan, China and Australia and was responsible for overseeing a large annual clinical development budget and was a key participant in regulatory agency negotiations, due diligence activities, industry meetings and annual analyst briefings. Dr Gittleson has been a scientific speaker at multiple medical conferences and regulatory workshops (FDA and EMA) and a keynote speaker at Women in Pharma & Leadership conferences for Women in ASX200 listed companies 2017, 2018 and 2019. Dr Gittleson is a qualified medical physician and holds a Bachelor of Science and a Bachelor of Medicine and Surgery both from the University of Witwatersrand and an Australian Medical Council Qualification. Dr Gittleson is a graduate of the Australian Institute of Company Directors and Stanford University's Company Directors Course.

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:

- Virtual Investor Roadshow - Singapore & Hong Kong, 22 – 25 January 2021.
- ShareCafé Small Cap "Hidden Gems" Webinar, Australia, 5 February 2021.
- Jett Foundation 4th Annual Rare Disease Day Conference, US, 26 February 2021
- FDA Rare Disease Day 2021, US, 5 March 2021
- Spark Plus "Biotech Day" Webinar, Singapore, 25 March 2021

Broker Research & Other Reports

Several leading Australian healthcare research analysts have released positive research notes on the Company during the quarter (reports are available on ANP website: https://www.antisense.com.au/broker-other-reports/):

"Small changes for a big difference" – Iain Wilkie / Scott Power, Morgans Financial

"Potential Competitor on the Canvas" - Marc Sinatra, Corporate Connect

"DMD around the grounds: symptoms persist" - Shane Storey/Melissa Benson, Wilsons Equity Research

Cash Flow

As at 31 March 2021 the Company reported cash of $8.3 million.

Research and Development payments for the quarter amounted to $1.13 million with ATL1102 drug compound manufacturing costs accounting for a significant portion of the expenditure. R&D expenditure for the quarter also included costs associated with continuation of the regulatory interactions with EMA and the US FDA as noted in the update.

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 $186k. 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	31 March 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development **	(1,131)	(2,397)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(67)	(168)
	(d) leased assets	-	-
	(e) staff costs	(305)	(873)
	(f) administration and corporate costs	(231)	(894)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	3
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	688
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,734)**	**(3,641)**

** 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	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	8,500
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	-	(611)
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**	-	**7,889**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	10,043	4,059
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,734)	(3,641)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

	Consolidated statement of cash flows	**Current quarter $A'000**	**Year to date (9 months) $A'000**
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	7,889
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**8,307**	**8,307**

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	307	7,943
5.2	Call deposits	8,000	2,100
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)**	**8,307**	**10,043**

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	186
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)	1,735
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,307
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,307
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5

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:

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:

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:

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: 28 April 2021.....

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.