ASX Announcement

27 January 2022

Quarterly Activities Report & Appendix 4C

- **Positive Opinion received on PIP from PDCO for EU and ratified by EMA**
- **Positive PIP Decision from UK MHRA**
- **ATL1102 Toxicology Protocol submitted to US FDA and update on PRV status**
- **$22.6 million raised via Placement and Entitlement Offer**
- **Dr Gil Price appointed as a non-executive director**
- **2021 AGM**
- **ATL1102 Intellectual Property Update**

Antisense Therapeutics Limited (Antisense or Company) is pleased to provide its Appendix 4C and quarterly update for the period ended 31 December 2021.

Positive Opinion received on ATL1102 Paediatric Investigation Plan and subsequently ratified by EMA

During the quarter the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) adopted a positive final Opinion on its Paediatric Investigation Plan (PIP) for the development of ATL1102 for Duchenne muscular dystrophy (DMD) following the PDCO meeting on 15 October 2021. Subsequent to the reporting of this news, the Company has received formal ratification by the EMA of this decision.

Phase IIb/III trial

The Phase IIb/III clinical trial is a multicentre, randomised, double-blind, placebo-controlled study to determine the efficacy, safety, and pharmacokinetic profile of ATL1102 (25 mg and 50 mg) administered once weekly by subcutaneous injection for 52 weeks in non-ambulatory participants with DMD, to be conducted as a potentially pivotal (approvable) trial with a follow-on open label extension trial. Participants will be randomised to either 25 mg ATL1102, 50 mg ATL1102 or placebo in a 1:1:1 ratio with stratification by corticosteroid use. Up to 114 participants are to be enrolled (38 per treatment arm) with 108 participants expected to complete the trial. Additional trial details and timelines are outlined in the investor presentation lodged with the ASX on 1 November 2021.

As previously announced, ANP has appointed globally renowned Clinical Research Organisation (CRO) Parexel to conduct and manage the Phase IIb/III European trial. Parexel are finalising evaluations of the trial sites via site inspections in the United Kingdom, Netherlands, Germany, Italy, France, Belgium, Spain, Bulgaria and Turkey for selection of the sites to participate in the study. Trial start up activities are underway as outlined in the Company's 14 December 2021 announcement with the anticipated study timelines as noted in the 1 November 2021 investor presentation lodged by the Company with the ASX.

Professor Thomas Voit MD (Director of NIHR GOSH UCL Biomedical Research Centre, UK) has been appointed as the Coordinating Principal Investigator (CPI) of the trial.

Positive PIP Decision received from UK MHRA

In December 2021 the Company received a positive Decision from the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK on the UK Paediatric Investigation Plan (PIP) submission for the development of ATL1102 for Duchenne muscular dystrophy (DMD) (a separate PIP submission was made to the MHRA following the UK's withdrawal from the European Union). The UK is a key location for the conduct of the study and is the base of our CPI, Professor Thomas Voit.

The measures outlined in the UK-PIP Decision are consistent with those adopted in the positive final Opinion on the Company's PIP for the development of ATL1102 for DMD provided by the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) and subsequently ratified by the EMA.

ATL1102 Toxicology Protocol submitted to US FDA

In December 2021 the Company submitted to the US Food and Drug Administration (FDA) the protocol synopsis for a nine-month chronic monkey toxicology study to support the dosing of patients with ATL1102 beyond six months in US for DMD or any other clinical application of ATL1102. The Company is expecting to receive feedback from the FDA on the protocol in 1Q'22.

A prior Type C guidance meeting held with US FDA provided the Company with clarity on the requirement for the chronic monkey study and design of a Phase IIb/III trial for the US. Given the apparent high-level alignment between EMA and FDA on Phase IIb/III study requirements, the feedback from the FDA provides the Company with the opportunity to engage with the agency to streamline the regulatory processes and to the extent possible harmonize the Company's overall global clinical development plans. The Company considers that it has potential optionality in its actions with FDA including to take the EU Phase IIb/III data to the FDA to be assessed as supportive data for a future marketing application or should the data warrant it, possibly an approval of ATL1102 for DMD without further trials.

FDA interactions to explore the optionality highlighted above are to continue in parallel with the conduct of Phase IIb/III pivotal trial in Europe. The timing of the initiation of the nine-month toxicology study will be dependent on these continued interactions with the agency.

An important consideration in the clinical and regulatory strategy outlined above is the news announced by ANP on 30 September 2020 that the US FDA had granted a Rare Pediatric Disease Designation to ATL1102 for the treatment of DMD. Should the Phase IIb/III pivotal trial in Europe be successful, the Company believes it could be in a position to receive a rare pediatric disease priority review voucher (PRV) if it obtains FDA approval for ATL1102 in the DMD indication (as the drug's first approval) before September 30, 2026 (being the extended sunset date of the RPD Priority Review Voucher Program approved by the US Congress). The Company may then choose to sell its PRV to use it as a source non-dilutive capital. From 2017 - 2021, sales of PRVs ranged between US$80 - $150 million.

$22.6 million raised via Placement and Entitlement Offer

During the quarter, the Company received gross proceeds of $22.6 million via a capital raising comprising a placement to institutional and sophisticated investors and a follow-on Entitlement Offer to shareholders. The funds received will be deployed towards preparation activities for initiation of the Company's pivotal Phase IIb/III trial of ATL1102 for DMD in Europe as detailed in ANP's recent announcements and the Company's AGM presentation lodged with the ASX on 15 December 2021.

Dr Gil Price, Antisense Therapeutics' US-based Consultant Medical Director appointed to the Company's board as a non-executive director

In line with the board's strategy of strengthening the Company's clinical and scientific resources and governance ahead of the imminent initiation of Phase IIb clinical trial of ATL1102 in DMD in Europe, the Board of Director has appointed Dr Gil Price as a Non-Executive Director. Dr Price brings to the board a deep understanding and experience in DMD drug development as a clinical physician and extensive commercial development experience combined with a depth of expertise across clinical asset investment strategy, evaluation, financing and execution gained serving as director on multiple boards of private, not-for-profit and public entities, including as non-executive director of Sarepta Therapeutics, Inc. (2007-2016).

Dr Price's engagement with Key Opinion Leaders in the treatment of DMD and DMD Patient Advocacy Groups has helped increase the awareness of the Company's ATL1102 for DMD development program

and to translate the features and benefits of the program to these audiences and to advocates internationally. This important work has recently resulted in the Company being invited to be a member of the Pharmaceutical Advisory Board for the development of the New Duchenne Guidance by Parent Project Muscular Dystrophy (PPMD) for the US FDA.

2021 Annual General Meeting

The Company's Annual General Meeting of shareholders was held on the 15 December 2021. All resolutions were carried on a poll and were passed with the majority of the vote (over 94%) in favour of the resolutions.

Three long serving non-executive directors (Bob Moses, Dr Graham Mitchell and William Goolsbee) retired at the AGM with non-executive directors Dr Charmaine Gittleson and Dr Gil Price (who had recently joined the board to help strengthen the Company's clinical and scientific resources and governance) elected by shareholders at the AGM with 99.95% of the vote in favour of their appointment.

The Chair then outlined the Company's proposed strategic plan and high-level key strategic factors for success. The Managing Director (MD) then highlighted the recent capital raising that had significantly strengthened the Company's balance sheet, noting that it was the most capital the Company had accessed in its history. The MD then advised of the substantial progress made with both European and US regulatory authorities (outlined earlier in this report) in regards to advancing the ATL1102 DMD program in these key markets and advancements in the Company's research collaboration with the Murdoch Children's Research Institute (MCRI), where animal studies were in preparation for initiation in Q1'22 (dosing of animals anticipated to commence early next month with first data due Q3'22, as noted in the AGM presentation). The MD also outlined the Company's capital management plans and commercialisation considerations for ATL1102 in DMD, noting that the Company was gearing up to potentially take ATL1102 all the way to through approval in Europe and possibly to market in that territory and the major value creation potential that such an initiative could deliver for shareholders.

ATL1102 Intellectual Property Update

Since reporting on the status of the Company's intellectual property portfolio in the 2021 Annual Report, the Company has advanced its patent portfolio as follows:

- International application PCT/AU2018/051353 covering ATL1102 treatment of Duchenne muscular dystrophy (DMD) has been progressed into the examination phase in Australia, Brazil, Canada, China, Japan, New Zealand, South Korea and Europe, together with US continuation–in part 16/404561 to protect the invention to 2039;

- International application PCT/AU2020/050445 covering ATL1102 treatment of other muscular conditions has been progressed with filings in the national phase in Australia, Brazil, Canada, China, Japan, New Zealand, South Korea, the USA and the regional phase in Europe, to protect the invention to 2040;

- New Australian Provisional Patent application 2021903024 was filed 20 September 2021 covering new ATL1102 effects on plasma proteins (proteomics) and ATL1102 applications in new potential disease settings including diabetic, respiratory and age-related diseases;

- European patent application 16861126.7 has been progressed to near issuance, and granted US patent 11041156 is now registered covering the use of ATL1102 for mobilizing leukemia cells in the treatment of acute myeloid leukemia (AML) to 2036.

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 Roadshows – October - November 2021
- Opentrader, Trading Edge; Post lockdown trading webinar – Australia, 17 November 2021
- ShareCafe Due Diligence Webinar – Australia, 23 November 2021
- Spark Plus Healthcare Day Webinar - Singapore, 25 November 2021
- 2021 Annual General Meeting – Melbourne, 15 December 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/):

"Paediatric Investigation Plan Almost Certain To Get the Tick and Other Notable Events" - Marc Sinatra, Corporate Connect

"Securing funding for DMD pivotal trial" - Dennis Hulme, Taylor Collison

"Transformational Capital Raise for Antisense Therapeutics" (with inclusion into Bioshares Model Portfolio) - Mark Pachacz, Bioshares

"Phase 2/3 here we come" – Stuart Roberts, Stocks Down Under

"Leaps and stepping stones" - Iain Wilkie / Scott Power, Morgans Financial

"Comprehensive Research Report" – Marc Sinatra, Corporate Connect

Cash Flow

As at 31 December 2021 the Company reported cash of $23.48 million.

The Company continues to efficiently manage expenditure planned for continuation of the regulatory interactions with EMA and US FDA, preparations for the conduct of Phase IIb clinical trial of ATL1102 in DMD in Europe as well as advancement of potential new indications for ATL1102. During the quarter the net expenditure incurred on those activities amounted to $1.28 million.

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 $343,412. 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 December 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (06 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development **	(1,284)	(1,802)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(78)	(125)
	(d) leased assets	-	-
	(e) staff costs	(521)	(859)
	(f) administration and corporate costs	(452)	(836)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	1
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)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,336)**	**(3,622)**

** 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 (06 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)	22,587	22,587
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	(1,502)	(1,502)
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**	21,085	21,085

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,734	6,020
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,336)	(3,622)
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 (06 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	21,085	21,085
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**23,483**	**23,483**

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	5,082	4,734
5.2	Call deposits	18,401	-
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)**	**23,483**	**4,734**

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	343
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)	(2,336)
8.2	Cash and cash equivalents at quarter end (item 4.6)	23,483
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	21,147
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	9

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: 27 January 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.