

ASX Announcement

25 January 2023

Quarterly Activities Report & Appendix 4C

Antisense Therapeutics Limited [ASX:ANP | US OTC:ATHJY | FSE:AWY] (Antisense or Company) is pleased to provide its Appendix 4C and quarterly update for the period ended 31 December 2022.

ATL1102 for DMD: Clinical Trial Application submitted for Phase IIb DMD trial in Europe

During the quarter the Company submitted a Clinical Trial Application (CTA) in three European countries (UK, Bulgaria and Turkey) for approval to conduct its Phase IIb trial of ATL1102 in non-ambulant boys with Duchenne muscular dystrophy (DMD)¹. The CTA submission for Ethics Committee (EC) approval to initiate trial sites in Australia is scheduled for submission to the EC for review in Q1'23.

CTA is undergoing evaluation by relevant regulatory bodies and is at various stages of the approval process. As previously highlighted¹, trial approvals are expected to come through in a staggered manner in early 2023 depending on the respective regulatory agencies' evaluation process. Timeline guidance for reporting of the results from the blinded phase of the Phase IIb trial remains unchanged and is anticipated in 1H'24.

ATL1102 tox study to support clinical program in the US

In the period the Company advised that it had initiated the process to conduct a nine-month chronic monkey toxicology study of ATL1102 at Contract Research Organisation (CRO) Pharmaron to support the advancement of the ATL1102 program in the US for Duchenne muscular dystrophy (DMD) or any other clinical application of ATL1102². Since that time, the study protocol has been agreed and test article (ATL1102) has been received at the Pharmaron site. Dosing of animals is scheduled to commence next month with the study outcomes remaining on track for reporting in 1H'24.

Successful completion of the toxicology study is expected to be the final requisite step for the FDA to allow dosing of ATL1102 for a term longer than 6 months in the US. Successful completion of the nine-month chronic monkey toxicology study should also allow ANP to apply for expedited program status with the US Food and Drug Administration (FDA) including Fast Track or potential Breakthrough Therapy designation. US FDA has already granted ATL1102 an Orphan Drug Designation and a Rare Pediatric Disease Designation for the treatment of DMD.

The reporting of key study findings in 1H'24 is around the same time as the six-month dosing results from the ATL1102 in DMD Phase IIb clinical study are expected which could then allow the Company to share with FDA and other regulatory bodies a compelling data package encompassing the Phase IIb study clinical results along with the outcomes from the nine-month toxicology study for potential discussions with the regulators on accelerated regulatory pathways to registration.

DMD combination therapy study

During the quarter, the dosing of animals has been completed in a muscular dystrophy (mdx) mouse model of DMD to assess the potential clinical utility of ATL1102 in combination with dystrophin restoration drugs to improve on therapeutic outcomes for patients with DMD on the dystrophin restoration drugs (study details announced 12 September 2022).

In this blinded and controlled study, run under the collaborative research agreement with the Murdoch Children's Research Institute's (MCRI), the mice were dosed alone with an antisense oligonucleotide to CD49d (mouse equivalent of ATL1102) or control oligonucleotide or saline treatments, or a dystrophin restoration drug alone and additionally a combination of the antisense oligonucleotide drug to CD49d with a dystrophin restoration drug (morpholino oligonucleotide exon skipping drug of the same drug chemistry as the exon skipping treatments marketed in the US). The samples were then processed under a two part analysis: functional (effect on muscle) and cellular (RNA and protein levels). Functional analysis results are due imminently with the cellular analysis to follow next month. Any applicable patent filings would be made ahead of disclosure of the results.

The dystrophin restoration drugs are approved conditionally in the US for the treatment of approximately a third of ambulant DMD patients with mutations to dystrophin exons 45, 51, and 53. As an indication of the potential market for dystrophin restoration drugs, Sarepta Therapeutics Ltd recently announced preliminary net product revenues for the fourth quarter and full-year 2022 are expected to total US\$235.5 million and US\$843.3 million, respectively for their 3 approved exon restoration drugs in the US alone.³

Long Neuro COVID-19

As previously advised⁴, the Company had completed a successful world first Long COVID-19 study that identified novel blood markers as potential targets for the diagnosis and treatment of the neurological deficits of Long COVID e.g. brain fog measured using established memory tests. A subset of the study results were included in a scientific publication pre-print.

(<https://www.medrxiv.org/content/10.1101/2021.08.08.21261763v4>).

Recent scientific publications report that neurological symptoms remain a major feature of Long COVID with cognitive impairment identified in approximately a quarter of subjects at 12 months post SARS-CoV2 infection. (<https://www.nature.com/articles/s41579-022-00846-2>).

The Company has continued discussions with targeted companies to explore interest in licensing/commercialising our Long Covid- 19 Intellectual Property, these discussions include an ongoing dialogue with a diagnostic company on a potential development collaboration.

Limb Girdle Muscular Dystrophy R2

There are no approved treatments for LGMDR2. Having successfully demonstrated target drug activity (reducing target and immune cell RNA in muscle) using an antisense oligonucleotide to CD49d (mouse equivalent of ATL1102) in a dysferlin mutation animal model⁵, during the quarter the Company advanced its planning for a chronic mouse study to assess key disease progression endpoints. Mice with the dysferlin mutation and disease characteristics have been sourced via Jain Foundation in the US with the study to be initiated in January 2023. Mice will be dosed for 4 months with results to follow.

Board and Management changes

During the quarter Antisense has strengthened its leadership team with the appointment of Anthony Filippis as the Company's Chief Commercial Officer⁶. Anthony's key focus will be on the negotiation and execution of partnering transactions, providing commercial advice and leadership on the Company's development programs and commercialisation plans, assisting in the process for accessing additional development capital and supporting the Company's investor relations activities with a strategic focus on the US to increase the Company's profile in that key market.

Non-Executive Director of the Company, Dr Gary Pace, retired from the Board of Directors following completion of his director term at the 2022 Annual General Meeting⁷.

As announced on 15 November 2022, following his significant tenure as the Company's Chief Executive Officer and Managing Director (CEO), Mark Diamond advised of his retirement as CEO. Mark will continue his responsibilities as CEO until a successor is appointed. The Board has commenced executive search

activity both externally and internally, for a new Chief Executive Officer that can build on Mark's legacy and spearhead the Company's next phase of growth. Mark will continue as CEO providing leadership and continuity until the appointment of a successor, to ensure a smooth transition.

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:

- Attendance at the JP Morgan Healthcare Week – San Francisco, USA, 9 - 11 January 2023
- US Institutional virtual roadshow – various dates October, November, December 2022
- Biotech & Medical Devices Webinar – Singapore, 3 November 2022
- Annual General Meeting Presentation – Melbourne, 17 November 2022
- US IR and Media engagements – October - December 2022

Cash Flow

As at 31 December 2022 the Company reported cash of \$16.6 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 new indications for ATL1102, e.g. 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 \$293,112. The payments are 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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This announcement contains certain market estimates and forward-looking statements regarding the Company's business & the therapeutic & commercial potential of its technologies & products in development. Any statement provided by the Company on market estimates, business goals, expectations, intentions or beliefs is a forward-looking statement and is based on the Company's views or assumptions at the time & therefore should be considered an at-risk statement. Such statements are subject to certain assumptions, risks & uncertainties, particularly those assumptions, 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 endeavour of both valuing and building a business around such products & services. Actual results could differ materially from those discussed in this announcement.

¹ ASX announcement 19 December 2022

² ASX announcement 14 November 2022

³ 9 January 2023 - [Sarepta Therapeutics Preliminary Fourth Quarter & Full year 2022 Net Product Revenues](#)

⁴ ASX announcements 19 August 2022

⁵ ASX announcement 20 June 2022

⁶ ASX announcement 5 October 2022

⁷ ASX Announcement 14 October 2022

Appendix 4C

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

Name of entity

Antisense Therapeutics Limited

ABN

41 095 060 745

Quarter ended ("current quarter")

31 December 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,214)	(1,827)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(74)	(122)
(d) leased assets	(26)	(53)
(e) staff costs	(456)	(865)
(f) administration and corporate costs	(468)	(862)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	75	135
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	909	909
1.8 Other (provide details if material)	34	88
1.9 Net cash from / (used in) operating activities	(1,220)	(2,597)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(3)	(13)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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)	(13)
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	17,846	19,233
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,220)	(2,597)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(13)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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	16,623	16,623

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	423	346
5.2	Call deposits	16,200	17,500
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)	16,623	17,846

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	293
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
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)	(1,220)
8.2 Cash and cash equivalents at quarter end (item 4.6)	16,623
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	16,623
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	14
<i>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.</i>	
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	
<i>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.</i>	

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: 25 January 2023.....

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.