ASX Announcement

27 July 2022

Quarterly Activities Report & Appendix 4C

- **New Muscle Disease Indication for ATL1102 – Limb Girdle Muscular Dystrophy R2**
- **EU & US regulatory progress**
- **Bonus Option Offer**

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

New Muscle Disease Indication for ATL1102 – Limb Girdle Muscular Dystrophy R2

During the quarter the Company announced positive results from a first study of antisense to CD49d in a limb girdle muscular dystrophy R2 (LGMDR2) mouse model. This successful scientific exploration into a new muscle disease indication for ATL1102 was a strategically minded move on behalf of the Company to capitalise on the extensive data package generated to date on ATL1102 and to broaden ANP's product pipeline. LGMDR2 is a rare genetic muscle disease that is caused by mutations in the dysferlin gene that leads to significant reduction or absence of dysferlin protein levels in muscle fibers. Dysferlin loss occurs in both males and females with the condition called dysferlinopathy or LGMDR2. LGMDR2 is characterized by muscle inflammation, fibrosis, adiposity (fat) and progressive weakness in the hip and shoulder area (i.e. the limb girdle) proximal muscles (those closest to the center of the body) with loss of ambulation and upper limb function in adulthood. LGMDR2 affects ~ 1 in 125,000 people. There are no disease modifying agents in advanced development and no treatments have proven to be beneficial to slow the progression of the disease.

This first study of antisense to CD49d in the LGMDR2 mouse model (Bla/J mice with dysferlin loss) was undertaken in collaboration with experts in genetic muscle disease at the Murdoch Children's Research Institute (MCRI) in Melbourne and the Jain Foundation in the USA. The Jain Foundation (https://www.jain-foundation.org/), a non-profit disease foundation established in the hopes of curing dysferlinopathy, is coordinating the worldwide efforts to find a treatment for dysferlinopathy and have substantial experience with LGMDR2.

The results from this first investigation of the potential of an antisense to CD49d drug in the Bla/J dysferlin deficient mouse model have shown the use of a low dose of the drug reduces the target (CD49d) and key immune cell (F4/80 macrophage and CD8+ T cells) RNA in the muscle. The results support the Company's plans to move forward with the second phase (chronic setting) of the program with a follow-on study in the same mouse model to test the potential of the low dose to reduce adipose (fat) levels, muscle loss and damage. **The second study is planned for 3Q/4QCY22** (pending the availability of suitably aged mice) and designed to run for four months, with results to follow shortly thereafter.

The use of ATL1102 as a treatment for dysferlinopathy is covered in ANP's patent application PCTAU2020/050445 directed at modifying muscle performance by reducing muscle adiposity. The recently filed provisional application 2021903024 also claims the use of ATL1102 to reduce thrombospondin-1 reported to be beneficial in treating the disease. The data from Bla/J mice studies can be used to support the prosecution of these claims and the filing of a new patent application.

The collaboration with the MCRI will also assess the potential of antisense inhibition of CD49d effects in the DMD mdx model in combination with a dystrophin restoration drug to improve therapeutic outcomes beyond that achieved by the single agent alone.

ATL1102 in DMD Phase IIb/III trial in Europe progress

During the quarter the Company provided a progress update on the activities in preparation to the conduct of the trial:

- Site evaluations had been completed with follow on site selection close to finalization;
- ANP has continued to engage with the KoL's in DMD treatment within the region with great interest shown by them to participate as study investigators;
- Interactions held with the DMD Hub https://dmdhub.org/ in the UK to review the protocol with the investigators and with Treat NMD https://treat-nmd.org/ to discuss potential support activities including assistance with trial recruitment via their Global Registry Enquiries and providing expert technical advice;
- The vendors and central laboratories who will conduct the specialised safety and efficacy assessment have been selected;
- Submission of the clinical trial applications to the national authorities to follow – see 'Material Events after the reporting date' section below.

US Regulatory Plans for ATL1102 in DMD

During the quarter ANP 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 FDA subsequently provided feedback on the protocol design which included their concurrence with the proposed high dose level in the study. The feedback allows ANP to finalise the protocol for the toxicology study with its expert advisors. The timing of the initiation of the nine-month toxicology study will be dependent on progress of ATL1102 in DMD in Europe and continued interactions on the regulatory path in the US with the FDA.

Receipt of R&D Tax Incentive Payment

On 14 April 2022 the Company advised that it has received from the Australian Taxation Office an R&D Tax Incentive refund payment of $570,999 for the 30 June 2021 financial year. The amount received was in relation to the expenditure incurred on eligible R&D activities undertaken in Australia.

Bonus Option Offer

On 12 April 2022, the Board of Antisense Therapeutics Limited (ANP) announced as part of the Company's strategic capital management plan and its wish to implement a reward regime for the Shareholders, a bonus offer of new unlisted options ("New Options") to eligible shareholders on the basis of one (1) Option issued for every twenty (20) ordinary shares held in ANP. These New Options were issued on 28 April 2022 for nil consideration. If fully exercised, the New Options, combined with options issued in December 2021, would raise approximately $36 million.

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:

- The 2nd Annual Oligonucleotides for CNS Summit – Boston, US, 15 June 2022
- Parent Project Muscular Dystrophy Annual Conference 2022 – Scottsdale Arizona US, 23-26 June 2022
- Webinar presentation on proteomics and disease marker identification in DMD – US, 28 June 2022
- US Virtual investor roadshow – April - May 2022
- 2022 Bioshares Biotech Summit – Albury, NSW 11-12 May 2022
- Investor Roadshow – Singapore, 18-19 May 2022

Material Events after the reporting date

Subsequent to the reporting date, the Company advised that it had submitted its first clinical trial application (CTA) for the Phase IIb/III clinical trial of ATL1102 in non-ambulant patients with Duchenne muscular dystrophy (DMD) to the Federal Institute for Drugs and Medical Devices in Germany (BfArM) for their evaluation and subsequent approval of the application.

The submission of the CTA is a significant milestone for ANP encapsulating an extensive effort by the Company in establishing an agreed clinical and regulatory pathway with the European Medicines Agency and in preparing the comprehensive documentation package required by the regulators for trial approval. The Company is continuing to work with its Clinical Research Organisation partner, Parexel, in advancing the regulatory process for the program in Europe and will continue to provide updates on material progress.

Cash Flow

As at 30 June 2022 the Company reported cash of $19.2 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. LGMDR2.

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 $164,410. The payments related to salaries, directors' fees and consulting fees on normal commercial terms.

This announcement has been authorised for release by the Board.

For more information please contact:

Antisense Therapeutics
Mark Diamond
Managing Director
+61 (0)3 9827 8999
www.antisense.com.au

Investment Enquiries
Gennadi Koutchin
XEC Partners
gkoutchin@xecpartners.com.au
1300 932 037

US/European IR & Media
Laine Yonker/Joe Green
Edison Investor Relations
lyonker@edisongroup.com
+1 646-653-7035

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 June 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development **	(1,954)	(4,838)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(155)	(342)
	(d) leased assets	-	-
	(e) staff costs	(370)	(1,597)
	(f) administration and corporate costs	(531)	(1,683)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	17
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	571	571
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,432)**	**(7,872)**

** 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 (12 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
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)
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

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	21,665	6,020
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,432)	(7,872)
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 (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	21,085
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**19,233**	**19,233**

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	817	3,256
5.2	Call deposits	18,416	18,409
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)**	**19,233**	**21,665**

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	164
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)	(2,432)
8.2	Cash and cash equivalents at quarter end (item 4.6)	19,233
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	19,233
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	8

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 July 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.