ASX Announcement

31 July 2020

# Quarterly Update & Appendix 4C

- DMD Phase II trial met primary and exceeded secondary endpoint expectations
- Preparations continue for the advancement of ATL1102 into a potentially pivotal Phase IIb clinical trial.

Antisense Therapeutics Limited (Antisense or Company) is pleased to provide its Appendix 4C and quarterly update for the period ended 30 June 2020.

## ATL1102 for DMD Phase II trial results support advancement into a potentially pivotal Phase IIb clinical trial

During the quarter the Company has reported the successful results of its ATL1102 Phase II DMD trial (see announcement 21 May 2020), supporting ongoing preparations for advancement into a potentially pivotal Phase IIb clinical trial.

The Company has been conducting an open label six-month dosing trial of ATL1102 in nine non-ambulant patients with Duchenne Muscular Dystrophy (DMD) at the neuromuscular centre of the Royal Children's Hospital in Melbourne.

Key highlights:

- Primary endpoint met with confirmation of drug's safety and tolerability;
- Strong effects on secondary endpoints on activity markers and disease progression;
- Improvement or stabilisation across different measures of motor function & strength;
- Activity on the targeted CD49d immune cells consistent with drug's proposed mechanism of action;
- MRI data suggests stabilisation of percentage of fat in muscles and preservation of functional muscle mass.

The primary objective of the ATL1102 trial was to assess the safety and tolerability of 25 mg of ATL1102 administered once weekly (subcutaneous injection) for 24 weeks in nine non-ambulatory DMD participants. ATL1102 met its primary end point and demonstrated an excellent safety profile in this trial. Overall, the study has shown that ATL1102 treatment results in consistent improvements or stabilisation across the different measures of motor function and strength.

Additionally, MRI assessment of the upper limb muscles of the patients with DMD has also shown the drug's apparent beneficial effects in stabilising the fat fraction percentage within the muscles of the forearm (increase in fat levels is another key marker of disease progression in non-ambulant DMD boys). The data shows a stabilisation in the percentage of fat in the forearm muscles and an increase/maintenance of functional muscle mass, which is both outstanding and unexpected for a drug treating the inflammation

## European Medicines Agency Scientific Advice and clinical supplies manufacture

During the quarter the Company has made a submission to the European Medicines Agency for Scientific Advice with the results of their evaluation to direct the Company on its preparation and submission of its clinical trial application for a Phase IIb trial in Europe and UK.

The Company is also in the process of preparing submissions for Orphan Drug Designation for ATL1102's use in DMD in the US and the EU.

The Company has also commenced activities for the manufacture of additional clinical supplies of ATL1102.

## 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:

- NWR Communications Virtual Health Conference, Australia, 4 May 2020.
- ATL1102 Phase II DMD results presentation webinar, Australia, 22 May 2020.
- Poster Presentation, Muscular Dystrophy Association Virtual Conference 2020 website, US June – August 2020
- Parent Project Muscular Dystrophy webinar, US 17 June 2020.
- ShareCafé Small Cap "Hidden Gems" Webinar, Australia, 26 June 2020.

## Cash Flow

As at 30 June 2020 the Company reported cash of $4.1m.

Increase in expenditure during the quarter reflects commencement of activities for the manufacture of clinical trial supplies of ATL1102 for the Phase IIb trial including analytical method development and process optimisation. The Company has made prepayments to lock in with its Contract Manufacture Organisation (CMO) the manufacture of this batch of ATL1102 and is planning to have clinical trial supplies available in line with the approval to commence the trial.

The Company continues to carefully monitor expenditure planned for continuation of the regulatory interactions with EMA and US FDA, submissions for Orphan Drug designation as well as advancement of potential new indications for ATL1102.

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 $174k. The payments related to salaries, directors' fees, and consulting fees on normal commercial terms.

The Company received $22,000 in grant funding from the Department of Industry, Innovation and Science and also received cashflow boost credits totalling $26,450 from both State and Federal Government initiatives (in line with their response associated with Covid-19), as disclosed in item 1.7.

*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 June 2020 |

| **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 | (356) | (1,774) |
| | (b) product manufacturing and operating costs | (441) | (441) |
| | (c) advertising and marketing | (55) | (231) |
| | (d) leased assets | - | - |
| | (e) staff costs | (236) | (1,111) |
| | (f) administration and corporate costs | (327) | (1,157) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 5 | 33 |
| 1.5 | Interest and other costs of finance paid | - | - |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 48 | 43 |
| 1.8 | Other | - | 587 |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,362)** | **(4,051)** |

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

| | | | |
|---|---|---|---|
| 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) | - | - |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of options | - | 5,495 |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | - | (289) |
| 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** | **-** | **5,206** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 5,421 | 2,904 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,362) | (4,051) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | - | - |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | - | 5,206 |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |

| | | | |
|---|---|---|---|
| **4.6** | **Cash and cash equivalents at end of period** | **4,059** | **4,059** |

| **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 | 359 | 1,110 |
| 5.2 | Call deposits | 3,700 | 4,311 |
| 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)** | **4,059** | **5,421** |

| **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 | 174 |
| 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) | (1,362) |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6) | 4,059 |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5) | - |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 4,059 |
| 8.5 | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | 3 |

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

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?

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?

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

## 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: 31 July 2020.....

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.