Antisense Therapeutics Limited
Appendix 4D
For the Half-year ended 31 December 2021

Name of entity	Antisense Therapeutics Limited
ABN	095 060 745
Half-year ended	31 December 2021 (Previous corresponding period: 31 December 2020)

Results for Announcement to the Market

The results of Antisense Therapeutics Limited for the half-year ended 31 December 2021 are as follows:

Revenues	up	70.71%	to	3,730
Loss after tax attributable to members	up	45.95%	to	2,982,540
Net loss for the period attributable to members	up	45.95%	to	2,982,540

The above result needs to be read in conjunction with the Company's 2021 Half-year report.

Explanation of Results

The Company reported a loss for the half year ended 31 December 2021 of $2,982,540

At 31 December 2021, the Company had cash reserves of $23,483,088

Dividends

No dividends have been paid or declared by the Company since the beginning of the current reporting period. No dividends were paid for the previous reporting period.

Net Tangible Assets Per Share

	31 December 2021	31 December 2020
Net tangible assets ($)	23,660,457	10,041,785
Shares (No.)	668,706,753	573,988,171
Net tangible assets per share (cents)	3.54	1.75

	31 December 2021	31 December 2020
Basic earnings/ (loss) per share (cents)	(0.50)	(0.40)
Diluted earnings/ (loss) per share (cents)	(0.50)	(0.40)

Status of Review of Accounts

The Appendix 4D is based on accounts which have been reviewed. The auditors report includes a material uncertainty related to going concern, and is included within the financial report which accompanies this Appendix 4D.

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Interim financial report for the half-year ended 31 December **2021**

Contents to financial report

Directors' report

The Directors of Antisense Therapeutics Limited ("ANP" or "the Company") provide the following Report in relation to the Company for the half-year ended 31 December 2021.

Directors

The following persons were Directors of the Company during the half-year and up to the date of this report. Directors were in office for this entire period unless otherwise stated.

Dr Charmaine Gittleson, Independent Non-Executive Chair	(Appointed: 22 March 2021)
Mr Mark Diamond, Managing Director	(Appointed: 31 October 2001)
Dr Gary W Pace, Independent Non-Executive Director	(Appointed: 9 November 2015)
Dr Ben Gil Price, Independent Non-Executive Director	(Appointed: 4 October 2021)
Mr Robert W Moses, Independent Non-Executive Director	(Appointed: 23 October 2001, Resigned: 15 December 2021)
Dr Graham Mitchell, Independent Non-Executive Director	(Appointed: 24 October 2001, Resigned: 15 December 2021)
Mr William Goolsbee, Independent Non-Executive Director	(Appointed: 15 October 2015, Resigned: 15 December 2021)

Results and review of operations

Results

The Company reported a loss for the half year ended 31 December 2021 of $2,982,540 (31 December 2020: $2,043,551). This loss is after fully expensing all research and development costs.

At 31 December 2021, the Company had cash reserves of $23,483,088 (30 June 2021: $6,020,403).

Review of operations

Detailed below is an update on the status of the Company's development projects and overall operations for the half-year ended 31 December 2021.

This report should be read in conjunction with the Company's 30 June 2021 Annual Report.

Capital raising

During the period, 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 the Company's announcements and the Company's AGM presentation lodged with the ASX on 15 December 2021.

Directors' report (continued)

ATL1102 for Duchenne muscular dystrophy (DMD)

The Company is undertaking clinical development of ATL1102 in patients with Duchenne muscular dystrophy (DMD). Duchenne Muscular Dystrophy (DMD) is an X-linked disease that affects 1 in 3600 to 5000 live male births (Bushby et al, 2010). DMD occurs as a result of mutations in the dystrophin gene which causes a defect in the protein or reduction or absence of the dystrophin protein. Children with DMD have dystrophin deficient muscles and are susceptible to contraction induced injury to muscle which triggers the immune system which exacerbates muscle damage (Pinto Mariz, 2015). Ongoing deterioration in muscle strength affects lower limbs leading to impaired mobility, and also affects upper limbs, leading to further loss of function and self-care ability. The need for wheelchair use can occur in early teenage years, with respiratory, cardiac, cognitive dysfunction also emerging. With no intervention, the mean age of life is approximately 19 years. The management of the inflammation associated with DMD is currently via the use of corticosteroids, which have insufficient efficacy and significant side effects.

ATL1102 is an antisense inhibitor of CD49d, a subunit of VLA-4 (Very Late Antigen-4). Antisense inhibition of VLA-4 expression has demonstrated activity in a number of animal models of inflammatory disease including asthma and MS with the MS animal data having been published in a peer reviewed scientific journal. ATL1102 was shown to be highly effective in reducing MS lesions in a Phase IIa clinical trial in RR-MS patients. The ATL1102 Phase IIa clinical data has been published in the medical Journal Neurology (Limmroth, V. et al Neurology, 2014; 83(20): 1780-1788).

A key challenge in the management of DMD patients is to reduce the inflammation that exacerbates the muscle fibre damage. It has been reported in scientific literature that patients with DMD who have a greater number of T cells with high levels of CD49d (ATL1102's biological target) on their surface have more severe and rapid disease progression. ATL1102 is being developed as a novel treatment for the inflammation that exacerbates muscle fibre damage in DMD patients for which the current available treatment is corticosteroids. Corticosteroids have a range of serious side effects when used for a prolonged period as required in DMD. As a consequence, there is an acknowledged high need for new therapeutic approaches for the treatment of inflammation associated with DMD.

The Company conducted an open label six-month dosing trial of ATL1102 in nine non-ambulant patients with DMD aged between 10 and 18 years at the neuromuscular centre of the Royal Children's Hospital (RCH) which operates the largest clinic in the southern hemisphere treating children with DMD. The Company reported the successful results of the ATL1102 Phase II DMD trial, supporting ongoing preparations for advancement into a potentially pivotal Phase IIb/III clinical trial to be conducted in Europe.

Progress

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.

As previously advised the Company 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.

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 Paediatric Investigation Plan

During the period 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 DMD following the PDCO meeting on 15 October 2021. Subsequent to the reporting of this news, the Company received formal ratification by the EMA of this decision. In December 2021 the Company received a positive Decision from the MHRA in the UK on the UK PIP submission for the development of ATL1102 for DMD.

Directors' report (continued)

Progress (continued)

Positive Paediatric Investigation Plan (continued)

A PIP is a development plan aimed at ensuring that the necessary data is obtained through studies in children. Approval of the PIP is required to support the authorisation of a medicine for children in the EU. The PIP addresses the entire paediatric development program for ATL1102 in DMD (including future ambulant DMD patient studies). The Company through its interactions with PDCO, is looking to ensure that its planned clinical studies including its Phase IIb/III clinical trial of ATL1102 in non-ambulant DMD boys, will be run in accordance with PDCO expectations for future product approval.

US Regulatory Plans for ATL1102 in DMD

In December 2021 the Company submitted to the US Food and Drug Administration (FDA) for feedback on 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.

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 that the US FDA has 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.

Potential of ATL1102 in ambulant DMD and fibrotic conditions

In September 2021, new ATL1102 Phase II non-ambulant DMD patient plasma protein data was presented at the 26th International Annual Congress of the World Muscle Society in the late breaking news poster titled "ATL1102 treatment in non-ambulant boys with DMD modulates Latent TGF-beta-binding protein 4, and thrombospondin-1, two disease genetic modifiers of ambulant DMD, and CXCL16".

Planned as part of the Phase II study, a large-scale protein analysis (known as a proteomics analysis) of retained blood plasma samples from the non-ambulant DMD patients treated with ATL1102 was undertaken to identify the proteins affected in the blood so as to provide further insight into the mode of action and biological activity of ATL1102.

- Statistically significant mean modulation at 24 weeks compared to baseline in Thrombospondin-1 (TSP-1) and Latent TGF-beta-binding protein 4 (LTBP4) levels, two proteins that modify the rate of loss of ambulation in DMD. ATL1102 modulation of these two DMD disease modifier proteins known to impact TGF-β and the rate of loss of ambulation in DMD patients supports ATL1102's potential use in ambulant patients with DMD, and as an agent to reduce fibrosis in other human diseases.

Directors' report (continued)

Progress (continued)
Potential of ATL1102 in ambulant DMD and fibrotic conditions (continued)

- Increase at 24 weeks in plasma VCAM-1 supportive of the ATL1102 mechanism of action of reducing CD49d on the surface of cells to which soluble VCAM-1 is bound, and in CXCL16 which can promote muscle regeneration appear to align with the positive effects on muscle structure observed under MRI in the ATL1102 Phase II trial. These plasma proteins were increased such that they approached the median levels seen in an external control dataset of health adults, supporting the beneficial nature of the outcomes in ATL1102 treated DMD patients. Positive effects on LTBP4 and TSP-1 positions ATL1102 as an exciting prospect for the treatment of both non-ambulant and ambulant patients with DMD and the treatment of other muscle and fibrotic conditions.

The protein changes observed in the plasma of the ATL1102 treated non ambulant DMD patients in the Phase II study is also consistent with the drug's positive effects on muscle function and strength reported in the ATL1102 Phase II trial.

Analysis of the plasma protein data is ongoing in order to further elucidate ATL1102's biological effects and to position the drug's development in disease settings. The Company will continue to report on any material developments from this ongoing data analysis and associated commercial opportunities.

Based on the positive outcomes from the protein analysis reported above, Australian Provisional Patent Application No. 2021903024 was filed 20 September 2021 with claims covering applications of ATL1102 in new potential disease settings including diabetic, respiratory and age-related diseases to support the Company's future commercial and partnering plans for ATL1102.

Board Composition

In October 2021 the Company announced that 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/III clinical trial of ATL1102 in DMD in Europe, the Board of Directors had 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 rrecently resulted in the Company being invited to be a member of the Pharmaceutical Advisory Board for the development of the New DMD Guidance by Parent Project Muscular Dystrophy(PPMD) for the US FDA.(see pg. 5)

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 were elected by shareholders at the AGM. In July 2021 the Company announced that Dr Gittleson was to transition to the position of Chair. The Company advised at the time that the transitioning of the Chair role was in recognition of the Company's maturation from a drug discovery to late-stage clinical development group with near term commercialisation aspirations.

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;

Directors' report (continued)

- 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

Participation in PPMD development of new Community-Led Duchenne Guidance for FDA

The Company accepted an invitation and nominated its US-based Non-Executive Director & Medical Director, Gil Price, MD to serve as a member of the Pharmaceutical Advisory Board (PAB) for the development of the New Duchenne Guidance by Parent Project Muscular Dystrophy (PPMD) for the US FDA.

Working closely with the Steering Committee and Working Group Chairs, comprised of individuals representing the patient advocate, caregiver, clinician, researcher, academic, and pharmaceutical industry, the PAB will focus on ensuring perspectives from companies with an interest Duchenne community are represented throughout the guidance.

PPMD successfully developed the first-ever patient group initiated draft guidance for companies developing treatments for Duchenne. Submitted to the FDA in June 2014, the work was a key resource informing companies and FDA about the evolving drug development landscape for Duchenne muscular dystrophy (DMD), as well as the patient focused views of benefit expectations and risk tolerance of the community. PPMD initiative has since become a landmark not only in the Duchenne community, but across rare disease communities exemplifying the value patients and caregivers can bring to drug development.

PPMD has now begun the process for modernizing the landmark Community-Led Guidance of 2014 document to ensure it reflects many advancements in knowledge, understanding, care, clinical trials and approvals over the recent years. Similar to the 2014, PPMD has formed a Steering Committee and Working Groups of over 80 stakeholders. This will help drive even more innovation as well as carve a path toward the ultimate goal of accessible therapies for all patients.

PPMD is the largest most comprehensive non-profit organization in the United States focused on finding a cure for DMD - their mission is to end DMD (www.parentprojectmd.org).

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 period the Company presented and participated at the following events:

- Scandinavian Alliance, Investor Webinar - Stockholm, Sweden, 15 July 2021
- Spark Plus Healthcare Day Webinar - Singapore, 27 July 2021
- Virtual Investor Roadshow - Singapore & Hong Kong, 1 - 3 September 2021
- Scandinavian Alliance, Investor Webinar - Stockholm, Sweden, 30 September 2021
- 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

Directors' report (continued)

- 2021 Annual General Meeting - Melbourne, 15 December 2021

What is Duchenne Muscular Dystrophy?

Duchenne muscular dystrophy (DMD) is an X-linked disease that affects 1 in 3600 to 5000 live male births (Bushby et al, 2010). DMD occurs as a result of mutations in the dystrophin gene which causes a defect in the protein or reduction or absence of the dystrophin protein. Children with DMD have dystrophin deficient muscles and are susceptible to contraction induced injury to muscle which triggers the immune system which exacerbates muscle damage (Pinto Mariz, 2015). Ongoing deterioration in muscle strength affects lower limbs leading to impaired mobility, and also affects upper limbs, leading to further loss of function and self-care ability. The need for wheelchair use can occur in early teenage years, with respiratory, cardiac, cognitive dysfunction also emerging. With no intervention, the mean age of life is approximately 19 years. The management of the inflammation associated with DMD is currently via the use of corticosteroids, which have insufficient efficacy and significant side effects.

ATL1102 for Multiple Sclerosis (MS) and other inflammatory indications

ATL1102 was previously shown to be highly effective in reducing MS inflammatory brain lesions in a Phase IIa clinical trial in Relapsing Remitting MS patients. The ATL1102 Phase II clinical data has been published in the medical Journal Neurology (Limmroth, V. et al Neurology). The Company previously reported that it had submitted an Investigational New Drug (IND) application to the US FDA for the conduct of a Phase IIb trial in MS patients and had received notification from the FDA that the study could proceed at a lower (25mg/week) dose for 6 months under a partial hold introduced by the FDA.

The Company advised that it sees exciting potential for ATL1102's use in other neuroinflammatory and muscular dystrophy disorders given the expected antisense platform and CD49d target based advantages in these applications. The Company has filed patent applications to support clinical development and commercialisation of ATL1102 in muscular dystrophies in addition to DMD and noted that it would continue to file new patents to broaden IP protection and add further commercial value to the ATL1102 asset while expanding the Company's product pipeline.

ATL1103 for Acromegaly

ATL1103 also referred to as atesidorsen is an antisense drug designed to block growth hormone receptor (GHr) expression thereby reducing levels of the hormone insulin-like growth factor-I (IGF-I) in the blood. Normalizing serum IGF-I levels is the therapeutic goal in the treatment of acromegaly.

The Company conducted a successful Phase II trial of ATL1103 with the trial having met its primary efficacy endpoint by showing a statistically significant average reduction in sIGF-I levels. The results of the Phase II trial have been published in the European Journal of Endocrinology (Trainer et al, Eur J Endocrinol, 2018 May 22 - 179: 97-108). The Company also conducted a successful high dose study of ATL1103 in adult patients with acromegaly in Australia. The US FDA and EC have granted Orphan Drug designation to ATL1103 for treatment of Acromegaly.

As the Company's current development focus is directed towards the clinical development of ATL1102 in DMD, no further resources are expected to be applied to ATL1103 clinical development, however the Company does continue to pursue potential out-licensing interest in ATL1103 to support and fund ATL1103's ongoing clinical development.

R&D tax incentives

The Company anticipates a research and development tax concession of $256,654 in relation to expenditure incurred on eligible R&D activities for the 31 December 2021 reporting period (31 December 2020: $204,444). The Company is finalising its 30 June 2021 financial year research and development tax concession $570,999, with external consultants which will be lodged prior to the due date.

Financial position

At 31 December 2021, the Company had cash reserves of $23,483,088 (30 June 2020: $4,059,442)

Directors' report (continued)

Events after balance sheet date

On 8th February 2022 the Company announced that dosing had commenced in an inflammatory muscle disease animal model under the previously advised collaborative research agreement with the Murdoch Children's Research Institute's to investigate the therapeutic potential of ATL1102 in a new muscle disease, where today there are no effective treatments. All animals successfully received their first dose of the antisense CD49d drug or control (oligonucleotide mismatch or saline) treatment.

COVID-19 statement

COVID-19 factors that are causing significant challenges for the community at large are presently not adversely impacting on the Company's activities. The Company is positioned to accommodate measures that are prudent for us to take to safeguard the health of our staff, patients and the broader community and our staff are able to work from home.

Biotechnology companies – Inherent risks

Pharmaceutical research and development (R&D)

Pharmaceutical R&D involves scientific uncertainty and long lead times. Risks inherent in these activities include uncertainty of the outcome of the Company's research results; difficulties or delays in development of any of the Company's drug candidates; and general uncertainty related to the scientific development of a new medical therapy.

The Company's drug compounds require significant pre-clinical and human clinical development prior to commercialisation, which is uncertain, expensive and time consuming. There may be adverse side effects or inadequate therapeutic efficacy of the Company's drug candidates which would prevent further commercialisation. There may be difficulties or delays in testing any of the Company's drug candidates. There may also be adverse outcomes with the broader clinical application of the antisense technology platform which could have a negative impact on the Company's specific drug development and commercialisation plans.

No assurance can be given that the Company's product development efforts will be successful, that any potential product will be safe and efficacious, that required regulatory approvals will be obtained, that the Company's products will be capable of being produced in commercial quantities at an acceptable cost or at all, that the Company will have access to sufficient capital to successfully advance the products through development or to find suitable development or commercial partners for the development and or commercialisation of the products and that any products, if introduced, will achieve market acceptance.

Partnering and licensing

Due to the significant costs in drug discovery and development it is common for biotechnology companies to partner with larger biotechnology or pharmaceutical companies to help progress drug development. While the Company has previously entered into such licensing agreements with pharmaceutical partners, there is no guarantee that the Company will be able to maintain such partnerships or license its products in the future. There is also no guarantee that the Company will receive back all the data generated by or related intellectual property from its licensing partners. In the event that the Company does license or partner the drugs in its pipeline, there is no assurance as to the attractiveness of the commercial terms nor any guarantee that the agreements will generate a material commercial return for the Company.

Regulatory approvals

Complex government health regulations, which are subject to change, add uncertainty to obtaining approval to undertake clinical development and obtain marketing approval for pharmaceutical products.

Delays may be experienced in obtaining such approvals, or the regulatory authorities may require repeat of different or expanded animal safety studies or human clinical trials, and these may add to the development cost and delay products from moving into the next phase of drug development and up to the point of entering the market place. This may adversely affect the competitive position of products and the financial value of the drug candidates to the Company.

Directors' report (continued)

Biotechnology companies – Inherent risks (continued)

Regulatory approvals (continued)

There can be no assurance that regulatory clearance will be obtained for a product or that the data obtained from clinical trials will not be subject to varying interpretations. There can be no assurance that the regulatory authorities will agree with the Company's assessment of future clinical trial results.

Competition

The Company will always remain subject to the material risk arising from the intense competition that exists in the pharmaceutical industry. A material risk therefore exists that one or more competitive products may be in human clinical development now or may enter into human clinical development in the future. Competitive products focusing on or directed at the same diseases or protein targets as those that the Company is working on may be developed by pharmaceutical companies or other antisense drug companies including Ionis or any of its other collaboration partners or licensees. Such products could prove more efficacious, safer, more cost effective or more acceptable to patients than the Company product. It is possible that a competitor may be in that market place sooner than the Company and establish itself as the preferred product.

Technology and Intellectual Property Rights

Securing rights to technology and patents is an integral part of securing potential product value in the outcomes of pharmaceutical R&D. The Company's success depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. There can be no assurance that any patents which the Company may own, access or control will afford the Company commercially significant protection of its technology or its products or have commercial application, or that access to these patents will mean that the Company will be free to commercialise its drug candidates. The granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology or products to avoid the Company's patented technology or try to invalidate the Company's patents, or that it will be commercially viable for the Company to defend against such potential actions of competitors.

Rounding

The amounts contained in this report and in the financial report have been rounded to the nearest $1 (where rounding is applicable) and where noted ($) under the option available to the Company under ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191. The Company is an entity to which the class order applies.

Directors' report (continued)

Auditor independence and non-audit services

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on the following page.

Signed in accordance with a resolution of the Directors.

Dr Charmaine Gittleson
Independent Non-Executive Chair

Mr Mark Diamond
Managing Director

Melbourne

Dated: 23 February 2022

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Building a better working world

Auditor's independence declaration to the directors of Antisense Therapeutics Limited

As lead auditor for the review of the half-year financial report of Antisense Therapeutics Limited for the half-year ended 31 December 2021, I declare to the best of my knowledge and belief, there have been:

a. No contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review;

b. No contraventions of any applicable code of professional conduct in relation to the review; and

c. No non-audit services provided that contravene any applicable code of professional conduct in relation to the review.

Ernst & Young

Matt Biernat
Partner
23 February 2022

Statement of profit or loss and other comprehensive income

For the half-year ended 31 December 2021

	Notes	31 December 2021 $	31 December 2020 $
Revenue	4	3,730	2,185
Other income	4	256,654	259,334
		260,384	**261,519**
Administrative expenses	5	(1,532,991)	(1,070,714)
Occupancy expenses		(1,707)	(7,528)
Patent expenses		(43,623)	(57,378)
Research and development expenses	5	(1,535,424)	(1,105,167)
Foreign exchange (gains)/losses		(708)	(1,444)
Depreciation expenses		(44,817)	(59,369)
Finance costs	10	(6,403)	(3,470)
Share-based payments		(77,251)	-
Loss before tax		**(2,982,540)**	**(2,043,551)**
Income tax benefit/(expense)		-	-
Loss for the period		**(2,982,540)**	**(2,043,551)**
Other comprehensive income/(loss) for the year, net of tax		**-**	**-**
Total comprehensive loss for the year, net of tax		**(2,982,540)**	**(2,043,551)**
Loss per share	9		
Basic loss per share (cents)		($0.50)	($0.40)
Diluted loss per share (cents)		($0.50)	($0.40)

The accompanying notes form part of these financial statements.

Statement of financial position

As at 31 December 2021

	Notes	31 December 2021 $	30 June 2021 $
Assets			
Current assets			
Cash and cash equivalents	6	23,483,088	6,020,403
Trade and other receivables	7	847,235	601,254
Prepayments		102,010	76,942
Other current assets	8	362,661	-
		24,794,994	6,698,599
Non-current assets			
Plant and equipment		8,502	11,569
Right-of-use assets	10	248,685	290,435
		257,187	302,004
Total assets		**25,052,181**	**7,000,603**
Liabilities			
Current liabilities			
Trade and other payables		394,707	512,082
Employee benefit liabilities	11	479,777	454,026
Lease liabilities	10	82,622	79,443
		957,106	1,045,551
Non-current liabilities			
Employee benefit liabilities	11	307	117
Lease liabilities	10	185,626	227,402
		185,933	227,519
Total liabilities		**1,143,039**	**1,273,070**
Net Assets		**23,909,142**	**5,727,533**
Equity			
Contributed equity	13	98,120,593	77,033,694
Reserves	14	3,868,669	3,791,418
Accumulated losses		(78,080,120)	(75,097,579)
Total equity		**23,909,142**	**5,727,533**

The accompanying notes form part of these financial statements.

Statement of changes in equity

For the half-year ended 31 December 2021

	Notes	Contributed equity	Option Reserves	Accumulated losses	Total
		$	$	$	$
As at 1 July 2020		**69,147,843**	**2,420,086**	**(67,036,940)**	**4,530,989**
Loss for the period		-	-	(2,043,551)	(2,043,551)
Total comprehensive loss		-	-	(2,043,551)	(2,043,551)
Issue of share capital	13	8,500,000	-	-	8,500,000
Transactions costs on options issues/capital raising		(614,149)	-	-	(614,149)
At 31 December 2020		**77,033,694**	**2,420,086**	**(69,080,491)**	**10,373,289**

	Notes				
As at 1 July 2021		**77,033,694**	**3,791,418**	**(75,097,580)**	**5,727,532**
Loss for the period		-	-	(2,982,540)	(2,982,540)
Total comprehensive loss		-	-	(2,982,540)	(2,982,540)
Issue of share capital	13	22,586,503	-	-	22,586,503
Share-based payments	14	-	77,251	-	77,251
Transactions costs on options issues/capital raising		(1,499,604)	-	-	(1,499,604)
At 31 December 2021		**98,120,593**	**3,868,669**	**(78,080,120)**	**23,909,142**

The accompanying notes form part of these financial statements.

Statement of cash flows

For the half-year ended 31 December 2021

	Notes	31 December 2021 $	31 December 2020 $
Operating activities			
Receipts from customers		12,800	-
Payments to suppliers and employers		(3,592,971)	(2,544,857)
R&D tax concession refund		-	650,603
Interest received		957	2,311
Interest paid		(6,403)	(3,470)
Other Income		-	50,000
Net cash flows used in operating activities		**(3,585,617)**	**(1,845,413)**
Investing activities			
Purchase of property, plant and equipment		-	(6,145)
Net cash flows used in investing activities		**-**	**(6,145)**
Financing activities			
Payment of lease liabilities		(38,597)	(52,150)
Issue of share capital		22,586,503	8,500,000
Transaction costs on options issues/capital raising		(1,499,604)	(614,149)
Net cash flows from financing activities		**21,048,302**	**7,833,701**
Net increase (decrease) in cash and cash equivalents		17,462,685	5,982,143
Cash and cash equivalents at 1 July		6,020,403	4,059,442
Cash and cash equivalents at 31 December	6	**23,483,088**	**10,041,585**

The accompanying notes form part of these financial statements.

Notes to the financial statements

For the half-year ended 31 December 2021

1. Summary of significant accounting policies

1.1 Basis of preparation

The condensed financial report for the half-year reporting period ended 31 December 2021 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

This half-year financial report does not include all notes of the type normally included in an Annual Report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and financing and investing activities of the Company as the Annual Report.

Accordingly, this report is to be read in conjunction with the Annual Report for the year ended 30 June 2020 and any public announcements made by Antisense Therapeutics Limited during the Half Year reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

1.2 Going concern

The Directors have prepared the half year financial report on a going concern basis, which contemplates continuity of normal business activities and the realisation of assets and the settlement of liabilities in the ordinary course of business.

The Company incurred a loss from ordinary activities of $2,982,540 during the half year ended 31 December 2021 (December 2020: $2,043,551) and incurred an operating cash outflow of $3,602,117 the half year ended 31 December 2021 (December 2020: $1,845,413). The cash on hand balance at 31 December 2021 is $23,483,088 (June 2021: $6,020,403).

As at 31 December 2021, the Company had a net assets position of $23,909,142 (June 2021: $5,727,532), and current assets exceed current liabilities by $23,837,888 (June 2021: current assets exceeded current liabilities by $5,653,047).

After consideration of the available facts and current forecasts, the Company will require additional funding to complete its ongoing clinical trial activities in the normal course of business which represents a material uncertainty on the Company's ability to continue as a going concern. The Directors have concluded that the going concern basis remains appropriate given the Company's track record of raising capital and partnering its development programs and the status of ongoing discussions with various capital market parties. Accordingly, the financial statements do not include adjustments relating to the recoverability and classification of recorded asset amounts, or the amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

2. Significant accounting judgements, estimates and assumptions

The preparation of the Company's interim financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods.

3. Dividends

No dividends have been declared for the period ended 31 December 2021 (31 December 2020: Nil).

For the half-year ended 31 December 2021

4 Revenue and other income

	31 December 2021	31 December 2020
	$	$
Revenue		
Interest from external parties	3,730	2,185
Total revenue	**3,730**	**2,185**
Other income		
Research and development tax concession	256,654	204,444
Gain on termination of leases	-	4,890
Other income	-	50,000
Total other income	**256,654**	**259,334**
Total revenue and other income	**260,384**	**261,519**

The Research and development tax concession anticipated refund for expenditure incurred for the 31 December 2021 reporting period is $256,654 (2020: $204,444).

Other income is Nil for 31 December 2021 (2020: $50,000). 2020 includes COVID-19 government assistance that is related to "Cashflow boost for employers" measure announced as part of the Australian Government's economic stimulus package of March 2020. No similar incentive program was received in this reporting period.

5 Expenses

	31 December 2021	31 December 2020
	$	$
Administrative expenses		
Business development expenses	534,894	415,237
Compliance expenses	348,406	196,389
Corporate employee expenses	629,549	429,672
Office expenses	20,142	29,416
	1,532,991	**1,070,714**

	31 December 2021	31 December 2020
	$	$
Research and development expenses		
ATL 1102	1,034,526	765,750
ATL 1103	63,765	54,810
Research & Development	437,133	284,607
	1,535,424	**1,105,167**

For the half-year ended 31 December 2021

6. Cash and cash equivalents

	31 December 2021	30 June 2021
	$	$
Cash at bank and on hand	5,082,183	120,041
Short-term deposits	18,400,905	5,900,362
	23,483,088	**6,020,403**

During the 31 December 2021 period, the Company allocated $15 million to a short-term deposit with a maturity date on 03 March 2022.

7. Trade and other receivables

	31 December 2021	30 June 2021
	$	$
Trade receivables	-	12,800
Research and development tax concession receivable	827,653	570,998
Interest receivable	2,795	22
Other receivables	16,787	17,434
	847,235	**601,254**

As at 31 December 2021, the Research and Development tax concession receivable comprises the anticipated return for 31 December 2021 of $256,655 and the 30 June 2021 of $570,998 currently being finalised by consultants.

8. Other current assets

	31 December 2021	30 June 2021
	$	$
Deposits Paid - R&D	362,661	-
	362,661	**-**

During the 31 December 2021 period, the Company entered into two manufacturing agreements with Avecia Inc and Parexel International respectively. The terms of the agreements included an immediate upfront project milestone payment for Project Acceptance, with further milestone payments due within the contract as they are met.

Notes to the financial statements (continued)

For the half-year ended 31 December 2021

9. Loss per share (EPS)

Basic EPS amounts are calculated by dividing profit for the period attributable to ordinary equity holders by the weighted average number of ordinary shares outstanding during the period.

Diluted EPS amounts are calculated by dividing the net profit attributable to ordinary equity holders (after adjusting for dilution factors) by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on impact of all the dilutive potential ordinary shares into ordinary shares.

	31 December 2021 $	31 December 2020 $
Loss per share		
Basic loss per share (cents)	($0.50)	($0.40)
Diluted loss per share (cents)	($0.50)	($0.40)

The following reflects the income and share data used in the basic and diluted EPS computations:

	31 December 2021 $	31 December 2020 $
Loss attributable to ordinary equity holders of the Parent		
Net profit/(earnings/(losses)) used in the calculation of basic and diluted earnings/(losses) per share	(2,982,540)	(2,043,551)
Loss attributable to ordinary equity holders of the Parent for basic earnings	**(2,982,540)**	**(2,043,551)**
Loss attributable to ordinary equity holders of the Parent adjusted for the effect of dilution	**(2,982,540)**	**(2,043,551)**

	31 December 2021	31 December 2020
Weighted average number of ordinary shares for basic EPS	595,841,381	508,326,073
Effect of dilution:		
Weighted average number of ordinary shares adjusted for the effect of dilution	**595,841,381**	**508,326,073**

There have been no other conversions to, call of, or subscriptions for ordinary shares, or issues of potential ordinary shares since the reporting date and before the completion of this financial report.

As at 31 December 2021, the Company had 102,055,097 unlisted options outstanding, which at the election of the option holder, are convertible into the following:

- 10,000,000 ordinary shares at $0.08 exercise price
- 35,000,000 ordinary shares at $0.145 exercise price
- 2,000,000 ordinary shares at $0.185 exercise price
- 8,000,000 ordinary shares at $0.27 exercise price
- 47,055,097 ordinary shares at $0.48 exercise price

For the half-year ended 31 December 2021

10. Leases

(i)The Company's leasing activities and how these are accounted for

The Company's leased asset consisted of:

• Principal place of business as at 31 December, 2020, Level 1, 14 Wallace Avenue, Toorak, Victoria. The lease is effective from 13 December 2020 for a term of two years, expiring 31 December 2022 with an option to extend for a further two years.
• Prior Principal place of business during the reporting period at 6-8 Wallace Avenue, Toorak, Victoria. The lease was terminated effective 31 December 2020.

The Company's lease agreement does not impose any covenants, but leased assets may not be used as security for borrowing purposes.

(ii)Amounts recognised in the balance sheet

	31 December 2021	30 June 2021
	$	$
Right-of-use assets		
Properties	248,685	290,435
	248,685	**290,435**

	31 December 2021	30 June 2021
	$	$
Lease liabilities		
Current	82,622	79,443
Non-current	185,626	227,402
	268,248	**306,845**

(iii)Amounts recognised in the statement of profit or loss

	31 December 2021	31 December 2020
	$	$
Depreciation expense	41,750	56,821
Interest expense (included in finance costs)	6,403	3,470
	48,153	**60,291**

11. Employee benefit liability

Annual leave and long service leave

	31 December 2021	30 June 2021
	$	$
Current		
Annual leave	147,999	112,115
Long service leave	331,778	304,833
	479,777	416,948
Non current		
Long service leave	307	-
	307	-

12. Commitments and contingencies

Commitments

At 31 December 2021, the Company had commitments of AUD$2,207,528 (2020: USD$870,000) in regard to clinical trial costs (including manufacture of clinical trial supplies).

13. Contributed equity

	Notes	31 December 2021	30 June 2021
		$	$
Ordinary fully paid shares	13.1	98,120,593	77,033,694
		98,120,593	**77,033,694**

13.1 - Ordinary fully paid shares

	No.	$
As at 1 July 2020	**488,785,281**	**69,147,843**
Shares issued during the period	85,202,890	8,500,000
Capital Raising costs relating to share issues	-	(614,149)
At 31 December 2020	**573,988,171**	**77,033,694**

	No.	$
As at 1 July 2021	**574,476,343**	**77,033,694**
Shares issued during the period	119,979	-
Placement of shares	83,333,332	20,000,000
Entitlement offer	10,777,099	2,586,503
Capital Raising costs relating to share issues	-	(1,499,604)
At 31 December 2021	**668,706,753**	**98,120,593**

For the half-year ended 31 December 2021

14. Reserves

The option reserve recognises the proceeds from the issue of options over ordinary shares and the expense recognised in respect of share based payments.

	Number of options	Total $
Opening balance at 1 July 2021	**55,000,000**	**3,791,418**
Options issued during the period	47,055,097	-
Options vested from prior period	-	77,251
Balance at 31 December 2021	**102,055,097**	**3,868,669**

15. Segment information

The Company has identified its operating segments based on the internal reports that are reviewed and used by the Managing Director (Chief Operating Decision Maker) in assessing performance and determining the allocation of resources.

The operating segments are identified by the Managing Director and his executive management team based on the manner in which the expenses are incurred. Discrete financial information about each of these operating segments is reported by the Managing Director to the Board on a regular basis.

The reportable segments are based on aggregated operating segments determined by similarity of expenses, where expenses in the reportable segments exceed 10% of the total expenses for either the current and/or previous reporting period.

Operating segments:

- ATL1102
- ATL1103

Year ended 31 December 2021	ATL1102	ATL1103	Total segments	Unallocated	Total segments + Unallocated
	$	$	$	$	$
Revenue	256,654	-	256,654	3,730	260,384
Other income	-	-	-	-	-
	256,654	**-**	**256,654**	**3,730**	**260,384**
Operating Expenses	(1,034,526)	(63,764)	(1,098,290)	(2,144,632)	(3,242,922)
Segment results	**(777,872)**	**(63,764)**	**(841,636)**	**(2,140,902)**	**(2,982,538)**

For the half-year ended 31 December 2021

15. Segment information (continued)

Year ended 31 December 2020	ATL1102	ATL1103	Total segments	Unallocated	Total segments + Unallocated
	$	$	$	$	$
Revenue	204,444	-	204,444	2,185	206,629
Other income	-	-	-	54,890	54,890
	204,444	**-**	**204,444**	**57,075**	**261,519**
Operating Expenses	(765,750)	(54,810)	(820,560)	(1,484,513)	(2,305,073)
Segment results	**(561,306)**	**(54,810)**	**(616,116)**	**(1,427,438)**	**(2,043,554)**

15.1 - Unallocated breakdown

	31 December 2021	31 December 2020
	$	$
Revenue and other income		
Interest received	3,730	2,185
Other income	-	54,890
	3,730	**57,075**

	31 December 2021	31 December 2020
	$	$
Expenses		
Compliance expenses	(348,406)	(196,389)
Employee expenses	(629,549)	(429,672)
Business development expenses	(534,894)	(415,237)
Patent expenses	(43,623)	(57,378)
Other expenses	(588,160)	(385,837)
	(2,144,632)	**(1,484,513)**

16. Events after the reporting period

No matters or circumstances have arisen since the end of the reporting period, not otherwise disclosed in this report, which significantly affected, or may significantly affect the operations of the Company the results of those operations, or the state of affairs of the Company, in future financial years.

Directors' declaration

In accordance with a resolution of the Directors of Antisense Therapeutics Limited, I state that:

1. In the opinion of the Directors:

   (a) the interim financial statements and notes of Antisense Therapeutics Limited for the financial half-year ended 31 December 2021 are in accordance with the *Corporations Act 2001*, including:

      (i) giving a true and fair view of the consolidated entity's financial position as at 31 December 2021 and of its performance for the half-year on that date; and

      (ii) complying with AASB134 Interim Financial Reporting and the *Corporations Regulations 2001*;

   (b) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

2. This declaration has been made after receiving the declarations required to be made to the Directors by the chief executive officer and chief financial officer in accordance with section 295A of the *Corporations Act 2001* for the financial half-year ended 31 December 2021.

On behalf of the board

Dr Charmaine Gittleson
Independent Non-Executive Chair

Mr Mark Diamond
Managing Director

Melbourne
Dated: 23 February 2022

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Independent auditor's review report to the members of Antisense Therapeutics Limited

Conclusion

We have reviewed the accompanying half-year financial report of Antisense Therapeutics Limited (the Company), which comprises the statement of financial position as at 31 December 2021, the statement of profit or loss and comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of the Company does not comply with the *Corporations Act 2001*, including:

a. Giving a true and fair view of the Company's financial position as at 31 December 2021 and of its financial performance for the half-year ended on that date; and

b. Complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity* (ASRE 2410). Our responsibilities are further described in the *Auditor's responsibilities for the review of the half-year financial report* section of our report. We are independent of the Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Material uncertainty related to going concern

We draw attention to Note 1.2 in the financial report, which describes the principal events and conditions that indicate that a material uncertainty exists that may cast significant doubt about the entity's ability to continue as a going concern. Therefore, the entity may be unable to realise its assets and discharge its liabilities in the normal course of business. Our opinion is not modified in respect of this matter.

Directors' responsibilities for the half-year financial report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

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Auditor's responsibilities for the review of the half-year financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Company's financial position as at 31 December 2021 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Ernst & Young

Matt Biernat
Partner
Melbourne
23 February 2022