

Antisense Therapeutics Limited

Appendix 4D

For the Half-year ended 31 December 2020

Name of entity Antisense Therapeutics Limited
ABN 095 060 745
Half-year ended 31 December 2020
(Previous corresponding period: 31 December 2019)

Results for Announcement to the Market

The results of Antisense Therapeutics Limited for the half-year ended 31 December 2020 are as follows:

Revenues	down	(92.05)% to	2,185
Loss after tax attributable to members	down	(52.76)% to	2,043,551
Net loss for the period attributable to members	down	(52.76)% to	2,043,551

The above result needs to be read in conjunction with the Company's 30 June 2020 Annual Report.

Explanation of Results

The Company reported a loss for the half year ended 31 December 2020 of \$2,043,551

At 31 December 2020, the Company had cash reserves of \$10,041,585

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

	<u>31 December 2020</u>	<u>31 December 2019</u>
Net tangible assets (\$)	10,041,785	4,309,506
Shares (No.)	573,988,171	465,488,272
Net tangible assets per share (cents)	1.75	0.93

	<u>31 December 2020</u>	<u>31 December 2019</u>
Basic earnings/ (loss) per share (cents)	(0.40)	(1.02)
Diluted earnings/ (loss) per share (cents)	(0.40)	(1.02)

Status of Review of Accounts

The Appendix 4D is based on accounts which have been reviewed. The auditors report includes an Emphasis of Matter regarding going concern material uncertainty, 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 **2020**

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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 2020.

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.

Mr Robert W Moses, Independent Non-Executive Chairman	(Appointed: 23 October 2001)
Mr Mark Diamond, Managing Director	(Appointed: 31 October 2001)
Dr Graham Mitchell, Independent Non-Executive Director	(Appointed: 24 October 2001)
Dr Gary W Pace, Independent Non-Executive Director	(Appointed: 9 November 2015)
Mr William Goolsbee, Independent Non-Executive Director	(Appointed: 15 October 2015)

Results and review of operations

Results

The Company reported a loss for the half year ended 31 December 2020 of \$2,043,551 (31 December 2019: \$4,326,273). This loss is after fully expensing all research and development costs.

At 31 December 2020, the Company had cash reserves of \$10,041,585 (30 June 2020: \$4,059,442).

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 2020.

This report should be read in conjunction with the Company's 30 June 2020 Annual Report.

Capital raising

On 11th November 2020 the Company announced it had received firm commitments under an institutional placement to raise A\$7.3 million at an offer price of A\$0.10 per share.

On 30th November the Company announced the successful completion of a Share Purchase Plan which closed oversubscribed, raising \$1.2 million.

Funds raised were prior to incurring capital raising costs of \$614,149.

Dual Listing on the Frankfurt Stock Exchange

On 9th November the Company announced it had commenced proceedings to apply for the Company to be dual listed on the Frankfurt Stock Exchange (FSE), and that it had appointed DGWA, the German Institute for Asset and Equity Allocation and Valuation (Deutsche Gesellschaft für Wertpapieranalyse GmbH) "DGWA" as its investor and corporate relations advisor in Europe.

On 23rd November the Company announced that its shares had been dual listed on the FSE under the code AWY.

ATL1102 for Duchennes Muscular Dystrophy (DMD)

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).

Directors' report (continued)

The Company is undertaking clinical development of ATL1102 in patients with Duchenne muscular dystrophy (DMD). DMD is caused by a mutation in the muscle dystrophin gene leading to severe progressive muscle loss and premature death. One of the most common fatal genetic disorders, DMD affects approximately one in every 3,500 to 5,000 males worldwide. 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 has 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 primary endpoints of the trial relate to the safety and tolerability of ATL1102 with the efficacy of ATL1102 assessed in terms of its effects on disease processes and progression (e.g. the upper limb strength and function of the boys) as secondary endpoints.

Progress

On 30th July the Company announced that the European Medicines Agency (EMA) had provided the Company feedback on the appropriateness of certain key trial design parameters including dose duration, safety monitoring plan, endpoints, and potential pivotal status for the planned Phase IIb study of ATL1102 in non-ambulant boys with DMD in Europe.

On the 3rd August 2020 the Company announced that it had submitted an Orphan Drug Designation application for ATL1102 in DMD to the US Food and Drug Administration (FDA) and on 31 August announced it had submitted an Orphan Drug Designation application for ATL1102 in DMD to the EMA.

On 30th September 2020 the Company announced that the FDA had granted designation of ATL1102 as a drug for a rare pediatric disease following submission of data from Phase II clinical trial of ATL1102. Further, the Company advised that under the FDA's Rare Pediatric Disease Priority Review Voucher Program, a company that receives an approval for a product designated for a rare pediatric disease may qualify for a voucher that can be redeemed to receive an expedited priority marketing authorization review or sold to another party. In recent years, a secondary market for the vouchers has emerged allowing companies to use the sale of PRVs to recoup expenses undertaken for drug research and development and present them with additional source of non-dilutive capital to support further advancement of clinical development. Since 2009 when the first PRV was awarded the values for these vouchers have ranged between US\$68 million and US\$350 million.

On 2nd October 2020 the Company reported that results from a post study analysis of data from the Phase II DMD trial were to be presented at the 25th International Annual Congress of the World Muscle Society. The Company reported that the mean PUL2.0 (Performance of Upper Limb Function) data from the ATL1102 treated patients was compared with the 24-week PUL2.0 data of 39 assessments in 20 non-ambulant patients from a natural history database of DMD patients from Rome, Italy - the Rome cohort (RC).

ATL1102 treated patients showed a statistically significant mean improvement in Total PUL2.0 scores (assessment of muscle function) at 24 weeks compared to the matched natural history control with a greater frequency of patients treated with ATL1102 showing improvement or maintenance of their Total PUL2.0 score relative to the RC group.

On 26th October the Company announced that the US FDA had granted Orphan Drug Designation (ODD) status to ATL1102 in DMD.

The Company noted that the FDA (via the ODD) provides incentives to help accelerate the development of products for rare diseases, which may include tax credits towards the cost of clinical trials, waiver of US prescription drug filing fees and orphan product exclusivity for seven years upon marketing authorisation.

Directors' report (continued)

Progress (continued)

On 14th December the Company announced that it had received notification that the European Commission (EC) had adopted the decision relating to the designation of ATL1102 as an orphan medicinal product for DMD, under Regulation (EC) No 141/2000 of the European Parliament and of the Council.

Orphan drug designation was granted by the EC based on a positive opinion issued by the EMA Committee for Orphan Medicinal Products on 11 November 2020.

Orphan status in the EU provides potential development and marketing incentives, such as reduced fees on scientific advice and marketing authorisation application, and market exclusivity in Europe for 10 years upon regulatory approval of ATL1102 with an additional 2 years of exclusivity for its pediatric use in DMD. During that exclusivity period, neither the EU nor the Member States shall accept another marketing authorisation application for a similar medicinal product in the same therapeutic indication.

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 period the Company presented and participated at the following events:

- Virtual Investor Roadshow - Singapore & Hong Kong, 6 - 9 July 2020
- 2020 Virtual Annual Conference - Parent Project Muscular Dystrophy, US, 22 July 2020
- StockPal Biotech & Healthcare Webinar, Singapore, 4 August 2020
- 25th International Annual Congress of the World Muscle Society, UK, 1 October 2020
- Reach Markets Webcast - The Insider, Australia, 18 November 2020
- Spark Plus "Australian Equities Day" Webinar, Singapore, 2 December 2020
- 3rd Annual Neuromuscular Drug Development Summit, Digital Event, US, 4 December 2020
- Phar-East Pharma & Biotech Festival, Digital Event, Singapore, 8 December 2020
- 10th Anniversary Virtual Conference, Little Steps Association for Duchenne-Becker Patients, Israel, 9 December 2020

What is Duchennes 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 reported that following positive clinical trial results in the Phase II clinical trial of ATL1102 in DMD, the Company was actively exploring development opportunities where inflammation plays a key role in disease progression and that the ATL1102 DMD trial potentially provides support for undertaking studies in MS patients at the FDA approved dose.

Directors' report (continued)

In addition to MS, 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.

What is Multiple Sclerosis?

Multiple Sclerosis (MS) is a life-long, chronic disease that progressively destroys the central nervous system (CNS). It affects approximately 400,000 people in North America and more than 1 million worldwide. It is a disease that affects more women than men, with onset typically occurring between 20 and 40 years of age. Symptoms of MS may include vision problems, loss of balance, numbness, difficulty walking and paralysis. In Australia MS affects over 15,000 people.

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 leading peer-reviewed medical Journal, 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.

What is Acromegaly?

Acromegaly is a serious chronic life threatening disease triggered by excess secretion of growth hormone (GH) by benign pituitary tumours. Oversupply of GH over stimulates liver, fat and kidney cells, through their GH receptors, to produce excess levels of Insulin-Like Growth Factor-I (IGF-I) in the blood manifesting in abnormal growth of the face, hands and feet, and enlargement of body organs including liver, kidney and heart. The primary treatments for acromegaly are to surgically remove the pituitary gland and/or drug therapy to normalize GH and serum IGF-I levels. In North America and Europe there are approximately 85,000 diagnosed acromegaly patients with about half requiring drug therapy.

R&D tax incentives

During the period the Company received from the Australian Taxation Office an R&D Tax Incentive payment of \$650,603 in relation to expenditure incurred on eligible R&D activities for the 30 June 2020 financial year.

Financial position

At 31 December 2020, the Company had cash reserves of \$10,041,585 (30 June 2020: \$4,059,442)

Directors' report (continued)

Events after balance sheet date

The Company announced on 15 February 2021 the granting by the US Food and Drug Administration (FDA) a Type C guidance meeting scheduled for 19 April 2021 ET to discuss the further development of ATL1102 in DMD in the US. Clarification of preclinical requirements to support clinical development of ATL1102 in the US in DMD patients will be sort, with an expectation that guidance on the path forward will be provided. The Company expects to provide an update in late May 2021 following receipt of the official minutes of the meeting.

No further 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.

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.

Directors' report (continued)

Biotechnology companies – Inherent risks (continued)

Regulatory approvals (continued)

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.

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.



Mr Robert W Moses
Independent Non-Executive Director



Mr Mark Diamond
Managing Director

Melbourne

Dated: 24 February 2021

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**Building a better
working world**

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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 2020, 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; and
- b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Antisense Therapeutics Limited and the entities it controlled during the financial period.



Ernst & Young



Matt Biernat
Partner
24 February 2021

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Statement of profit or loss and other comprehensive income

For the half-year ended 31 December 2020

		31 December 2020	31 December 2019
	Notes	\$	\$
Revenue	4	2,185	27,494
Other income	4	259,334	309,469
		261,519	336,963
Administrative expenses	5	(1,070,714)	(885,239)
Occupancy expenses	5	(7,528)	(3,683)
Patent expenses		(57,378)	(51,469)
Research and development expenses	5	(1,105,167)	(1,240,657)
Foreign exchange (gains)/losses		(1,444)	(553)
Depreciation expenses		(59,369)	(54,426)
Finance costs	10	(3,470)	(7,123)
Share-based payments		-	(2,420,086)
Loss before tax		(2,043,551)	(4,326,273)
Income tax benefit/(expense)		-	-
Loss for the period		(2,043,551)	(4,326,273)
Other comprehensive income/(loss) for the year, net of tax		-	-
Total comprehensive loss for the year, net of tax		(2,043,551)	(4,326,273)
Loss per share	9		
Basic loss per share (cents)		(\$0.40)	(\$1.02)
Diluted loss per share (cents)		(\$0.40)	(\$1.02)

The accompanying notes form part of these financial statements.

Statement of financial position

As at 31 December 2020

		31 December 2020	30 June 2020
	Notes	\$	\$
Assets			
Current assets			
Cash and cash equivalents	6	10,041,585	4,059,442
Trade and other receivables	7	239,098	689,315
Prepayments		77,849	208,425
Other current assets	8	670,508	256,917
		<u>11,029,040</u>	<u>5,214,099</u>
Non-current assets			
Plant and equipment		12,246	8,649
Right-of-use assets	10	331,504	129,470
		<u>343,750</u>	<u>138,119</u>
Total assets		<u>11,372,790</u>	<u>5,352,218</u>
Liabilities			
Current liabilities			
Trade and other payables		245,473	291,677
Employee benefit liabilities		416,948	394,287
Lease liabilities	10	82,500	112,575
		<u>744,921</u>	<u>798,539</u>
Non-current liabilities			
Lease liabilities	10	254,580	22,690
		<u>254,580</u>	<u>22,690</u>
Total liabilities		<u>999,501</u>	<u>821,229</u>
Net Assets		<u>10,373,289</u>	<u>4,530,989</u>
Equity			
Contributed equity	12	77,033,694	69,147,843
Reserves	13	2,420,086	2,420,086
Accumulated losses		(69,080,491)	(67,036,940)
Total equity		<u>10,373,289</u>	<u>4,530,989</u>

The accompanying notes form part of these financial statements.

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Statement of changes in equity

For the half-year ended 31 December 2020

	Contributed equity	Option Reserves	Accumulated losses	Total
	\$	\$	\$	\$
As at 1 July 2019	63,938,429	-	(61,128,738)	2,809,691
Loss for the period	-	-	(4,326,273)	(4,326,273)
Total comprehensive loss	-	-	(4,326,273)	(4,326,273)
Issue of share capital (Note 12)	3,630,807	-	-	3,630,807
Issue of options (Note 12)	-	2,420,086	-	2,420,086
Transactions costs on options issues/capital raising	(43,774)	-	-	(43,774)
At 31 December 2019	67,525,462	2,420,086	(65,455,011)	4,490,537
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	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

The accompanying notes form part of these financial statements.

Statement of cash flows

For the half-year ended 31 December 2020

	31 December 2020	31 December 2019
Notes	\$	\$
Operating activities		
Payments to suppliers and employers	(2,544,857)	(2,023,114)
R&D tax concession refund	650,603	568,639
Government Grant	-	14,902
Interest received	2,311	14,316
Interest paid	(3,470)	(7,123)
Other Income	50,000	-
Net cash flows used in operating activities	(1,845,413)	(1,432,380)
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	(52,150)	(47,688)
Issue of share capital	8,500,000	3,630,807
Transaction costs on options issues/capital raising	(614,149)	(43,774)
Proceeds received from underwriting - Shares Pending issue	-	118,160
Net cash flows from financing activities	7,833,701	3,657,505
Net increase (decrease) in cash and cash equivalents	5,982,143	2,225,125
Cash and cash equivalents at 1 July	4,059,442	2,903,542
Cash and cash equivalents at 31 December	10,041,585	5,128,667

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The accompanying notes form part of these financial statements.

Notes to the financial statements

For the half-year ended 31 December 2020

1. Summary of significant accounting policies

1.1 Basis of preparation

The condensed financial report for the half-year reporting period ended 31 December 2020 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*.

(a) Government grants

Government grants are recognised where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is recognised as income in equal amounts over the expected useful life of the related asset.

The Company currently receives grant funding in the form of the R&D Tax Incentive together with the Innovation Connections Grant.

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 \$2,043,551 during the half year ended 31 December 2020 (\$4,326,273 half year to 31 December 2019) and incurred an operating cash outflow of \$1,845,413 (\$1,432,380 half year to 31 December 2019). The cash on hand balance at 31 December 2020 is \$10,041,585 (\$4,059,442 as at 30 June 2020).

As at 31 December 2020, the Company had a net assets position of \$10,373,289 (June 2020: \$4,530,990), and current assets exceed current liabilities by \$10,284,119 (June 2020: current assets exceeded current liabilities by \$4,415,561).

The Company may need to access additional capital within the next 12 months for further clinical development of its various development projects and to continue to pay its debts as and when they fall due.

After consideration of the available facts the Directors have concluded that the going concern basis is 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.

Notes to the financial statements (continued)

For the half-year ended 31 December 2020

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 2020 (31 December 2019: Nil).

4 Revenue and other income

	31 December 2020	31 December 2019
	\$	\$
Revenue		
Interest from external parties	2,185	12,592
Government grants	-	14,902
Total revenue	2,185	27,494
Other income		
Research and development tax concession	204,444	309,469
Gain on termination of leases	4,890	-
Other Income	50,000	-
Total other income	259,334	309,469
Total revenue and other income	261,519	336,963

Research and development tax concession for the 31 December 2020 reporting period includes \$197,679 anticipated refund for expenditure incurred in the period (2019: \$309,469).

COVID-19 government assistance \$50,000 is included in other income. This is a "Cashflow boost for employers" measure announced as part of the Australian Government's economic stimulus package of March 2020.

5 Expenses

	31 December 2020	31 December 2019
	\$	\$
Administrative expenses		
Business development expenses	415,237	294,272
Compliance expenses	196,389	119,984
Corporate employee expenses	429,672	449,056
Office expenses	29,416	21,927
	1,070,714	885,239

Notes to the financial statements (continued)

For the half-year ended 31 December 2020

5 Expenses (continued)

	31 December 2020	31 December 2019
	\$	\$
Occupancy expenses		
Other expenses	7,528	3,683
	<u>7,528</u>	<u>3,683</u>

	31 December 2020	31 December 2019
	\$	\$
Research and development expenses		
ATL 1102	765,750	906,032
ATL 1103	54,810	64,750
Research & Development	284,607	269,875
	<u>1,105,167</u>	<u>1,240,657</u>

6. Cash and cash equivalents

	31 December 2020	30 June 2020
	\$	\$
Cash at bank and on hand	7,941,320	359,442
Short-term deposits	2,100,265	3,700,000
	<u>10,041,585</u>	<u>4,059,442</u>

7. Trade and other receivables

	31 December 2020	30 June 2020
	\$	\$
Trade receivables	10,075	-
Research and development tax concession receivable	197,678	643,837
Interest receivable	255	381
Other receivables	31,090	45,097
	<u>239,098</u>	<u>689,315</u>

Notes to the financial statements (continued)

For the half-year ended 31 December 2020

8. Other current assets

	31 December 2020	30 June 2020
	\$	\$
Deposits Paid - R&D	670,508	256,917
	<u>670,508</u>	<u>256,917</u>

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 2020	31 December 2019
	\$	\$
Loss per share		
Basic loss per share (cents)	(\$0.40)	(\$1.02)
Diluted loss per share (cents)	(\$0.40)	(\$1.02)

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

	31 December 2020	31 December 2019
	\$	\$
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	(2,043,551)	(4,326,273)
Loss attributable to ordinary equity holders of the Parent for basic earnings	<u>(2,043,551)</u>	<u>(4,326,273)</u>
Loss attributable to ordinary equity holders of the Parent adjusted for the effect of dilution	<u>(2,043,551)</u>	<u>(4,326,273)</u>
	31 December 2020	31 December 2019
Weighted average number of ordinary shares for basic EPS	508,326,073	423,620,000
Effect of dilution:		
Weighted average number of ordinary shares adjusted for the effect of dilution	<u>508,326,073</u>	<u>423,620,000</u>

Notes to the financial statements (continued)

For the half-year ended 31 December 2020

9. Loss per share (EPS) (continued)

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 20, the Company had 45,000,000 unlisted options outstanding, which are convertible into 10,000,000 ordinary shares at \$0.08 exercise price, at the election of the option holder and 35,000,000 ordinary shares at \$0.145 exercise price, at the election of the option holder. Upon conversion, these shares could potentially dilute basic earnings per share in the future, but were not included in the calculation of diluted earnings per share because they are anti-dilutive for the current period.

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.

Leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Company. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable
- amounts expected to be payable by the lessee under residual value guarantees
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

The lease payments are discounted using the company's incremental borrowing rate.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability
- any lease payments made at or before the commencement date, less any lease incentives received
- any initial direct costs, and
- restoration costs.

(ii) Amounts recognised in the balance sheet

In December 2020, the Company entered into a two-year commercial lease on an office in Toorak, with the option to extend for a further two years. This calculation has included the additional two years as the Company is reasonably certain that the extension will be taken up.

The Company's decision to include the extension clause of the rental lease, is based on historical data. The impact of including the extension within the calculation increased the Right-of-use asset and lease liability accordingly.

Notes to the financial statements (continued)

For the half-year ended 31 December 2020

10. Leases (continued)

(ii) Amounts recognised in the balance sheet (continued)

	31 December 2020
Right-of-Use assets	\$
Carrying amount as at 1 July 2020	129,470
Take up new Right-of-Use asset, 14 Wallace Ave	335,815
Depreciation expense	(56,821)
Termination of old lease, 6-8 Wallace Ave	(76,960)
Balance as at 31 December 2020	<u>331,504</u>

Lease liabilities

Carrying amount as at 1 July 2020	135,265
Take up new lease liability, 14 Wallace Ave	335,815
Interest expense	3,470
Principal liability payments	(55,620)
Termination of old lease, 6-8 Wallace Ave	(81,850)
Balance as at 31 December 2020	<u>337,080</u>

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

	31 December 2020
	\$
Depreciation charge on right-of-use asset	56,821
Interest expense (included in finance costs)	3,470
Gain on termination of leased assets	(4,890)
	<u>55,401</u>

The total cash outflow for leases as at 31 December 2020 was \$61,557.

11. Commitments and contingencies

Commitments

At 31 December 2020, the Company had commitments of USD\$870,000 (2019:\$Nil) with regards to the GMP manufacture as per original agreement signed in February 2020. A subsequent Change Order was implemented, due to deferment of manufacturing to the second half of FY2021 signed 15 May 2020, moving the milestone payments into FY2021. Commencement of manufacturing occurred in January, with anticipated completion later in FY2021.

12. Contributed equity

	31 December 2020	30 June 2020
Notes	\$	\$
Ordinary fully paid shares	12.1 <u>77,033,694</u>	<u>69,147,843</u>
	<u>77,033,694</u>	<u>69,147,843</u>

12.1 - Ordinary fully paid shares

	No.	\$
As at 1 July 2019	420,103,487	63,938,430
Shares issued during the period	45,384,785	3,630,806
Capital Raising costs relating to share issues	-	(43,774)
At 31 December 2019	<u>465,488,272</u>	<u>67,525,462</u>

Notes to the financial statements (continued)

For the half-year ended 31 December 2020

12. Contributed equity (continued)

	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	<u>573,988,171</u>	<u>77,033,694</u>

13. 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.

	31 December 2020 No.	31 December 2020 \$	30 June 2020 No.	30 June 2020 \$
Share Based Payments	45,000,000	2,420,086	45,000,000	2,420,086

14. 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 2020	ATL1102 \$	ATL1103 \$	Total segments \$	Unallocated \$	Total segments + Unallocated \$
Revenue	204,444	-	204,444	2,185	206,629
Other income	-	-	-	54,890	54,890
	<u>204,444</u>	<u>-</u>	<u>204,444</u>	<u>57,075</u>	<u>261,519</u>
Operating Expenses	(765,750)	(54,810)	(820,560)	(1,484,513)	(2,305,073)
Segment results	<u>(561,306)</u>	<u>(54,810)</u>	<u>(616,116)</u>	<u>(1,427,438)</u>	<u>(2,043,554)</u>

Notes to the financial statements (continued)

For the half-year ended 31 December 2020

14. Segment information (continued)

Year ended 31 December 2019	ATL1102	ATL1103	Total segments	Unallocated	Total segments + Unallocated
	\$	\$	\$	\$	\$
Revenue	-	-	-	336,963	336,963
Operating Expenses	(906,032)	(64,750)	(970,782)	(3,692,454)	(4,663,236)
Segment results	(906,032)	(64,750)	(970,782)	(3,355,491)	(4,326,273)

14.1 - Unallocated breakdown

	31 December 2020	31 December 2019
	\$	\$
Revenue and other income		
Interest received	2,185	12,592
R&D tax concession	-	309,469
Government grants	-	14,902
Other income	54,890	-
	57,075	336,963

	31 December 2020	31 December 2019
	\$	\$
Expenses		
Compliance expenses	(196,389)	(119,984)
Employee expenses	(429,672)	(449,056)
Business development expenses	(415,237)	(294,272)
Patent expenses	(57,378)	(51,468)
Other expenses	(385,837)	(2,777,674)
	(1,484,513)	(3,692,454)

15. Events after the reporting period

The Company announced on 15 February 2021 the granting by the US Food and Drug Administration (FDA) a Type C guidance meeting scheduled for 19 April 2021 ET to discuss the further development of ATL1102 in DMD in the US. Clarification of preclinical requirements to support clinical development of ATL1102 in the US in DMD patients will be sort, with an expectation that guidance on the path forward will be provided. The Company expects to provide an update in late May 2021 following receipt of the official minutes of the meeting.

No further 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 2020 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 2020 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 2020.

On behalf of the board



Mr Robert W Moses
Independent Non-Executive Chairman



Mr Mark Diamond
Managing Director

Melbourne
Dated: This the 24th Day of February 2021.



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Independent Auditor's Review Report to the Members of Antisense Therapeutics Limited

Report on the Half-Year Financial Report

Conclusion

We have reviewed the accompanying half-year financial report of Antisense Therapeutics Limited (the Company) and its subsidiaries (collectively the Group), which comprises the statement of financial position as at 31 December 2020, the statement of profit and loss and other comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a statement of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the half-year financial report of the Group is not in accordance with the *Corporations Act 2001*, including:

- a) giving a true and fair view of the consolidated financial position of the Group as at 31 December 2020 and of its consolidated 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*.

Emphasis of Matter - Material Uncertainty Related to Going Concern

Without qualifying our opinion, we draw attention to Note 1.2 in the financial report which describes the principal conditions that indicate the existence of a material uncertainty 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.

Directors' Responsibility 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 is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, anything has come to our attention that causes us to 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 Group's consolidated financial position as at 31 December 2020 and its consolidated financial performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor

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of the Group, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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.

Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

A handwritten signature in black ink that reads 'Ernst & Young'.

Ernst & Young

A handwritten signature in black ink that reads 'Matt Biernat'.

Matt Biernat
Partner
Melbourne
24 February 2021

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