

**Pinnacle Listed Practical Interim Limited**  
**Appendix 4D**  
**Half-year report**

**1. Company details**

**Name of entity:** Paradigm Biopharmaceuticals Limited  
**ABN:** 94 169 346 963  
**Reporting period:** 31 December 2021  
**Previous reporting period:** 31 December 2020

**2. Results for announcement to the market**

	\$	\$ and % increase/(decrease) over previous corresponding period
<b>Revenue from continuing activities</b>	749,966	495,492 194.71%
<b>(Loss) from continuing activities after tax attributable to members</b>	(26,985,037)	6,254,542 30.17%
<b>Net (loss) for the period attributable to members</b>	(27,011,851)	6,281,356 30.30%
<b>Dividends (distributions)</b>	<b>Amount per security</b>	<b>Franked amount per security</b>
<b>Final Dividend</b>	N/A	N/A
<b>Interim Dividend</b>	N/A	N/A
<b>Record date for determining entitlements to the dividends (if any)</b>	N/A	

For personal use only

## 2. Results for announcement to the market continued

**Brief explanation of any of the figures reported above necessary to enable the figures to be understood:**

Paradigm Biopharmaceuticals is a late-stage clinical development company with a phase 3 asset under development for treatment of osteoarthritis. In the absence of partnering milestone income or material revenue contributions, profit before tax losses can be expected in the future, as the company continues to incur further Clinical, Regulatory and Commercial expenses to continue the development of Zilosul, a potential blockbuster treatment for osteoarthritis.

During the six months to 31 December 2021, Paradigm Biopharmaceuticals committed significant resources to progressing its clinical program for the development of injectable Pentosan Polysulfate Sodium (iPPS). The Company successfully opened an Investigational New Drug (IND) Phase 3 trial (PARA\_OA\_002) for treatment of pain and function of knee osteoarthritis. A phase 2 study for MPS VI commenced in Brazil, iPPS presents as the first possible drug therapy targeted specifically at complications associated with MPS including pain and arthropathy in the MPS-VI patient population. Toxicity studies for ongoing chronic (including covering repeat treatment) dosing toxicity studies in both adult and juvenile rats and dogs continued during the period. Our investment in pipeline assets continue with milestones achieved for early-stage research in Acute Respiratory Distress Syndrome (ARDS) and Heart Failure. In terms of Commercial development, some important market research was completed to inform Paradigm about market access for Zilosul, including information on reimbursed pricing in key markets.

## 3. Net tangible assets

	Current Period	Previous corresponding period
<b>Basic loss per ordinary security</b> (cents per share)	(11.8) cents	(9.1) cents
<b>Diluted loss per ordinary security</b> (cents per share)	(11.8) cents	(9.1) cents
<b>Net tangible asset backing per ordinary security</b> (cents per share)	21.51 cents	37.75 cents

## 4. Control gained over entities

Not applicable.

## 5. Loss of control over entities

Not applicable.

**6. Audit qualification or review**

<b>This report is based on accounts to which one of the following applies:</b>			
(Tick one)			
The accounts have been reviewed	<input checked="" type="checkbox"/>	The accounts are in the process of being reviewed	<input type="checkbox"/>
<b>If the accounts are subject to audit dispute or qualification, a description of the dispute or qualification: N/A</b>			

**7. Attachments**

The report of half year ended 31 December 2021 is attached.

**8. Signed**



Signed \_\_\_\_\_

Mr. Paul Rennie  
Chairman  
24<sup>th</sup> February 2022

For personal use only

**PARADIGM**  
BIOPHARMA

For personal use only

**Unlocking  
new  
potential**

Half-Year Report  
31 December 2021



## Contents

# 01

---

Highlights

# 12

---

Notes to the Financial Statements

# 02

---

Osteoarthritis Update

# 17

---

Directors' Declaration

# 05

---

Directors' Report

# 18

---

Independent Auditor's Review Report

# 06

---

Auditor's Independence Declaration

# 20

---

Corporate Directory

# 07

---

Consolidated Interim Financial Statements

### General Information

The financial statements cover Paradigm Biopharmaceuticals Limited as a Consolidated entity, consisting of Paradigm Biopharmaceuticals Limited and its controlled entities (together referred to as the 'Consolidated entity') at the end of the half-year ended 31 December 2021. The financial statements are presented in Australian dollars, which is Paradigm Biopharmaceuticals Limited's functional and presentation currency.

Paradigm Biopharmaceuticals Limited is a listed public company limited by shares, incorporated and domiciled in Australia. A description of the nature of the Consolidated Entity's operations and its principal activities are included in the Directors' Report, which is not part of the financial statements.

The financial statements were authorised for issue, in accordance with a resolution of Directors, on 24 February 2022.

For personal use only

# Highlights

**Paradigm Biopharmaceuticals Limited (PAR) is a global biopharmaceutical company driven to improve patients' lives through repurposing existing drugs and pioneering new solutions for unmet medical needs.**



We take an existing approved drug, which has demonstrated safety in its approved indications



We repurpose that drug in a new patented therapeutic application with high unmet need



We reduce the time, cost and risk associated with drug development

## Market research

**\$2,500 to \$3,000 USD**

Market research confirms a reimbursed price for Zilosul of \$2,000 to \$3,000 USD per course is achievable in the US market for pain and function indication.

## Phase 2 study

Positive interim data from the phase 2 study in MPS 1 presented to international experts at the ICIEM Conference in November 2021.

## Trials commenced

Paradigm commenced two new clinical trials in the 6 months to December 2021, MPS 6 a phase 2 study and PARA\_OA\_002 a phase 3 trial.



IND for osteoarthritis cleared by the US FDA.



First subject dosed in PARA\_OA\_002.

For personal use only

# Osteoarthritis Update

## The Multiple Mechanisms of Actions of PPS

Pentosan Polysulfate Sodium (PPS) is a highly sulfated sulphated polysaccharide demonstrating multiple mechanisms of action.

The multiple actions of PPS are mediated by targeting both NF-kB-dependent and NF-kB independent pathways (Figure 1).

The activation of the transcription factor NF-kB is involved in key pathological processes in both acute and chronic diseases. Figure 1 illustrates the actions of PPS, which is an inhibitor of NF-kB. A number of peer-reviewed scientific publications have confirmed that PPS binds to NF-kB and prevents the translocation of NF-kB into the nucleus of the cell where NF-kB initiates the expression of genes that lead to the inflammatory cascade.

The inhibition of NF-kB by PPS, results in the regulation of pathological processes involved in inflammation mediated by transcription of inflammatory cytokines; pain through the production of nerve growth factor (NGF); adverse tissue remodelling or tissue degradation through the increased levels of enzymes such as ADAMTS4 and 5; and vascular inflammation and dysfunction through the induction of cell adhesion molecules.

In addition to targeting NF-kB directly, PPS can also act in an NF-kB independent manner.

Examples of NF-kB independent effects of PPS include:

- PPS acting as a direct enzyme inhibitor of ADAMTS-4 and ADAMTS-5 (Troeborg et al., 2012<sup>1</sup>).
- PPS as a direct inhibitor of NGF gene expression (Stapledon et al., 2019<sup>2</sup>).

- Its anti-thrombotic properties, which improve vascular perfusion (Ghosh and Cheras, 2001<sup>3</sup>).
- Its tissue regenerative properties, by directly increasing the production of hyaluronic acid, which is degraded in osteoarthritic joints and other tissues including the myocardium in heart failure (Verbruggen and Veys, 1992<sup>4</sup>) (Francis et al., 1993<sup>5</sup>).

The key message is that the multiple mechanisms of actions of PPS regulate disease processes such as inflammation, pain, adverse tissue remodelling and vascular dysfunction that are common to many acute and chronic medical indications.

Therefore, PPS has a substantial advantage in yielding clinically meaningful outcomes compared to pharmaceutical agents with mono-specific actions which target single disease pathways.

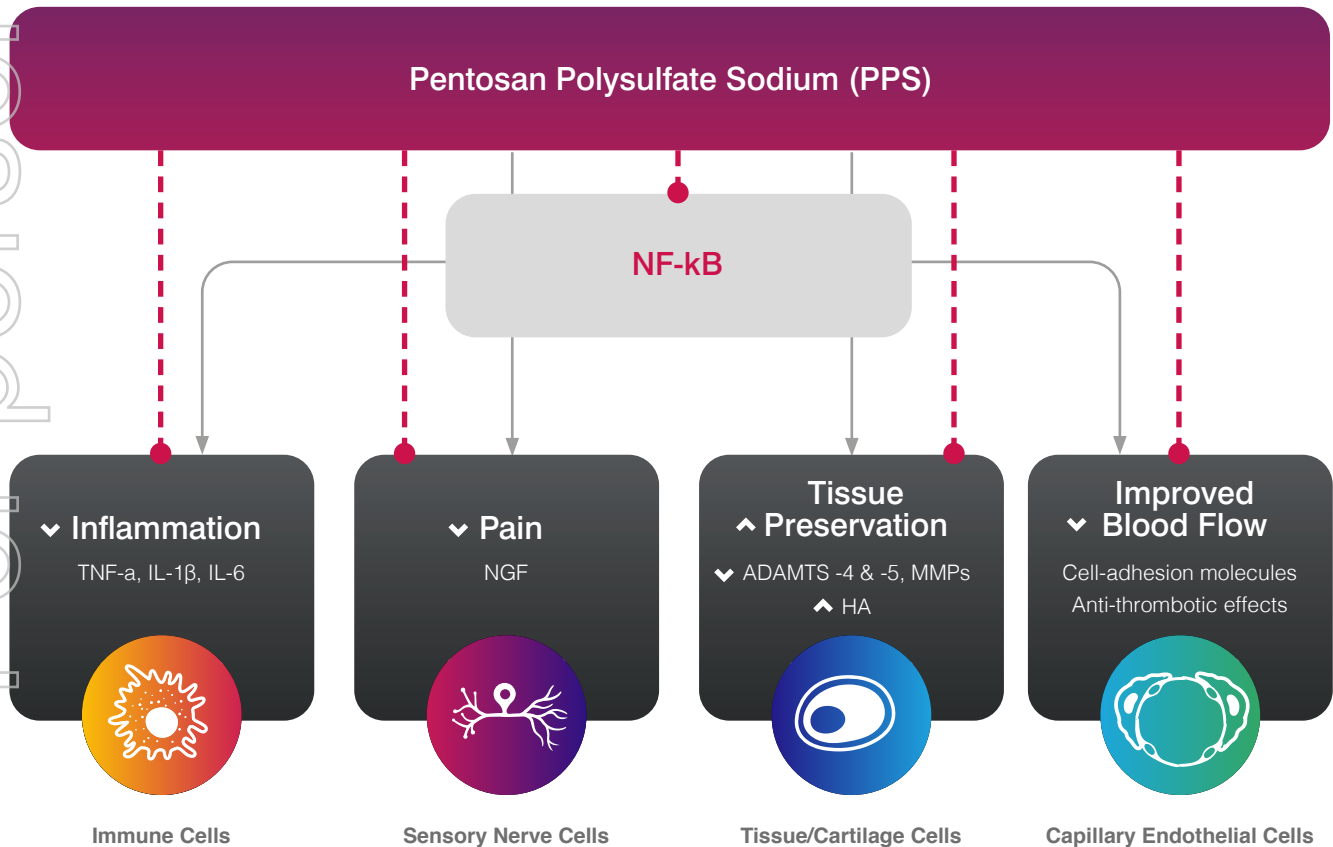


Figure 1. The multiple NF-kB-dependent and NF-kB-independent mechanisms of action of PPS.



## About the R&D Pipeline

The multiple mechanisms of action of PPS allow the repurposing of PPS across a number of acute and chronic medical indications such as acute respiratory distress syndrome (**ARDS**); heart failure and alpha virus-induced arthralgia.

Paradigm's approach has been to obtain robust scientific data using preclinical proof-of-concept animal disease models to support the mechanisms of action of PPS, which target specific disease indications.

**In viral induced ARDS**, PPS actions involve targeting the inflammatory response via anti-inflammatory effects mediated by the inhibition of NF-κB (Sunaga et al., 2012<sup>6</sup>)(Bwalya et al., 2017<sup>7</sup>).

**In heart failure**, PPS actions involve targeting ADAMTS-4 present in myocardial tissues which causes adverse tissue remodelling; as well as inflammation and vascular endothelial cell activation which affect cardiac function (Vistnes et al., 2014<sup>8</sup>).

**In alpha viral-induced arthritis**, where examples are Ross River virus and Chikungunya virus and PPS actions involve targeting inflammation and pain (Herrero et al., 2015<sup>9</sup>)(Krishnan et al., 2021<sup>10</sup>) (Rudd et al., 2021<sup>11</sup>).

In summary, the multiple mechanisms of action of PPS provide the rationale for the use of PPS in treating other medical indications beyond OA and MPS.

## References

1. Troeberg L, Mulloy B, Ghosh P, et al. Pentosan polysulfate increases affinity between ADAMTS-5 and TIMP-3 through formation of an electrostatically driven trimolecular complex. *Biochem J* [Internet]. 2012 [cited 2019 Aug 28];443:307–315. doi:10.1042/BJ20112159.
2. Stapledon CJM, Tsangari H, Solomon LB, et al. Human osteocyte expression of Nerve Growth Factor: The effect of Pentosan Polysulphate Sodium (PPS) and implications for pain associated with knee osteoarthritis. Heymann D, editor. *PLoS ONE* [Internet]. 2019 [cited 2020 Mar 3];14:e0222602. doi:10.1371/journal.pone.0222602.
3. Ghosh P, Cheras PA. Vascular mechanisms in osteoarthritis. *Best Practice & Research Clinical Rheumatology* [Internet]. 2001 [cited 2019 Oct 3];15:693–709. doi:10.1053/berh.2001.0188.
4. Verbruggen G, Veys EM. Intra-articular injection of pentosanpolysulphate results in increased hyaluronan molecular weight in joint fluid. *Clin Exp Rheumatol* [Internet]. 1992;10:249–254. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/1374695>.
5. Francis DJ, Hutadilok N, Kongtawelert P, et al. Pentosan polysulphate and glycosaminoglycan polysulphate stimulate the synthesis of hyaluronan in vivo. *Rheumatol Int* [Internet]. 1993 [cited 2019 Sep 18];13:61–64. doi:10.1007/BF00307735.
6. Sunaga T, Oh N, Hosoya K, et al. Inhibitory Effects of Pentosan Polysulfate Sodium on MAP-Kinase Pathway and NF- B Nuclear Translocation in Canine Chondrocytes In Vitro. *J Vet Med Sci* [Internet]. 2012;74:707–711. doi:10.1292/jvms.11-0511.
7. Bwalya EC, Kim S, Fang J, et al. Pentosan polysulfate inhibits IL-1 induced iNOS, c-Jun and HIF-1 upregulation in canine articular chondrocytes. Gualillo O, editor. *PLoS ONE* [Internet]. 2017 [cited 2019 Aug 28];12:e0177144. doi:10.1371/journal.pone.0177144.
8. Vistnes M, Aronsen JM, Lunde IG, et al. Pentosan Polysulfate Decreases Myocardial Expression of the Extracellular Matrix Enzyme ADAMTS4 and Improves Cardiac Function In Vivo in Rats Subjected to Pressure Overload by Aortic Banding. Frangogiannis N, editor. *PLoS ONE* [Internet]. 2014 [cited 2019 Aug 28];9:e89621. doi:10.1371/journal.pone.0089621.
9. Herrero LJ, Foo S-S, Sheng K-C, et al. Pentosan Polysulfate: a Novel Glycosaminoglycan-Like Molecule for Effective Treatment of Alphavirus-Induced Cartilage Destruction and Inflammatory Disease. Diamond MS, editor. *J Virol* [Internet]. 2015 [cited 2019 Aug 28];89:8063–8076. doi:10.1128/JVI.00224-15.
10. Krishnan R, Duiker M, Rudd PA, et al. Pentosan polysulfate sodium for Ross River virus-induced arthralgia: a phase 2a, randomized, double-blind, placebo-controlled study. *BMC Musculoskelet Disord* [Internet]. 2021 [cited 2021 Mar 17];22:271. doi:10.1186/s12891-021-04123-w.
11. Rudd PA, Lim EXY, Stapledon CJM, et al. Pentosan polysulfate sodium prevents functional decline in chikungunya infected mice by modulating growth factor signalling and lymphocyte activation. Roques P, editor. *PLoS ONE* [Internet]. 2021 [cited 2021 Sep 17];16:e0255125. doi:10.1371/journal.pone.0255125.



# Directors' Report

The Directors present their report, together with the financial statements, on the Consolidated entity consisting of Paradigm Biopharmaceuticals Limited (Paradigm or the Company) and the entities it controlled at the end of, or during, the half-year ended 31 December 2021.

## Directors

The following persons were Directors of the Company during the whole of the financial half-year and up to the date of this report, unless otherwise stated:

Paul Rennie  
John Gaffney  
Donna Skerrett  
Amos Meltzer  
Helen Fisher

## Principal Activities

The principal activities of the Consolidated entity are researching and developing therapeutic products for human use.

## Results

The Consolidated entity made a loss for the six-month period ended 31 December 2021 of \$26,985,037 (31 December 2020: Loss of \$20,730,495).

## Review of Operations

On the 30 September 2021, Paradigm announced the first patient dosed in the MPS 6 trial. The study is designed to enrol patients with MPS-6 who are currently receiving Enzyme Replacement Therapy (**ERT**) and exhibit pain and functional deficiency due to musculoskeletal symptoms associated with the underlying disease. Participants will continue to receive ERT through the study. Subjects will be administered PPS or placebo at a 1.5mg/kg ( $\geq 9$  years of age) or 1.0mg/kg ( $< 9$  years of age)

subcutaneous injection once weekly for 24 weeks.

Pentosan Polysulfate Sodium (**PPS**) presents the first possible drug therapy targeted specifically at complications associated with MPS including pain and arthropathy in the MPS-6 patient population. As individuals treated with ERT continue to experience pain and other symptoms that impact quality of life (**QOL**), PPS is being investigated for use as an adjunctive treatment to ERT to alleviate progressive arthropathy via the multiple actions of PPS on disease-modifying pathways.

On the 3 November 2021, Paradigm announced that the Investigational New Drug (**IND**) application for osteoarthritis was cleared by the US Federal Drug Administration (**FDA**), allowing Paradigm to commence its phase 3 trial evaluating injectable PPS for the treatment of pain associated with knee osteoarthritis.

On the 8 November 2021, Paradigm announced outcomes from market access research on Zilosul's target product profile in key NH markets. The research, undertaken by global market research firm Clarivate, shows that the target product profile (**TPP**) for pain and function would (assuming sustained efficacy and robust safety data) provide high treatment value for knee osteoarthritis (**kOA**) by covering some important unmet needs by providing an alternative treatment to reduce pain and improve function for kOA patients.

Physicians contacted as part of the research indicated Zilosul was likely to be a second line therapy for treating pain and function associated with kOA. Feedback from payer's included in the research indicated a reimbursed price in the US market of USD\$2,000 to \$3,000 per course, was achievable for a pain and function label.

The results from this market research validates Paradigm's earlier estimates of US\$2,500 per course for Zilosul is achievable. The research also confirms Paradigm's clinical program which includes studies to confirm duration of effect and retreatment are important studies that will provide data for reimbursement in key markets. Importantly the research also indicated potential for a higher price and a move to a first line therapy for Zilosul if disease modification can be attained.

On the 22 November, Paradigm announced Paul Rennie had stepped down as CEO & Managing Director of Paradigm and will become Non-Executive Chairman of Paradigm. Dr Donna Skerrett, Paradigm's Chief Medical Officer, is announced as interim CEO. A global search for a permanent CEO is well progressed.

On the 23 November, Paradigm announced positive Interim data for MPS at the International Congress of Inborn Errors of Metabolism (**ICIEM**). The study at the Adelaide Women's and Children's Hospital has enrolled 3 patients who are over halfway through their 48-week treatment regime. The data shows that PPS has been well tolerated by the subjects and has resulted in improvements in 2 and 6 minute walk tests, improved range of motion and improvements in other activities important to daily function of patients.

On the 16 December, Paradigm released top line summary data of its PPS proof-of-concept heart failure model. The findings of the pilot study were encouraging and delivered promising data to support the mechanism of action (**MoA**) of PPS as an inhibitor of ADAMTS enzymes, relieving heart failure.



In terms of financial performance, Paradigm recorded a loss before tax of \$26,985,037, an increase on prior year loss before tax of \$6,254,542. Paradigm Biopharmaceuticals is a late-stage clinical development company with a phase 3 asset under development for treatment of osteoarthritis. In the absence of partnering milestone income or material revenue contributions, profit before tax losses can be expected in the future, as the company continues to incur further Clinical, Regulatory and Commercial expenses to continue the development of Zilosul, a potential blockbuster treatment for osteoarthritis.

Paradigm has recorded revenue for the 6 months to December 2021 of \$45,200, this is linked to sales associated with the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS). Revenue from SAS will continue to be modest as product allocation for this program remains limited.

The increase in loss before tax compared to prior corresponding period of \$6,254,542 is mainly driven by research and development costs. The two main drivers of the increase in spend relate to Pre-Clinical and Clinical activity. The Pre-Clinical impact relates to the continued ongoing chronic (including covering repeat treatment) dosing toxicity studies in both adult and juvenile rats and dogs. These studies are required for New Drug Application (NDA) process. Paradigm are working on completing these studies concurrently with clinical studies in MPS and OA. These studies are multiyear studies that are being undertaken now to ensure these studies and data from it are understood to de-risk the NDA process. These toxicity studies are a one-time study that can be used for other iPPS assets involving subcutaneous delivery (within existing dosing regimes of our clinical programs).

The other area of the business where activity increased compared to prior period was within Clinical Development. With the PARA\_OA\_002 phase 3 study receiving Regulatory approval by the Australian TGA and US FDA in the 6 months to December 2021 there was a ramp up of activity in terms of establishing:

- critical infrastructure to support the trial including local and centralized systems to manage the many data points required for monitoring of the trial,
- tendering and then contracting the set-up of 10 central laboratories which is essential to support the logistics and operational requirements of our testing regime to support the trial,
- commence operationalizing of clinical trial sites in Australia and the US including contracting, local ethics approval, training, materials and supplies for the trial and system set up, training and data integration,

In addition to these costs, there were also increased activity in our MPS I and MPS VI phase 2 studies with both studies operational for the full 6 months to December 2021. Sites are established in Australia and Brazil to run these 2 studies where subject enrolment and dosing is ongoing.

Other income is higher for the 6 months to December 2021 mainly due to revaluations of USD on hand. Commercial expenses for the period also increased, this is primarily due to market access research associated with our commercial development of Zilosul.

In the second half of fiscal year 2022 Paradigm expects Clinical Development costs to continue to progress for PARA\_OA\_002 as site activation increases across the US and recruitment

of subjects in both Australia and US increases. In addition to these costs, we'd anticipate expenditure related to establish Regulatory approvals in the UK and Europe to PARA\_OA\_002 and some set up costs for the PARA\_OA\_006 duration of effect study.

## Significant changes in the state of affairs

On the 10 September 2021, Paradigm offered shares under its Employee Share Scheme (ESP). The invitation to participate in the ESP was for 2,700,000 shares at an issue price of \$2.41 per share, the strike price was set at a 25% premium to the 30 day VWAP. The shares will vest in equal amounts of 900,000 shares in 12 months, 24 months, and 36 months.

## Auditor's Independence Declaration

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.

This report is made in accordance with a resolution of Directors, pursuant to Section 306(3)(a) of the *Corporations Act 2001*.

On behalf of the Directors



**Mr Paul Rennie**  
Chairman  
24 February 2022

For personal use only

# Auditor's Independence Declaration



## RSM Australia Partners

Level 21, 55 Collins Street Melbourne VIC 3000  
PO Box 248 Collins Street West VIC 8007

T +61 (0) 3 9286 8000  
F +61 (0) 3 9286 8199

[www.rsm.com.au](http://www.rsm.com.au)

### AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the review of the financial report of Paradigm Biopharmaceuticals Limited for the half year ended 31 December 2021, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- (i) the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- (ii) any applicable code of professional conduct in relation to the review.

**RSM AUSTRALIA PARTNERS**

**R J MORILLO MALDONADO**  
Partner

24 February 2022  
Melbourne, Victoria

**THE POWER OF BEING UNDERSTOOD**  
AUDIT | TAX | CONSULTING

RSM Australia Partners is a member of the RSM network and trades as RSM. RSM is the trading name used by the members of the RSM network. Each member of the RSM network is an independent accounting and consulting firm which practices in its own right. The RSM network is not itself a separate legal entity in any jurisdiction.  
RSM Australia Partners ABN 36 965 185 036

Liability limited by a scheme approved under Professional Standards Legislation



For personal use only

# Consolidated Interim Financial Statements

## Contents

Consolidated Interim Statement of Profit or Loss and Other Comprehensive Income	08
Consolidated Interim Statement of Financial Position	09
Consolidated Interim Statement of Changes in Equity	10
Consolidated Interim Statement of Cash Flows	11
Notes to the Financial Statements	12
Directors' Declaration	17
Independent Auditor's Review Report	18

For personal use only



# Consolidated Interim 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 from continuing operations		45,200	-
Cost of sales		(70,647)	-
Other income	2	704,766	254,475
Research and development expenses		(23,449,532)	(17,195,123)
General and administration expenses		(3,780,668)	(3,651,532)
Commercial expenses		(419,794)	(119,482)
Finance costs		(14,362)	(18,833)
<b>Loss before income tax</b>		<b>(26,985,037)</b>	<b>(20,730,495)</b>
Income tax expense/(benefit)		-	-
<b>Loss for the half-year</b>		<b>(26,985,037)</b>	<b>(20,730,495)</b>
<b>Other comprehensive income</b>			
<i>Items that may be reclassified subsequently to profit or loss</i>			
Foreign currency translation		(26,814)	-
<b>Other comprehensive income for the half-year, net of tax</b>		<b>(26,814)</b>	-
<b>Total comprehensive (loss) attributable to members of the Consolidated entity</b>		<b>(27,011,851)</b>	<b>(20,730,495)</b>
<b>Loss per share (cents)</b>			
Basic and diluted (loss) per share	10	(11.8) cents	(9.1) cents

The above consolidated interim statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

# Consolidated Interim Statement of Financial Position

as at 31 December 2021

	Notes	31 December 2021 \$	30 June 2021 \$
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents	3	54,984,064	71,034,983
Trade and other receivables	4	7,155,798	8,507,640
Prepaid expenses		1,693,222	1,388,748
Financial assets held at amortised cost		46,200	46,200
<b>Total current assets</b>		<b>63,879,284</b>	<b>80,977,571</b>
<b>Non-current assets</b>			
Intangible assets	5	2,947,588	2,947,588
Plant and equipment		76,435	92,696
Right-of-use assets	6	591,102	671,709
Security deposits receivable		-	102,616
<b>Total non-current assets</b>		<b>3,615,125</b>	<b>3,814,609</b>
<b>Total assets</b>		<b>67,494,409</b>	<b>84,792,180</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables	7	13,326,200	4,986,440
Employee benefits		491,285	672,404
Lease liabilities		143,569	134,616
<b>Total current liabilities</b>		<b>13,961,054</b>	<b>5,793,460</b>
<b>Non-current liabilities</b>			
Employee benefits		71,952	108,209
Lease liabilities		451,097	525,372
Make good provision		90,628	91,853
<b>Total non-current liabilities</b>		<b>613,677</b>	<b>725,434</b>
<b>Total liabilities</b>		<b>14,574,731</b>	<b>6,518,894</b>
<b>Net assets</b>		<b>52,919,678</b>	<b>78,273,286</b>
<b>EQUITY</b>			
Issued capital	8	147,068,972	146,989,484
Share-based payments reserve	9	7,637,274	6,453,995
Currency translation reserve		31,220	58,034
Accumulated losses		(101,817,788)	(75,228,227)
<b>Total equity</b>		<b>52,919,678</b>	<b>78,273,286</b>

The above consolidated interim statement of financial position should be read in conjunction with the accompanying notes.

For personal use only

## Consolidated Interim Statement of Changes in Equity

### for the half-year ended 31 December 2021

	Issued Capital \$	Share Option Reserve \$	Accumulated Losses \$	Currency Translation Reserve \$	Total \$
<b>Balance at 1 July 2020</b>	145,865,076	3,585,189	(41,268,546)	-	108,181,719
Loss for the period	-	-	(20,730,495)	-	(20,730,495)
Total Comprehensive income/(loss) for the half-year	-	-	(20,730,495)	-	(20,730,495)
<i>Transactions with owners in their capacity as owners:</i>					
Fair value of shares issued to eligible employees under the plan	-	1,351,819	-	-	1,351,819
Transfer from share-based payments reserve on exercise of options	-	(162,637)	162,637	-	-
Shares issued relating to repayment of limited recourse loan for ESP	103,675	-	-	-	103,675
Exercise of unlisted options	542,170	-	-	-	542,170
<b>Balance at 31 December 2020</b>	<b>146,510,921</b>	<b>4,774,371</b>	<b>(61,836,404)</b>	<b>-</b>	<b>89,448,888</b>
<b>Balance at 1 July 2021</b>	<b>146,989,484</b>	<b>6,453,995</b>	<b>(75,228,227)</b>	<b>58,034</b>	<b>78,273,286</b>
Loss for the period	-	-	(26,985,037)	-	(26,985,037)
Other comprehensive income/(loss)	-	-	-	(26,814)	(26,814)
Total Comprehensive income/(loss) for the half-year	-	-	(26,985,037)	(26,814)	(27,011,851)
<i>Transactions with owners in their capacity as owners:</i>					
Fair value of shares issued to eligible employees under the plan	-	1,578,755	-	-	1,578,755
ESP lapsed in the period	-	(335,705)	335,705	-	-
Transfer from share-based payments reserve on exercise of options	-	(59,771)	59,771	-	-
Shares issued relating to repayment of limited recourse loan for ESP	79,488	-	-	-	79,488
<b>Balance at 31 December 2021</b>	<b>147,068,972</b>	<b>7,637,274</b>	<b>(101,817,788)</b>	<b>31,220</b>	<b>52,919,678</b>

The above consolidated interim statement of changes in equity should be read in conjunction with the accompanying notes.



# Consolidated Interim Statement of Cash Flows

for the half-year ended 31 December 2021

	Note	31 December 2021 \$	31 December 2020 \$
<b>Cash flows from operating activities</b>			
Research and development and other tax incentive received		1,314,282	50,000
Revenue from continuing operations		54,750	-
Payments to suppliers and employees (inclusive of GST)		(18,117,223)	(19,541,798)
Interest received		34,086	229,392
Interest repayment of lease liabilities		(14,362)	(18,833)
<b>Net cash outflow from operating activities</b>	11	<b>(16,728,467)</b>	<b>(19,281,239)</b>
<b>Cash flows from investing activities</b>			
Payments for intangible assets		-	(850)
Payments for equipment		-	(20,130)
<b>Net cash outflow from investing activities</b>		<b>-</b>	<b>(20,980)</b>
<b>Cash flows from financing activities</b>			
Proceeds from exercise of share options		-	542,170
Payment of share issue costs		-	-
Limited recourse loan repaid under ESP		79,488	103,675
Principal repayment of lease liabilities		(66,547)	(59,446)
<b>Net cash inflow from financing activities</b>		<b>12,941</b>	<b>586,399</b>
<b>Net decrease in cash and cash equivalents</b>		<b>(16,715,526)</b>	<b>(18,715,821)</b>
<b>Cash and cash equivalents at the beginning of the financial period</b>		<b>71,034,983</b>	<b>103,922,241</b>
<b>Effects of exchange rate changes on cash and cash equivalents</b>		<b>664,607</b>	<b>-</b>
<b>Cash and cash equivalents at the end of the financial period</b>		<b>54,984,064</b>	<b>85,206,420</b>

The above consolidated interim statement of cash flows should be read in conjunction with the accompanying notes.

For personal use only

# Notes to Financial Statements

31 December 2021

## 1. Significant Accounting Policies

These general-purpose financial statements for the interim half-year reporting period ended 31 December 2021 have been prepared in accordance with Australian Accounting Standard AASB 134 'Interim Financial Reporting' and the *Corporations Act 2001*, as appropriate for for-profit oriented entities. Compliance with AASB 134 ensures compliance with International Financial Reporting Standard IAS 34 'Interim Financial Reporting'.

These general-purpose financial statements do not include all the notes of the type normally included in annual financial statements. Accordingly, these financial statements are to be read in conjunction with the Annual Report for the year ended 30 June 2021 and any public announcements made by the Company during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

The principal accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period, unless otherwise stated.

### New or Amending Accounting Standards and Interpretations Adopted

The Consolidated entity has adopted all of the new, revised or amending Accounting Standards and Interpretations issued by the Australian Accounting Standards Board (AASB) that are mandatory for the current reporting period.

Any new or amending Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

## 2. Other Income

	31 December 2021 \$	31 December 2020 \$
Interest received	40,160	204,475
ATO Cashflow boost payment	-	50,000
Realised gains	664,606	-
	<b>704,766</b>	<b>254,475</b>

## 3. Cash and Cash Equivalents

	31 December 2021 \$	30 June 2021 \$
Cash on hand	10	10
Cash at bank	54,797,847	70,884,973
Cash on deposit	186,207	150,000
	<b>54,984,064</b>	<b>71,034,983</b>

## 4. Trade and Other Receivables

	31 December 2021 \$	30 June 2021 \$
GST receivable	60,207	94,290
Interest receivable	6,751	678
R&D tax incentive receivable	7,077,840	8,392,122
Trade receivables	11,000	20,550
	<b>7,155,798</b>	<b>8,507,640</b>

## 5. Intangible Assets

	31 December 2021 \$	30 June 2021 \$
Patents	9,926,366	9,926,366
Less: accumulated amortisation and impairment losses	(6,978,778)	(6,978,778)
<b>Total intangible assets</b>	<b>2,947,588</b>	<b>2,947,588</b>
<b>Reconciliation</b>		
Carrying amount at the beginning of the period	2,947,588	2,947,588
Additions during the period	-	850
Amortisation expense	-	(850)
<b>Balance at the end of the financial year</b>	<b>2,947,588</b>	<b>2,947,588</b>

## 6. Right-of-use Assets

	31 December 2021 \$	30 June 2021 \$
Land and buildings – right-of-use	967,258	967,258
Less: Accumulated depreciation	(376,156)	(295,549)
	<b>591,102</b>	<b>671,709</b>

## 7. Trade and Other Payables

	31 December 2021 \$	30 June 2021 \$
Trade creditors	4,328,598	2,973,357
Accruals and other creditors	8,997,602	2,013,083
	<b>13,326,200</b>	<b>4,986,440</b>

Other creditors include payroll tax payable, superannuation payable, bonus payable and PAYG withheld tax payable.

## 8. Issued Capital

	31 December 2021 Number of Shares	30 June 2021 Number of Shares	31 December 2021 \$	30 June 2021 \$
<b>Ordinary shares – fully paid</b>	<b>232,305,798</b>	<b>229,905,798</b>	<b>147,068,972</b>	<b>146,989,484</b>
Movements in ordinary share capital				
<b>Details</b>	<b>Shares</b>	<b>\$</b>		
Balance as at 1 July 2021	229,905,798	146,989,484		
Shares issued under ESP	2,700,000	-		
ESP shares lapsed in the period	(300,000)	-		
Limited recourse loan repaid under ESP	-	79,488		
<b>Balance as at 31 December 2021</b>	<b>232,305,798</b>	<b>147,068,972</b>		

For personal use only

# Notes to Financial Statements

31 December 2021

continued

## 9. Share-based Payment Reserve

	31 December 2021 \$	30 June 2021 \$
Balance as at the beginning of the period	6,453,995	3,585,189
Fair values of shares issued/to be issued to eligible employees under the ESP	1,578,755	3,206,309
ESP options lapsed in the period	(335,705)	-
Transfer from share reserve on exercise of options	(59,771)	(337,503)
	<b>7,637,274</b>	<b>6,453,995</b>

Once an offer of shares under the Employee Share Plan (**ESP**) is approved by the Board, monies are loaned by the Consolidated entity interest free and on a non-recourse basis to employees to finance the purchase of shares in the Company. The ESP shares are registered in the name of participants. Shares offered under the ESP are subject to a 3 year vesting period where the shares will vest in 3 equal amounts. The shares are subject to a restriction on disposal for a period of 5 years (from date of issue) and for further periods whilst they remain financed. On cessation of employment, the entitlement to any shares held for less than three years is pro-rated.

On 10 September 2021, an invitation of ESP shares of 2,700,000 based on financial year 2021 performance was approved and issued at a price of \$2.41 per share. These shares were issued with vesting conditions. Each tranche of shares will vest in 12 months, 24 months and 36 months.

Fair values at loan date are determined using a Binomial Hedley pricing model that takes into account the issue price, the term of the loan, the share price at loan date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the loan.

ESP Shares	Grant date	Vesting condition	Number
September 2021	10/09/2021	900,000 shares are vested on 10 September 2022, 900,000 shares are vested on 10 September 2023 and 900,000 shares are vested on 10 September 2024	2,700,000

### 31 December 2021

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Expired/forfeited	Balance at the end of the year
7/11/2019	7/11/2024	\$2.93	2,791,146	-	(240,000)	-	2,551,146
10/07/2020	10/07/2025	\$3.24	2,215,000	-	-	(300,000)	1,915,000
19/11/2020	19/11/2025	\$3.05	1,100,000	-	-	-	1,100,000
10/09/2021	10/09/2026	\$2.41	-	2,700,000	-	-	2,700,000
			<b>6,106,146</b>	<b>2,700,000</b>	<b>(240,000)</b>	<b>(300,000)</b>	<b>8,266,146</b>

### 30 June 2021

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Expired/forfeited	Balance at the end of the year
7/11/2019	7/11/2024	\$2.93	2,913,518	-	(175,000)	52,628	2,791,146
10/07/2020	10/07/2025	\$3.24	-	2,215,000	-	-	2,215,000
19/11/2020	19/11/2025	\$3.05	-	1,100,000	-	-	1,100,000
			<b>2,913,518</b>	<b>3,315,000</b>	<b>(175,000)</b>	<b>52,628</b>	<b>6,106,146</b>

For the ESP granted during the current financial year, the valuation model inputs used to determine the fair value at the grant date, are as follow:

Grant date	Expiry date	Share price at grant date	Exercise price	Expected volatility	Dividend yield	Risk-free rate	Fair value at grant date
10/09/2021	10/09/2026	\$1.93	\$2.41	75.00%	0.00%	0.65%	\$0.99

## UNLISTED OPTIONS

### 31 December 2021

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Balance at the end of the year
24/03/2020	24/03/2023	\$1.75	550,000	-	-	550,000
28/02/2020	28/02/2023	\$1.75	275,000	-	-	275,000
			<b>825,000</b>	-	-	<b>825,000</b>

### 30 June 2021

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Balance at the end of the year
24/03/2020	24/03/2023	\$1.75	550,000	-	-	550,000
28/02/2020	28/02/2023	\$1.75	275,000	-	-	275,000
			<b>825,000</b>	-	-	<b>825,000</b>

## 10. Loss Per Share

	31 December 2021	31 December 2020
Net loss for the period attributable to ordinary shareholders	(26,985,037)	(20,730,495)
	<b>Number</b>	Number
Weighted average number of ordinary shares used in calculating basic loss per share	231,279,568	227,745,785
Weighted average number of ordinary shares used in calculation diluted loss per share	<b>231,279,568</b>	<b>227,745,785</b>
	<b>Cents</b>	Cents
Basic loss per share	(11.8)	(9.1)
Diluted loss per share	(11.8)	(9.1)

825,000 unexercised options (Period ended 31 December 2020: 1,561,250) have been excluded from the calculation of the diluted loss per share above as it would have an anti-dilutive impact.

For personal use only

# Notes to Financial Statements

31 December 2021

continued

## 11. Reconciliation of Cash Flows Provided by Operating Activities

	31 December 2021	31 December 2020
<b>Loss for the half-year</b>	<b>(26,985,037)</b>	<b>(20,730,495)</b>
Depreciation and amortisation	96,868	103,183
Foreign exchange unrealised losses	(691,421)	
Share-based payment	1,578,755	1,351,819
Change in operating assets and liabilities		
(Increase)/decrease in trade receivables	1,460,531	(12,964)
(Increase)/decrease in other receivables	(6,073)	24,917
(Increase) in other assets	(304,474)	(1,716,579)
Decrease in payables	7,905,008	1,585,383
Decrease in provisions	217,376	113,497
<b>Net cash used in operating activities</b>	<b>(16,728,467)</b>	<b>(19,281,239)</b>

## 12. Contingent Liabilities

The Consolidated entity had no contingent liabilities as the reporting date (30 June 2021: nil).

## 13. Events Subsequent to Reporting Date

The impact of the Coronavirus (**COVID-19**) pandemic is ongoing for the Consolidated Entity up to 31 December 2021. It is not practicable to estimate the potential impact, positive or negative, after the reporting date. The situation is rapidly developing and is dependent on measures imposed by the Australian Government and other countries, such as maintaining social distancing requirements, quarantine, travel restrictions and any economic stimulus that may be provided.

No other matter or circumstance has arisen since 31 December 2021 that has significantly affected, or may significantly affect the Consolidated entity's operations, the results of those operations, or the Consolidated entity's state of affairs in future financial years.

# Directors' Declaration

31 December 2021

In the Directors' opinion:

- the attached financial statements and notes comply with the *Corporations Act 2001*, Australian Accounting Standard AASB 134 'Interim Financial Reporting', the *Corporations Regulations 2001* and other mandatory professional reporting requirements;
- the attached financial statements and notes give a true and fair view of the Consolidated Entity's financial position as at 31 December 2021 and of its performance for the financial half-year ended on that date; and
- there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of Directors made pursuant to Section 303(5)(a) of the *Corporations Act 2001*.

On behalf of the Directors



**Mr Paul Rennie**  
Chairman  
24 February 2022

For personal use only



# Independent Auditor's Review Report

31 December 2021



## RSM Australia Partners

Level 21, 55 Collins Street Melbourne VIC 3000  
PO Box 248 Collins Street West VIC 8007

T +61(0) 3 9286 8000  
F +61(0) 3 9286 8199

[www.rsm.com.au](http://www.rsm.com.au)

## INDEPENDENT AUDITOR'S REVIEW REPORT TO THE MEMBERS OF PARADIGM BIOPHARMACEUTICALS LIMITED

### Conclusion

We have reviewed the accompanying half-year financial report of Paradigm Biopharmaceuticals Limited ('the Company') and the entities it controlled during the period (together 'the Consolidated entity'), which comprises the consolidated statement of financial position as at 31 December 2021, the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory notes, 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 accompanying half-year financial report of Paradigm Biopharmaceuticals Limited does not comply with the *Corporations Act 2001* including:

- (a) 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 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 Financial Report* section of our report. We are independent of the Consolidated entity 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.

We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to the directors of Paradigm Biopharmaceuticals Limited, would be in the same terms if given to the directors as at the time of this auditor's review report.

## THE POWER OF BEING UNDERSTOOD AUDIT | TAX | CONSULTING

RSM Australia Partners is a member of the RSM network and trades as RSM. RSM is the trading name used by the members of the RSM network. Each member of the RSM network is an independent accounting and consulting firm which practices in its own right. The RSM network is not itself a separate legal entity in any jurisdiction.

RSM Australia Partners ABN 36 965 185 036

Liability limited by a scheme approved under Professional Standards Legislation

For personal use only



*Directors' Responsibility for the Half-Year Financial Report*

The directors of Paradigm Biopharmaceuticals Limited 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 for the Review of the 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 Consolidated entity's financial position as at 31 December 2021 and of 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.

A handwritten signature in black ink that reads 'RSM'.

**RSM AUSTRALIA PARTNERS**

A handwritten signature in black ink that reads 'R J Morillo Maldonado'.

**R J MORILLO MALDONADO**  
Partner

24 February 2022  
Melbourne, Victoria

For personal use only

# Corporate Directory

## Directors

### Mr Paul Rennie

Managing & Executive Director

### Dr Donna Skerrett

Executive Director

(Appointed on 3 July 2020)

### Mr John Gaffney

Non-Executive Director

### Mr Amos Meltzer

Non-Executive Director

(Appointed on 9 December 2020)

### Ms Helen Fisher

Non-Executive Director

(Appointed on 23 February 2021)

## Company Secretary

Mr Kevin Hollingsworth

## Principal Place of Business

Level 15, 500 Collins Street

Melbourne VIC 3000

## Registered Office

Level 15, 500 Collins Street

Melbourne VIC 3000

## Auditor

RSM Australia Partners

Level 21, 55 Collins Street

Melbourne VIC 3000

## Solicitors

K&L Gates

Level 25, South Tower

525 Collins Street

Melbourne VIC 3000

## Share Registry

Computershare Limited

Yarra Falls, 452 Johnston Street

Abbotsford VIC 3067

Telephone: (61-3) 1300 137 328

## Bankers

Commonwealth Bank

Level 20, Tower One

Collins Square

727 Collins Street

Melbourne VIC 3008

## Stock Exchange

ASX Limited

Level 4, North Tower

525 Collins Street

Melbourne VIC 3000

ASX Code: **PAR**

## Website

[www.paradigmbiopharma.com](http://www.paradigmbiopharma.com)

For personal use only

For personal use only

For personal use only