Paradigm Biopharmaceuticals Limited
Appendix 4D
Half-year report

1. Company details

Name of entity:	Paradigm Biopharmaceuticals Limited
ABN:	94 169 346 963
Reporting period:	31 December 2022
Previous reporting period:	31 December 2021

2. Results for announcement to the market

	$	**$ and % increase/(decrease) over previous corresponding period**
Revenue from continuing activities	1,188,845	438,879 58.52%
(Loss) from continuing activities after tax attributable to members	(31,867,427)	4,882,390 18.09%
Net (loss) for the period attributable to members	(31,921,451)	4,909,600 18.18%
Dividends (distributions)	**Amount per security**	**Franked amount per security**
Final Dividend	N/A	N/A
Interim Dividend	N/A	N/A
Record date for determining entitlements to the dividends (if any)	N/A	

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, losses before tax 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 2022, Paradigm Biopharmaceuticals achieved a number of exciting developments, starting with a successful $66MAUD capital raise in August 2022. Recruitment in the phase 3 study PARA_OA_002 continued to progress in the six months to December 2022 with the first formal safety review of the study successfully conducted in December 2022. The first subject was enrolled in the observational follow up study PARA_OA_006, following completion of day 168 follow-up of PARA_OA_002. The Company also announced positive top line data from the phase 2 PARA_OA_008 study in October 2022. The six month follow up data from the PARA_OA_008 study is due to be released in Q1CY23. The phase 2 study for Mucopolysaccharidosis type VI (MPS VI) completed a successful safety review. Following the safety review, a cohort of subjects aged 5 to 9 are now eligible to be enrolled in the study.

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3. Net tangible assets

	Current Period	Previous corresponding period
Basic loss per ordinary security (cents per share)	(11.29) cents	(11.8) cents
Diluted loss per ordinary security (cents per share)	(11.29) cents	(11.8) cents
Net tangible asset backing per ordinary security (cents per share)	25.06 cents	21.51 cents

4. Control gained over entities

Not applicable.

5. Loss of control over entities

Not applicable.

6. Audit qualification or review

This report is based on accounts to which one of the following applies: (Tick one)			
The accounts have been reviewed	✓	The accounts are in the process of being reviewed	
If the accounts are subject to audit dispute or qualification, a description of the dispute or qualification: N/A			

7. Attachments

The report of half year ended 31 December 2022 is attached.

8. Signed

Signed _____

Mr. Paul Rennie
Managing Director
27th February 2023

PARADIGM
BIOPHARMA

Half-Year Report
31 December
2022

Innovative treatments in medicine

Contents

Paradigm Biopharmaceuticals Ltd. (ASX:PAR) is a late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies. Paradigm's current focus is developing iPPS for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of PPS, such as in osteoarthritis (phase 3) and mucopolysaccharidosis (phase 2).

OA Program

Current Locations
- United States
- Australia
- United Kingdom

Potential Locations
- Canada – near term
- Belgium – CY23
- Czechia – CY23
- Poland – CY23

General Information

The Financial Statements cover Paradigm Biopharmaceuticals Limited as a Consolidated entity consisting of Paradigm Biopharmaceuticals Limited and the entities it controlled at the end of, or during, the year. 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 is included as part of the Financial Statements.

The Financial Statements were authorised for issue, in accordance with a resolution of Directors, on 25 August 2022. The Directors have the power to amend and reissue the Financial Statements.

Highlights

First subject enrolled in PARA_OA_006, the observational follow-up study from the PARA_OA_002 phase 3 pivotal study

Formal safety reviews completed on both the MPS VI phase 2 trial and PARA_OA_002 phase 3 pivotal study

Research partnership executed with NFL Alumni Health

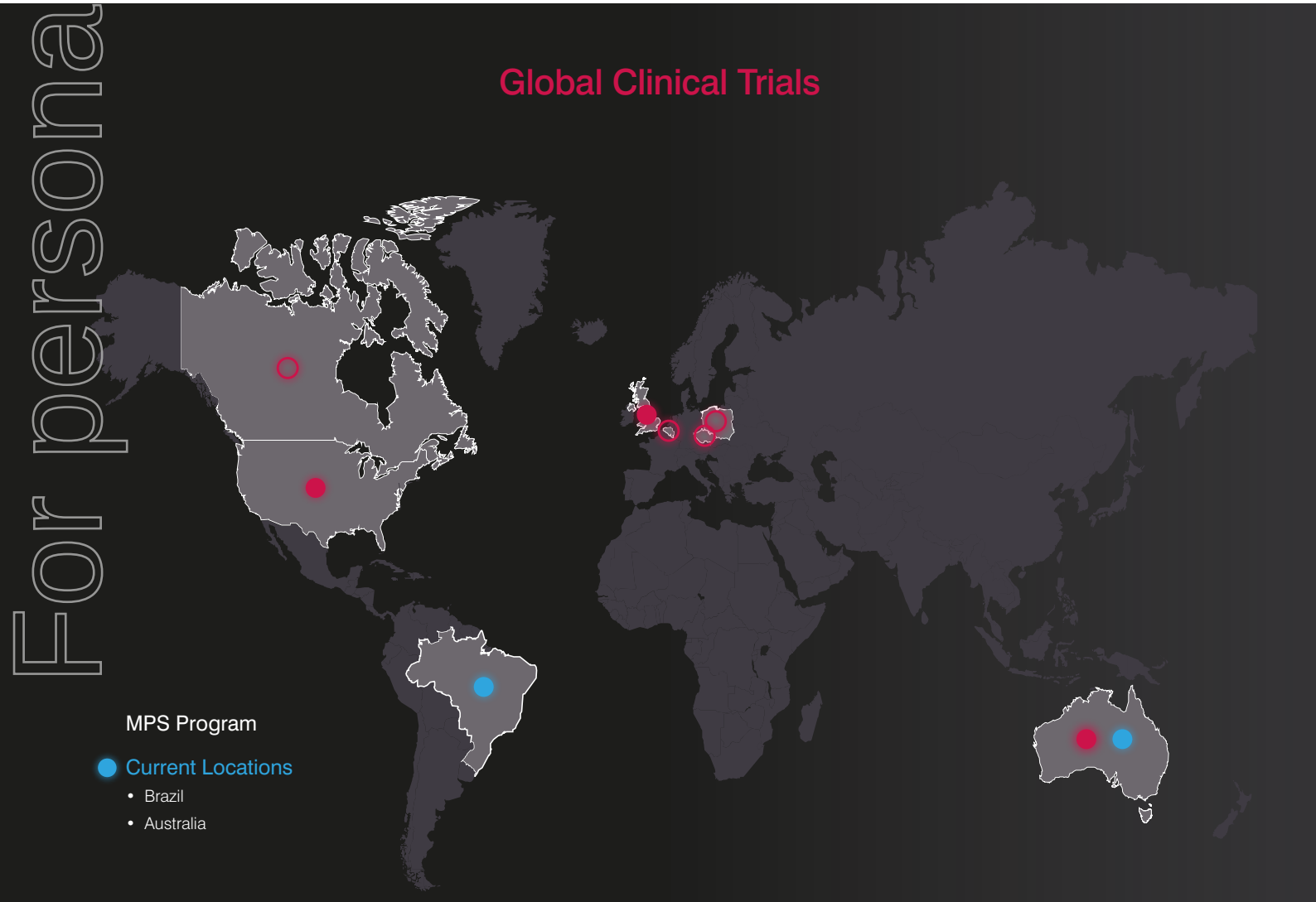
A$66m

Capital raised in August 2022

Oct 2022

Announced promising top-line results from PARA_OA_008 phase 2 study. 6-month follow-up date due Q1CY23

Global Clinical Trials



Understanding iPPS

Osteoarthritis is a painful degenerative inflammatory joint condition that progressively impacts on activities of daily living. In particular, osteoarthritis of the knee is a major cause of disability in the elderly and is currently estimated to affect over half a billion people worldwide[1]. Current treatments are solely focused on symptom management, as there are no established disease-modifying therapies[2].

To help address this significant unmet need, Paradigm is developing injectable pentosan polysulfate sodium (iPPS or Zilosul®) to reduce pain and improve mobility in people living with osteoarthritis. In 2022, Paradigm received Fast Track designation from the US FDA to accelerate the development pathway, with an initial focus on osteoarthritis of the knee. A significant part of the drug development process is clinical studies, used to establish the effectiveness, safety and dosing profiles of a new medication, and preclinical studies, to understand more about the potential mechanism of action.

Investigating the Disease-modifying Effects of iPPS in Human Osteoarthritis

Following on from a phase 2 trial examining the effect of iPPS on knee pain and bone marrow lesions in people with knee osteoarthritis (PARA_OA_005), Paradigm has undertaken another phase 2, randomised, double-blinded, placebo-controlled clinical trial in 61 people with knee osteoarthritis. This study (PARA_OA_008) examines the effect of 6 weeks of iPPS treatment on pain and function scores, as well as its potential disease-modifying effect on biomarkers from the knee joint space (synovial fluid) at 8 weeks (day 56) and 6 months (day 168) from the start of treatment. Additional MRI imaging analysis will be performed at 6 months. The 6-week treatment period consisted of either twice-weekly placebo, or once-weekly iPPS and once-weekly placebo, or twice-weekly iPPS.

This clinical research would provide solid evidence that iPPS has a strong potential as a disease-modifying therapy.

From these early results, iPPS-treated patients show reductions in the levels of pro-inflammatory signalling molecules (TNF-α and IL-6), which are known to be upregulated in osteoarthritis[3,4]. Reduced levels of these inflammatory signalling molecules may in turn influence levels of the pain mediator molecule NGF, which is often increased in the synovial fluid of osteoarthritis sufferers[5,6]. COMP is a structural protein found in cartilage in the joints. Increased levels of COMP in the serum have been correlated with degraded knee joint surfaces as seen by X-ray[7]. Similarly, increased synovial levels of the ARGS biomarker are seen in patients with osteoarthritis[8]. Both degradation by-products were reduced in the synovial fluid of iPPS-treated knee osteoarthritis patients. The last biomarker, TIMP-1, is a naturally occurring inhibitor of cartilage-degrading enzymes. An increased level in iPPS-treated patients may contribute to the slowing of the disease process.

Additionally, in patients treated with twice-weekly iPPS, their mean percentage change from baseline in self-reported Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC®) pain assessment scores was 50%, compared to 30% for placebo. For self-reported WOMAC functional assessment scores, patients treated with iPPS had mean percentage changes from baseline of 50%, compared to 25% for placebo.

These early pain and function results are consistent with those from the previous PARA_OA_005 clinical trial, and response to treatment gathered from real-world evidence where osteoarthritis sufferers have been prescribed Zilosul® via the TGA special access scheme (SAS). The pain and function scores, as well as the newly acquired data on biomarker impact, provide compelling results indicating that iPPS improves outcomes in patients with knee osteoarthritis through myriad potential mechanisms, including via inflammation, pain and chrondroprotective pathways. Should these positive biomarker effects continue through to the 6-month timepoint (first half of 2023), this clinical research would provide solid evidence that iPPS has a strong potential as a disease-modifying therapy.

Analysis of top-line day 56 biomarker results was reported in early October 2022.

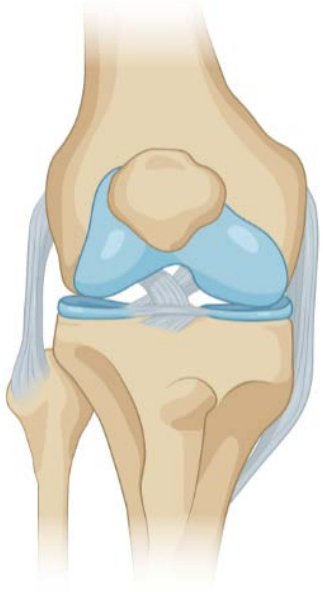
Synovial biomarker	Function	Effect of iPPS versus placebo
IL-6	Pro-inflammatory cytokine	Reduced
TNF-α	Pro-inflammatory cytokine	Reduced
NGF	Pain mediator	Reduced
COMP	By-product of cartilage degradation	Reduced
ARGS	By-product of cartilage degradation	Reduced
TIMP-1	Inhibitor of cartilage degradation	Increased

PPS attenuates the NGF pain pathway[5]

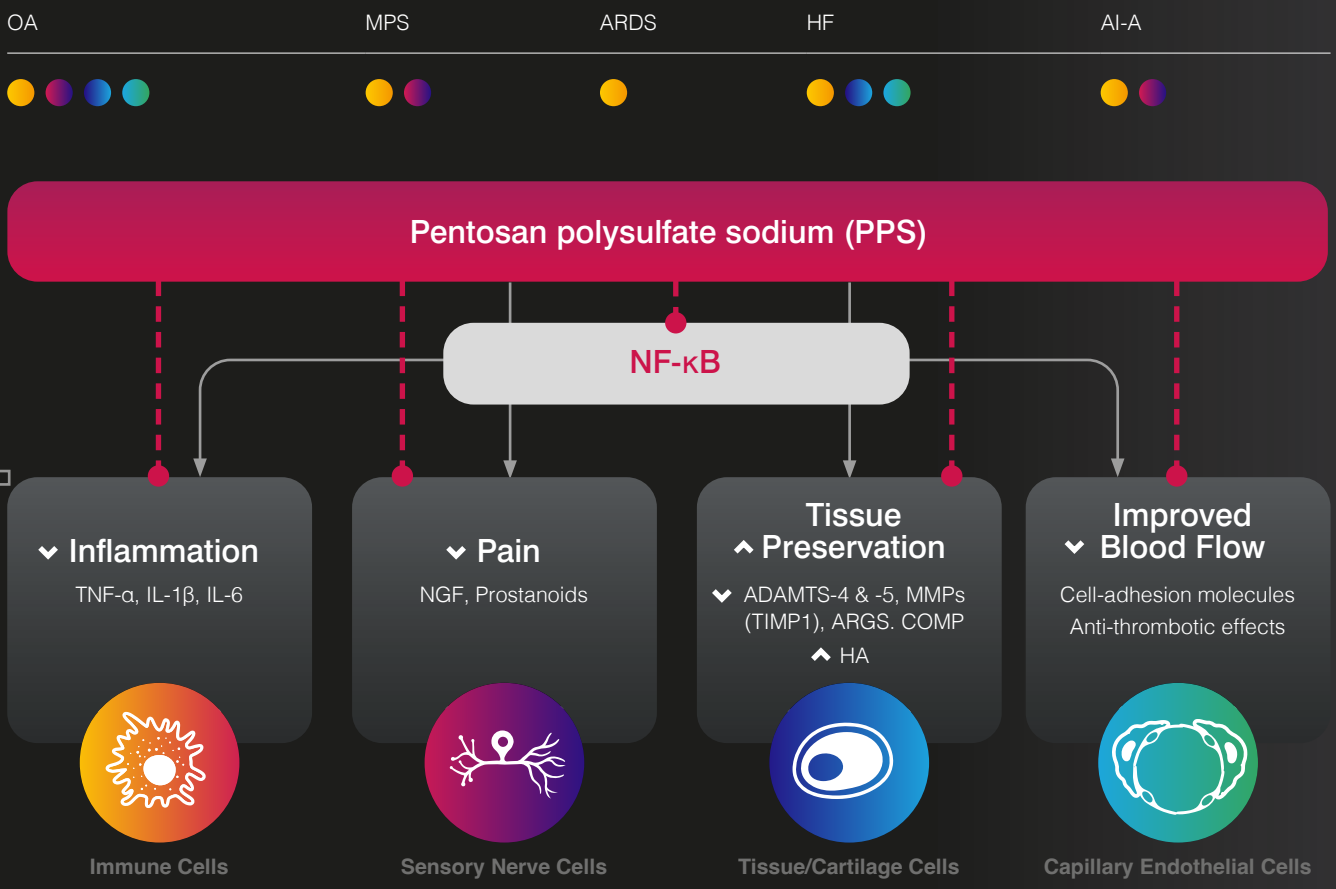
PPS reduces inflammation[9]

PPS decreases activity of enzymes that degrade bone and cartilage[10]

PPS improves blood flow[11]



Current hypothesis for PPS mechanism of action



Legend: OA osteoarthritis; MPS mucopolysaccharidosis; ARDS acute respiratory distress syndrome; HF heart failure; AI-A alphavirus-induced arthralgia; SAS Special Access Scheme; EAP Early Access Program; TNF-α tumour necrosis factor alpha; IL-1b interleukin-1b; IL-6 interleukin-6; NGF nerve growth factor; ADAMTS-4 & -5 A disintegrin and metalloproteinase with thrombospondin motifs 4 & 5; MMPs matrix metalloproteinases; ARGS alanine-arginine-glycine-serine aggrecan; TIMP1 tissue inhibitor of metalloproteinases 1; COMP cartilage oligomeric matrix protein; HA hyaluronic acid. References: [12, 13,14,15,16,17]

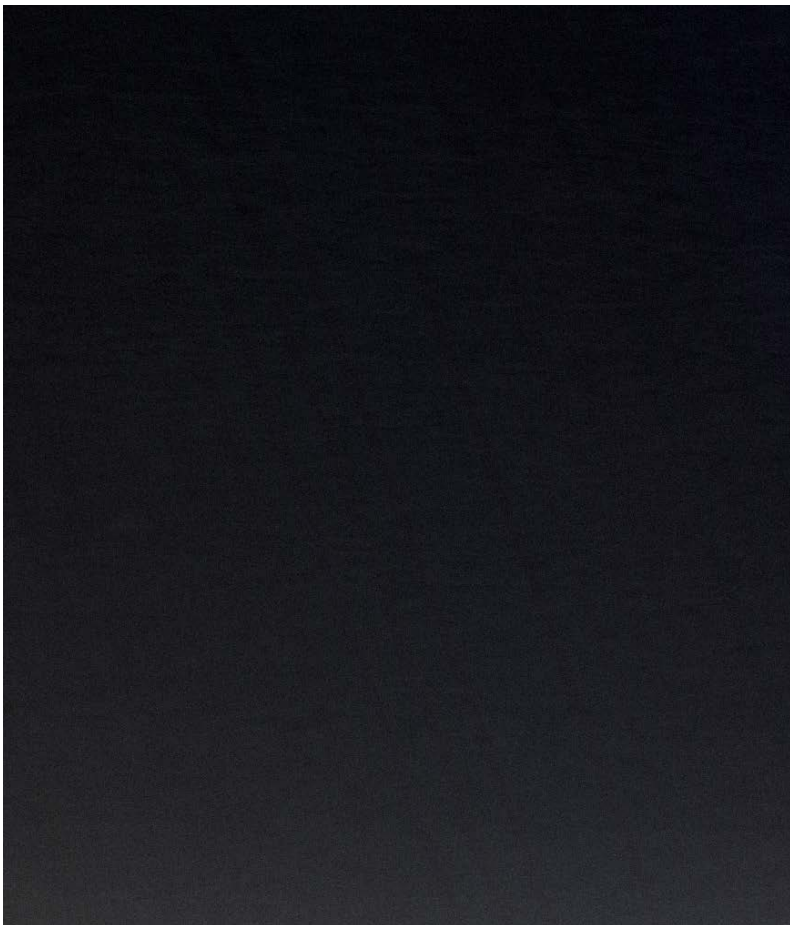
Understanding iPPS
continued

1/8

Australians have osteoarthritis[1]

>500m

People worldwide have knee osteoarthritis[1]



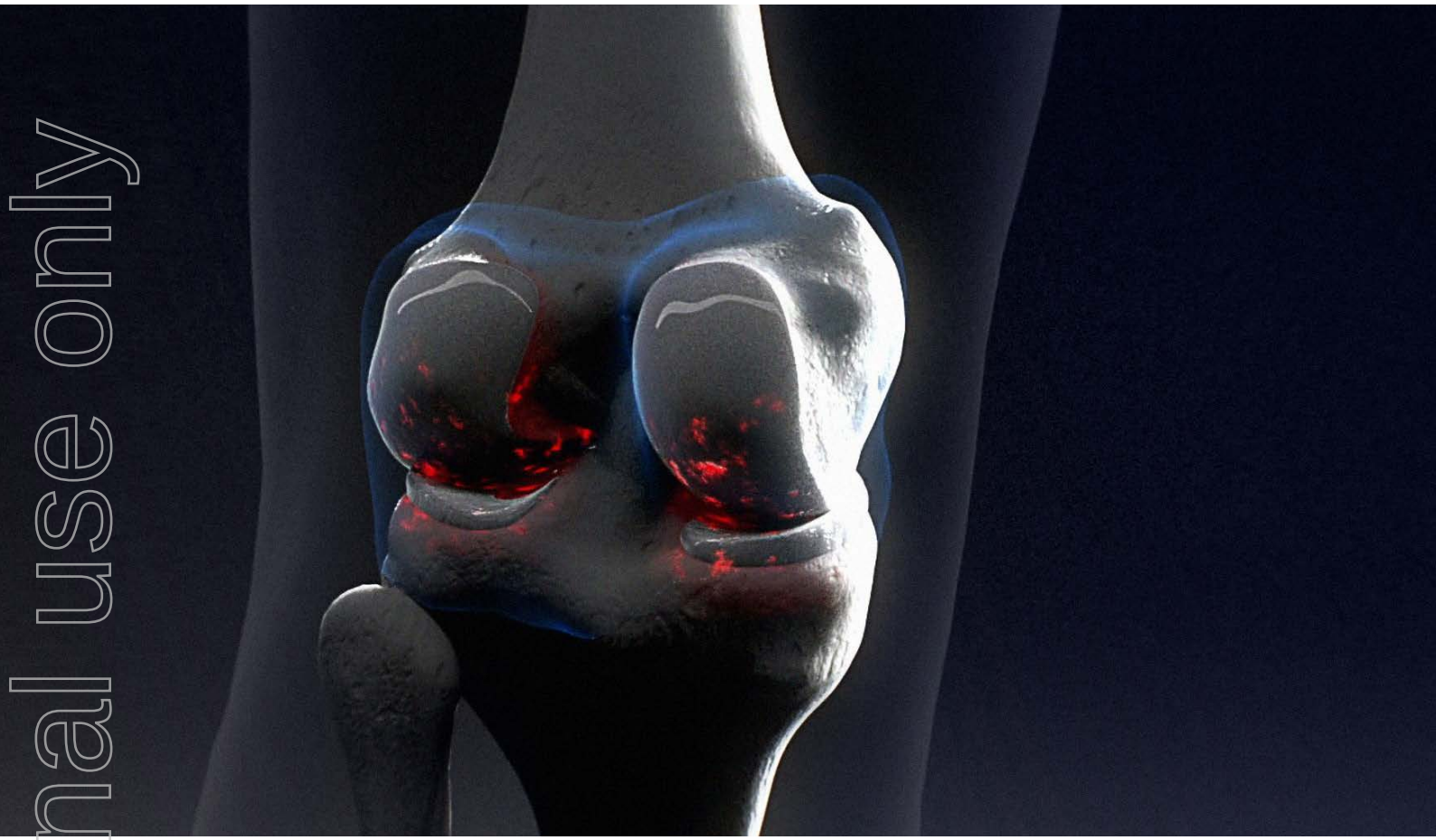
Confirming the iPPS Mechanism and Potential Disease Modification Outcomes in a Canine Model

This ongoing animal study invited members of the public to register their pet dogs for the trial if their dogs had naturally occurring osteoarthritis of the knee/stifle (hind limb) or elbow (front limb) confirmed by clinical assessment or X-ray. Dogs were randomised 2:1 into an iPPS treatment or saline (placebo) group with assessments before the trial, at week 8 (2 weeks after treatment completed), and at week 26. This study will offer further insight into the iPPS mechanism of action as synovial and serum biomarkers are also being investigated, in addition to joint function and imaging analysis at week 26.

Early results indicate that serum and synovial biomarker changes followed the same encouraging trends as the human clinical trial. Animals will undergo continued monitoring throughout the study and results will be interpreted and compared to results from the human PARA_OA_008 trial.

Canine osteoarthritis is a progressive degenerative disorder with pathology and risk factors that mimic those of humans. As the dog's lifespan is shorter than humans, all stages of development from birth to adulthood through to ageing are represented over a compressed timeframe. Therefore, this short-term canine model could provide an insight into what may happen within the human knee over approximately 3 years. This study will provide valuable translational data on the potential duration of clinical effect.

While osteoarthritis remains a significant burden worldwide, these promising early results provide hope that a disease-modifying osteoarthritis therapy might be a step closer to a reality.



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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 2022.

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 6-month period ended 31 December 2022 of $31,867,427 (31 December 2021: loss of $26,985,037).

Review of Operations

On 15 August 2022, Paradigm announced a fully underwritten capital raise of $66MAUD, which comprised a $45.7MAUD institutional placement and a 1 for 15 pro-rata non-renounceable entitlement offer of $20.3MAUD, raised at $1.30 per share. The placement received strong participation from domestic and offshore institutional investors. Following the completion of the placement, Allianz SE became a substantial holder.

On 26 September 2022, Paradigm announced the completion of a safety review into the phase 2 study being conducted in Brazil for mucopolysaccharidosis type VI (MPS VI). The safety monitoring physician confirmed a safety review was completed with no serious adverse events reported in the 9- to 16-year-old cohort. Following enzyme replacement therapy (ERT), MPS patients, often children, continue to experience joint pain and stiffness that limit their mobility and function. Early therapeutic intervention is critical in the paediatric population to improve the debilitating symptoms that remain. Therefore, this safety review is a pleasing milestone for this study, which now allows for the inclusion of subjects aged 5 to 9 years to assess the safety and tolerability of iPPS in this younger paediatric population. In addition to these positive safety review results, the Company announced an abstract of our phase 2 study in MPS type VI was accepted for a poster presentation at the WORLD*Symposium*™ in February 2023. The WORLD*Symposium*™ is one of the largest annual research conferences focused on new therapies for lysosomal storage diseases, such as MPS VI. Professor Roberto Giugliani MD, PhD, MSc, the Principal Investigator of Paradigm's phase 2 MPS VI study, will be presenting the poster.

On the 4 October 2022, Paradigm provided an update on top-line results from the phase 2 osteoarthritis study, PARA_OA_008. The top-line day 56 data was analysed by an independent clinical research organisation and demonstrated favourable synovial fluid biomarker change from baseline for the iPPS treatment group. The observed biomarker changes indicate potential mechanistic effects through pain, inflammation and chondroprotective pathways. In addition to the favourable biomarker data, Western Ontario and MacMaster Universities osteoarthritis (OA) Index (WOMAC) data was also collected from baseline. iPPS treatment showed statistically significant improvements at day 56 in pain, function, stiffness and overall WOMAC scores for twice-weekly iPPS compared to the placebo arm. The proportions of patients achieving ≥30% and ≥50% improvement in pain were 73% and 60% respectively. The results showed that iPPS was well tolerated in this randomised, placebo-controlled study. There were no serious adverse events and no adverse events of special interest in any patient receiving iPPS or placebo.

Paradigm also announced preliminary data from 9 dogs treated with iPPS in the ongoing canine model of naturally occurring osteoarthritis. Initial data in this study demonstrates a trend towards functional improvement in osteoarthritic dogs following iPPS treatment, as well as a trend towards reductions in cartilage-degrading biomarkers both locally within the joint (synovial fluid) and systemically (serum).

The PARA_OA_008 phase 2 clinical trial will continue to monitor trial participants following treatment out to 6- and 12-month timepoints. The 6-month timepoint will provide further data on the duration of effect of iPPS on WOMAC pain and function compared to placebo, in addition to observations on changes to the joint structure via MRI of iPPS-treated subjects compared to placebo. Secondary and exploratory endpoints on synovial fluid biomarkers will also be analysed. Paradigm expects to report on the 6-month data in Q1 CY2023.

A number of other exciting developments relating to the phase 3 clinical program of osteoarthritis were achieved in the 6 months to December 2022. Our first UK subject was randomised in October 2022 following the establishment and activation of UK trial sites. A research partnership was executed with NFL Alumni Health in the US. The partnership hopes to inform NFL Alumni members about osteoarthritis (OA) and how to participate in the clinical trial. In December 2022, an abstract detailing day 56 results from the phase 2 synovial fluid biomarker clinical trial PARA_OA_008 was accepted for a poster presentation at the 2023 Osteoarthritis Research Society International (OARSI) World Congress on Osteoarthritis. Also in December, Paradigm announced the results from the first safety review meeting of the Data Monitoring Committee (DMC) for the pivotal PARA_OA_002 clinical trial. The DMC review of trial progress and safety data concluded that the PARA_OA_002 clinical trial should proceed without modification.

In terms of financial performance, Paradigm recorded a loss before tax of $31,867,427, an increase on the prior corresponding period loss before tax of $4,882,390. Paradigm Biopharmaceuticals Limited is a late-stage clinical development company with a phase 3 asset under development for treatment of osteoarthritis. In the absence of partnering income or

A number of other exciting developments relating to the phase 3 clinical program of osteoarthritis were achieved in the 6 months to December 2022.

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 2022 of $4,710. 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 and resource allocation remains focused on the clinical program.

The increase in loss before tax compared to the prior corresponding period of $4,882,390 is mainly driven by research and development costs. The 2 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 to meet New Drug Application (NDA) requirements. Paradigm is working on completing these studies concurrently with clinical studies in MPS and OA. These studies are multi-year studies that are currently being undertaken to ensure that the data are available and understood prior to NDA filing to de-risk the process. The toxicity studies are one-time studies that can be used to support iPPS investigations in other indications involving subcutaneous delivery and similar dosing regimens.

The other business area in which activity increased compared to the prior period was within clinical development. Clinical development costs relating to MPS increased on the prior corresponding period due to increased costs associated with patient enrolment in the MPS VI phase 2 study. Clinical development costs associated with Paradigm's lead asset, Zilosul®, increased over the prior corresponding period due to:

- Increased recruitment and treatment costs for the PARA_OA_002 pivotal study as subject enrolment continues to progress.
- Increased expenditure associated with PARA_OA_008 with respect to subject monitoring and analytical costs related to the top-line data that was released on 4 October 2022.
- Increased expenditure in the PARA_OA_006 study, the observational follow-on study from PARA_OA_002 relating to study setup and first subject enrolment.
- Milestone payments to our Clinical Research Organisations (CRO) related to progressing the overall clinical OA development program.

Other income is higher for the 6 months to December 2022 mainly due to the FY22 R&D tax incentive claim received in November 2022 being higher than estimated at June 30 2022. Interest received has increased due to having higher funds on deposit following the successful capital raise, in addition to improved interest rates on deposit accounts. Administration costs increased compared to the prior corresponding period due to increased head count to support organisational growth, increased business development-related expenditure and one-off administration costs. Included in the one-off administration costs are costs associated with the transition of the CEO role in November 2022.

After appointing Mr Marco Polizzi as CEO on 1 July 2022, Mr Polizzi stood down from his position as CEO on the 22 November 2022. Mr Paul Rennie, Paradigm's founder and non-Executive Chair of the board was appointed as Managing Director.

In the second half of FY23, Paradigm has a number of exciting and important deliverables as the Company continues to execute on its development strategy for iPPS. Paradigm expects to provide an update on data (WOMAC pain and function, MRI and biomarker analysis) from the PARA_OA_008 phase 2 study, where the 6-month follow-up data is expected to be released in Q1CY23. Complete 20-week follow-up data (3-year human equivalent) from the canine OA model is due in 1HCY23, and will likely provide further insight into how iPPS impacts osteoarthritis. It is expected that recruitment for the first stage of the adaptive PARA_OA_002 phase 3 study will be 100% complete in 1HCY23. The Company also expects additional updates to be provided on further IP generation and business development activities relating to partnering assets from our asset pipeline.

Before closing, I would like to recognise the contribution made to Paradigm by Mr Kevin Hollingsworth. Kevin was the Company's long-standing Company Secretary, who passed away in August 2022. Kevin had been with Paradigm since its ASX listing in 2015, and was instrumental in establishing the organisation through its founding years.

Significant Changes in the State of Affairs

On the 15 August 2022, the Company announced a $66MAUD capital raise.

No matters or circumstances have arisen since 31 December 2022 that have 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 periods.

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
Managing Director
27 February 2023

Auditor's Independence Declaration

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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 2022, 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

27 February 2023
Melbourne, Victoria

Consolidated Interim Statement of Profit or Loss and Other Comprehensive Income

for the half-year ended 31 December 2022

	Notes	31 December 2022 $	31 December 2021 $
Revenue from continuing operations		4,710	45,200
Cost of sales		(7,361)	(70,647)
Other income	2	1,184,135	704,766
Other expenses		(284,493)	-
Research and development expenses		(27,729,766)	(23,449,532)
General and administration expenses		(4,563,413)	(3,780,668)
Commercial expenses		(462,485)	(419,794)
Finance costs		(8,754)	(14,362)
Loss before income tax		**(31,867,427)**	**(26,985,037)**
Income tax expense/(benefit)		-	-
Loss for the half-year		**(31,867,427)**	**(26,985,037)**
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss			
Foreign currency translation		(54,024)	(26,814)
Other comprehensive loss for the half-year, net of tax		**(54,024)**	**(26,814)**
Total comprehensive (loss) attributable to members of the Consolidated entity		**(31,921,451)**	**(27,011,851)**
Loss per share (cents)			
Basic and diluted (loss) per share	10	(11.29) cents	(11.8) 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 2022

	Notes	31 December 2022 $	30 June 2022 $
ASSETS			
Current assets			
Cash and cash equivalents	3	83,926,269	39,674,413
Trade and other receivables	4	265,435	6,718,798
Prepaid expenses		952,412	730,715
Financial assets held at amortised cost		-	46,200
Total current assets		**85,144,116**	**47,170,126**
Non-current assets			
Intangible assets	5	2,947,588	2,947,588
Plant and equipment		51,555	60,657
Right-of-use assets	6	361,591	510,498
Total non-current assets		**3,360,734**	**3,518,743**
Total assets		**88,504,850**	**50,688,869**
LIABILITIES			
Current liabilities			
Trade and other payables	7	13,668,427	7,088,279
Employee benefits		681,186	594,955
Lease liabilities		102,001	147,758
Total current liabilities		**14,451,614**	**7,830,992**
Non-current liabilities			
Employee benefits		99,740	76,355
Lease liabilities		287,781	468,911
Total non-current liabilities		**387,521**	**545,266**
Total liabilities		**14,839,135**	**8,376,258**
Net assets		**73,665,715**	**42,312,611**
EQUITY			
Issued capital	8	209,549,632	147,194,772
Share-based payments reserve	9	8,621,790	9,261,765
Currency translation reserve		(182,406)	(128,382)
Accumulated losses		(144,323,301)	(114,015,544)
Total equity		**73,665,715**	**42,312,611**

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 Changes in Equity

for the half-year ended 31 December 2022

	Issued Capital $	Share Option Reserve $	Accumulated Losses $	Currency Translation Reserve $	Total $
Balance at 1 July 2021	146,989,484	6,453,995	(75,228,227)	58,034	78,273,286
Loss for the period	-	-	(26,985,037)	-	(26,985,037)
Other comprehensive (loss)	-	-	-	(26,814)	(26,814)
Total comprehensive (loss) for the half-year	-	-	(26,985,037)	(26,814)	(27,011,851)
Transactions with owners in their capacity as owners:					
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
Balance at 31 December 2021	**147,068,972**	**7,637,274**	**(101,817,788)**	**31,220**	**52,919,678**
Balance at 1 July 2022	**147,194,772**	**9,261,765**	**(114,015,544)**	**(128,382)**	**42,312,611**
Loss for the period	-	-	(31,867,427)	-	(31,867,427)
Other comprehensive (loss)	-	-	-	(54,024)	(54,024)
Total comprehensive (loss) for the half-year	-	-	(31,867,427)	(54,024)	(31,921,450)
Transactions with owners in their capacity as owners:					
Fair value of shares issued to eligible employees under the plan	-	919,695	-	-	919,695
ESP lapsed in the period	-	(1,518,174)	1,518,174	-	-
Transfer from share-based payments reserve on exercise of options	-	(41,496)	41,496	-	-
Shares issued relating to repayment of limited recourse loan for ESP	132,090	-	-	-	132,090
Shares issued under placement	45,678,599	-	-	-	45,678,599
Shares issued under rights issue	20,309,082	-	-	-	20,309,082
Payment of share issue costs	(3,764,911)	-	-	-	(3,764,911)
Balance at 31 December 2022	**209,549,632**	**8,621,790**	**(144,323,301)**	**(182,406)**	**73,665,715**

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 2022

	Note	31 December 2022 $	31 December 2021 $
Cash flows from operating activities			
Research and development and other tax incentive received		7,404,899	1,314,282
Revenue from continuing operations		23,043	54,750
Payments to suppliers and employees (inclusive of GST)		(25,329,203)	(18,117,223)
Interest received		155,700	34,086
Interest repayment of lease liabilities		(8,754)	(14,362)
Net cash outflow from operating activities	11	**(17,754,315)**	**(16,728,467)**
Cash flows from investing activities			
Proceeds for financial assets held at amortised cost		46,200	-
Net cash inflow from investing activities		**46,200**	**-**
Cash flows from financing activities			
Proceeds from share issue		65,987,681	-
Payment of share issue costs		(3,764,911)	-
Limited recourse loan repaid under ESP		132,090	79,488
Principal repayment of lease liabilities		(56,372)	(66,547)
Net cash inflow from financing activities		**62,298,488**	**12,941**
Net increase/(decrease) in cash and cash equivalents		**44,590,373**	**(16,715,526)**
Cash and cash equivalents at the beginning of the financial period		**39,674,413**	**71,034,983**
Effects of exchange rate changes on cash and cash equivalents		**(338,517)**	**664,607**
Cash and cash equivalents at the end of the financial period		**83,926,269**	**54,984,064**

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

Notes to Financial Statements

31 December 2022

1. Significant Accounting Policies

These general-purpose Financial Statements for the interim half-year reporting period ended 31 December 2022 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 2022, 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. The adoption of these Accounting Standards and Interpretations did not have any significant impact on the financial performance or position of the Consolidated entity.

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

2. Other Income

	31 December 2022 $	31 December 2021 $
Interest received	318,837	40,160
Realised gains	-	664,606
R&D tax incentive	775,890	-
Gain on lease modification	89,408	-
	1,184,135	**704,766**

3. Cash and Cash Equivalents

	31 December 2022 $	30 June 2022 $
Cash on hand	10	10
Cash at bank	83,737,759	39,524,403
Cash on deposit	188,500	150,000
	83,926,269	**39,674,413**

4. Trade and Other Receivables

	31 December 2022 $	30 June 2022 $
GST receivable	97,808	66,965
Interest receivable	167,627	4,491
R&D tax incentive receivable	-	6,629,009
Trade receivables	-	18,333
	265,435	**6,718,798**

Notes to Financial Statements

31 December 2022
continued

5. Intangible Assets

	31 December 2022 $	30 June 2022 $
Patents	9,926,366	9,926,366
Less: accumulated amortisation and impairment losses	(6,978,778)	(6,978,778)
Total intangible assets	**2,947,588**	**2,947,588**
Reconciliation		
Carrying amount at the beginning of the period	2,947,588	2,947,588
Additions during the period	-	-
Amortisation expense	-	-
Balance at the end of the financial year	**2,947,588**	**2,947,588**

6. Right-of-use Assets

	31 December 2022 $	30 June 2022 $
Land and buildings – right-of-use	813,579	967,258
Less: Accumulated depreciation	(451,988)	(456,760)
	361,591	**510,498**

7. Trade and Other Payables

	31 December 2022 $	30 June 2022 $
Trade creditors	3,450,029	4,482,397
Accruals and other creditors	10,218,398	2,605,882
	13,668,427	**7,088,279**

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

8. Issued Capital

	31 December 2022 Number of Shares	30 June 2022 Number of Shares	31 December 2022 $	30 June 2022 $
Ordinary shares – fully paid	**282,237,382**	**232,680,798**	**209,549,632**	**147,194,772**

Movements in ordinary share capital

Details	**Shares**	**$**
Balance as at 1 July 2022	232,680,798	147,194,772
Shares issued under placement	35,137,384	45,678,599
Shares issued under rights issue	15,622,340	20,309,082
Shares issued under ESP	2,000,000	-
Payment of share issue costs	-	(3,764,911)
ESP shares lapsed	(3,203,140)	-
Limited recourse loan repaid under ESP	-	132,090
Balance as at 31 December 2021	**282,237,382**	**209,549,632**

9. Share-based Payment Reserve

	31 December 2022 $	30 June 2022 $
Balance as at the beginning of the period	9,261,765	6,453,995
Fair values of shares issued/to be issued to eligible employees under the ESP	919,695	3,270,037
ESP options lapsed in the period	(1,518,174)	(335,705)
Transfer from share reserve on exercise of options	(41,496)	(126,562)
	8,621,790	**9,261,765**

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. Once the shares vest, the shares remain under the Company's Loan Funding Agreement as set out in the **ESP**. The loan becomes payable (unless extended by the company in its absolute discretion) on the first to occur of the following:

1. The repayment date (5 years from the date on which the Company advances the loan to the participant).
2. 90 days after the participant ceases for any reason to be employed or engaged by the Company.
3. By the legal personal representative of the participant, 6 months after the participant ceases to be an employee or consultant of the Company due to their death.

On 1 July 2022, an invitation of **ESP** shares of 2,000,000 was approved and issued at a price of $0.96 per share. These shares were issued with vesting conditions. Each tranche of shares will vest in 12 months, 24 months and 36 months. However, these shares were bought back on 30 December 2022.

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
July 2022	01/07/2022	666,667 shares are vested on 01 July 2023, 666,667 shares are vested on 1 July 2024 and 666,666 shares are vested on 01 July 2026	2,000,000

31 December 2022

Grant Date	Expiry Date	Exercise Price	Balance at the Start of the Year	Granted	Exercised	Expired/ Forfeited	Balance at the End of the Year
07/11/2019	07/11/2024	$2.93	2,245,890	-	(210,000)	(263,140)	1,772,750
10/07/2020	10/07/2025	$3.24	1,915,000	-	-	(450,000)	1,465,000
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	-	-	(490,000)	2,210,000
25/01/2022	25/01/2027	$1.89	375,000	-	-	-	375,000
01/07/2022	01/07/2027	$0.96	-	2,000,000	-	(2,000,000)	-
			8,335,890	**2,000,000**	**(210,000)**	**(3,203,140)**	**6,922,750**

30 June 2022

Grant Date	Expiry Date	Exercise Price	Balance at the Start of the Year	Granted	Exercised	Expired/ Forfeited	Balance at the End of the Year
07/11/2019	07/11/2024	$2.93	2,685,890	-	(440,000)	-	2,245,890
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
25/01/2022	25/01/2027	$1.89	-	375,000	-	-	375,000
			6,000,890	**3,075,000**	**(440,000)**	**(300,000)**	**8,335,890**

Notes to Financial Statements

31 December 2022
continued

Unlisted Options

31 December 2022

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
			825,000	**-**	**-**	**825,000**

30 June 2022

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
			825,000	**-**	**-**	**825,000**

10. Loss Per Share

	31 December 2022	31 December 2021
Net loss for the period attributable to ordinary shareholders	(31,867,427)	(26,985,037)
	Number	Number
Weighted average number of ordinary shares used in calculating basic loss per share	269,213,496	231,279,568
Weighted average number of ordinary shares used in calculation diluted loss per share	**269,213,496**	**231,279,568**
	Cents	Cents
Basic loss per share	(11.29)	(11.80)
Diluted loss per share	(11.29)	(11.80)

825,000 unexercised options (period ended 31 December 2021: 825,000) have been excluded from the calculation of the diluted loss per share above as it would have an anti-dilutive impact.

11. Reconciliation of Cash Flows Provided by Operating Activities

	31 December 2022	31 December 2021
Loss for the half-year	**(31,867,427)**	**(26,985,037)**
Gain on lease modification	(89,408)	-
Depreciation and amortisation	76,900	96,868
Foreign exchange unrealised losses	284,493	(691,421)
Share-based payment	919,695	1,578,755
Change in operating assets and liabilities		
(Increase) / decrease in trade receivables	6,616,500	1,460,531
(Increase) / decrease in other receivables	(163,137)	(6,073)
(Increase) / decrease in other assets	(221,697)	(304,474)
Increase / (decrease) in payables	6,799,382	8,014,311
Increase / (decrease) in provisions	(109,616)	108,073
Net cash used in operating activities	**(17,754,315)**	**(16,728,467)**

12. Commitments

The Consolidated entity has no expenditure contracted for at the reporting date but not recognised as liabilities (30 June 2022: nil).

13. Contingent Liabilities

The Consolidated entity had no contingent liabilities as the reporting date (30 June 2022: nil).

14. Events Subsequent to Reporting Date

No matters or circumstances have arisen since 31 December 2022 that have 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 periods.

Directors' Declaration

31 December 2022

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 2022 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
27 February 2023

Independent Auditor's Review Report

31 December 2022

RSM Australia Partners

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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 2022, 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 then ended, 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 2022 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.

Independent Auditor's Review Report

31 December 2022

continued

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 2022 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.

RSM AUSTRALIA PARTNERS

R J MORILLO MALDONADO
Partner

27 February 2023
Melbourne, Victoria

Corporate Directory

Directors

Mr Paul Rennie
Managing & Executive Director

Dr Donna Skerrett
Executive Director

Mr John Gaffney
Non-Executive Director

Mr Amos Meltzer
Non-Executive Director

Ms Helen Fisher
Non-Executive Director

Company Secretary

Abby Macnish

Principal Place of Business

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Melbourne VIC 3000

Registered Office

Level 15, 500 Collins Street
Melbourne VIC 3000

Auditor

RSM Australia Partners
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Melbourne VIC 3000

Solicitors

K&L Gates
Level 25, South Tower
525 Collins Street
Melbourne VIC 3000

Share Registry

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Commonwealth Bank
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Melbourne VIC 3008

Stock Exchange

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