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 2023
Previous reporting period:	31 December 2022

2. Results for announcement to the market

	$	**$ and % increase/(decrease) over previous corresponding period**
Revenue from continuing activities	1,273,114	84,269 7.09%
(Loss) from continuing activities after tax attributable to members	(48,958,387)	17,090,960 53.63%
Net (loss) for the period attributable to members	(48,987,933)	17,066,482 53.46%
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 Ltd. 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 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 iPPS, a potential blockbuster treatment for osteoarthritis.

Paradigm recorded a loss before tax of $48,958,387, an increase on the prior corresponding period loss before tax of $17,090,960. The increase in loss before tax compared to the prior corresponding period of $17.09m, is mainly driven by research and development costs. The three main drivers of the increase in spend related to phase 3 clinical trial activity, in particular investment into the first stage of the phase 3 clinical program to increase global clinical trial sites, interim analysis conducted on the first 300 participants, and close out activities for the PARA_OA_002 and PARA_OA_006 studies. The loss was also attributed to costs associated with the phase 2 successful PARA_OA_008 clinical trial and the clinical studies completed in the orphan disease Mucopolysaccharidoses.

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3. Net tangible assets

	Current Period	Previous corresponding period
Basic loss per ordinary security (cents per share)	(16.33) cents	(11.29) cents
Diluted loss per ordinary security (cents per share)	(16.33) cents	(11.29) cents
Net tangible asset backing per ordinary security (cents per share)	8.78 cents	25.06 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 2023 is attached.

8. Signed

Signed _____

Mr. Paul Rennie
Managing Director
28th February 2024

PARADIGM
BIOPHARMA

People.
Science.
Potential.

Half-Year Report
31 December 2023

Paradigm Biopharmaceuticals Ltd. is a late-stage clinical development company. We are driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies. Paradigm has a vision to be recognised as a global leader in the development and commercialisation of innovative pharmaceutical therapies. Paradigm's values of innovation, transparency, adaptability, collaboration, respect, and accountability comprise the central pillars of the organisation and influence all activities and decisions.

Contents

Highlights

500 million

More than 500 million people worldwide have knee osteoarthritis.

579

579 participants randomised in stage 1 of PARA_OA_002.

$30.1m

$30.1m capital raised in Q4 to provide funding for the ongoing phase 3 pOA program.

Osteoarthritis (OA) is a chronic and progressive degenerative joint condition causing pain and stiffness which can severely impact quality of life. OA is a major worldwide public health concern and its incidence continues to rise, from 247.51 million sufferers in 1990 to 527.81 million in 2019, an increase of 113%[1].

Current OA treatments only provide minimal symptomatic improvements. They have substantial limitations in treating the long-lasting pain frequently associated with OA, they do not protect joints from OA-related structural deterioration, nor do they target the underlying pathophysiology associated with OA. Consequently, there remains a significant unmet medical need for developing new OA treatment options.

Paradigm's most recent goal has been to gather and consolidate feedback from the key regulatory agencies, the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Australian Therapeutic Goods Administration (TGA) to design a phase 3 clinical trial for injectable pentosan polysulfate sodium (iPPS) for the treatment of pain and dysfunction associated with knee osteoarthritis (OA).

Designing a harmonised trial acceptable to all major jurisdictions would theoretically streamline the approval process in multiple key markets. As part of Paradigm's Investigational New Drug (IND) application to the FDA in 2021, Paradigm submitted the available nonclinical and clinical data, which incorporated PPS dosage information. The application included data from Paradigm's phase 2 PARA_005 clinical trial which used the dosing regimen of 2mg/kg iPPS twice weekly for 6 weeks, and data from the historical clinical studies conducted in 2005 by Kumagai et al[2] (2mg/kg weekly for 6 weeks) and Ghosh et al 2010[3] (iPPS administered 3mg/kg weekly for 4 weeks). Following review of the IND application, the FDA requested Paradigm to determine the minimal effective iPPS dose during the first stage of the phase 3 PARA_OA_002 clinical trial.

Paradigm has Extensive Clinical Evidence Supporting the iPPS Optimal Dose

Paradigm's phase 2 PARA_OA_008 clinical trial and stage 1 of the phase 3 PARA_OA_002 clinical trial generated sound evidence of clinical efficacy and safety in humans and aided in determining the optimal dose (minimal effective dose) of iPPS for the treatment of pain and function associated with knee OA. The primary endpoints for the phase 3 program were a change from baseline in Western Ontario and McMaster Universities Osteoarthritic Index (WOMAC) pain and function at Day 56 (2 weeks following final treatment dose). In preparation for a submission to the FDA of the protocol for the next stage of the phase 3 program in Q1 calendar year 2024, Paradigm is pleased to provide a short summary on the durable pain and functional treatment effects produced by the optimal iPPS dosing regimen throughout the OA clinical program to date.

References

Data used is available in Paradigm's public disclosures to the ASX.

1. Long H, Liu Q, Yin H, et al. Prevalence trends of site-specific osteoarthritis from 1990 to 2019: findings from the Global Burden of Disease Study 2019. Arthritis & Rheumatology Internet. 2022 cited 2022 Mar 4;74. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/art.42089.
2. Ghosh P, Edelman J, March L, et al. Effects of pentosan polysulfate in osteoarthritis of the knee: A randomized, double-blind, placebo-controlled pilot study. Curr Ther Res Clin Exp. 2005;66:552–571.
3. Kumagai K, Shirabe S, Miyata N, et al. Sodium pentosan polysulfate resulted in cartilage improvement in knee osteoarthritis – An open clinical trial. BMC Clin Pharmacol. 2010;10:7.

Highlights continued

PARA_005

This phase 2b study assessed the efficacy, safety, and tolerability of 2 mg/kg iPPS twice weekly for 6 weeks compared to placebo (randomised 1:1) in 112 evaluable participants with knee OA and bone marrow lesions. Results from this study demonstrated that iPPS reduces pain and improves function in participants with OA and moderate to severe knee pain. Although the maximum iPPS treatment effect (pain reduction) generally occurred at Day 39, a clinically meaningful treatment effect was maintained through to Day 165 (end of study) for most pain reduction endpoints, and the change from baseline remained higher for the iPPS group compared to placebo. Using the Knee injury and Osteoarthritis Outcome Score (KOOS) pain scale in this phase 2b study, a reduction in pain of 37.2% was observed with iPPS versus 23.1% with placebo at Day 53. KOOS is an extension of WOMAC, which is being used in PAR's Phase 3 program. Favourable treatment effects were observed from Day 39 through to study completion at Day 165. A similar durability of treatment effect on function was observed using the KOOS function scale.

PARA_OA_008

The primary objective of the phase 2 PARA_OA_008 exploratory study was to investigate changes in synovial fluid biomarkers associated with OA disease progression following a 6-iPPS treatment compared with placebo in 61 participants with knee OA. Participants in the study were also asked to provide baseline pain scores using the self-assessed WOMAC Osteoarthritis Index. After treatment was initiated, participant pain scores were measured at predetermined timepoints from Day 11 out to Day 365 (12 months), with Day 56 the first timepoint for WOMAC assessment following completion of treatment.

Although the study was not powered to demonstrate statistical significance in pain or function metrics, iPPS treatment showed statistically significant improvements at Day 56 in pain, function, and overall WOMAC scores for twice weekly 2mg/kg iPPS for 6 weeks compared to the placebo arm. The proportions achieving clinically meaningful ≥30% and ≥50% improvements in pain were 73% and 60% in the iPPS group, respectively. The mean percentage change from baseline in WOMAC pain was 50% compared to 30%, p=0.045 for the twice-weekly iPPS and placebo groups, respectively. The mean percentage change from baseline in WOMAC function is 50% compared to 25%, p=0.017 for twice-weekly iPPS compared to placebo, respectively.

Positive trends or statistical significance were demonstrated at Day 365 for pain (p=0.054), function (p=0.048), and overall (p=0.054). Importantly, at Day 365, 55% of participants maintained a clinically meaningful 30% improvement in pain and function compared to baseline. A 50% improvement in function was reported for 53% of twice-weekly iPPS-treated participants at Day 168 and 55% at Day 365, compared to 23% and 28% for the placebo group, respectively. In the twice-weekly iPPS group effects on WOMAC pain demonstrated a durable response and separation from the placebo group on Day 168 and Day 365.

Throughout the PARA_OA_008 study it was clear the twice-weekly 2mg/kg iPPS dosing regimen demonstrated a drug effect size superior to the once-weekly 2mg/kg regimen, with no clear differences in safety observed between the doses. A large effect size indicates a higher likelihood for a clinically meaningful difference as it is independent of the study sample size.

PARA_OA_002

A 2-stage, adaptive, randomised, double-blind, placebo-controlled, multicentre study to evaluate the minimum effective dose and treatment effect of iPPS compared with placebo in participants with knee OA. The primary endpoint of the phase 3 trial are improvements in WOMAC pain and function from baseline to Day 56.

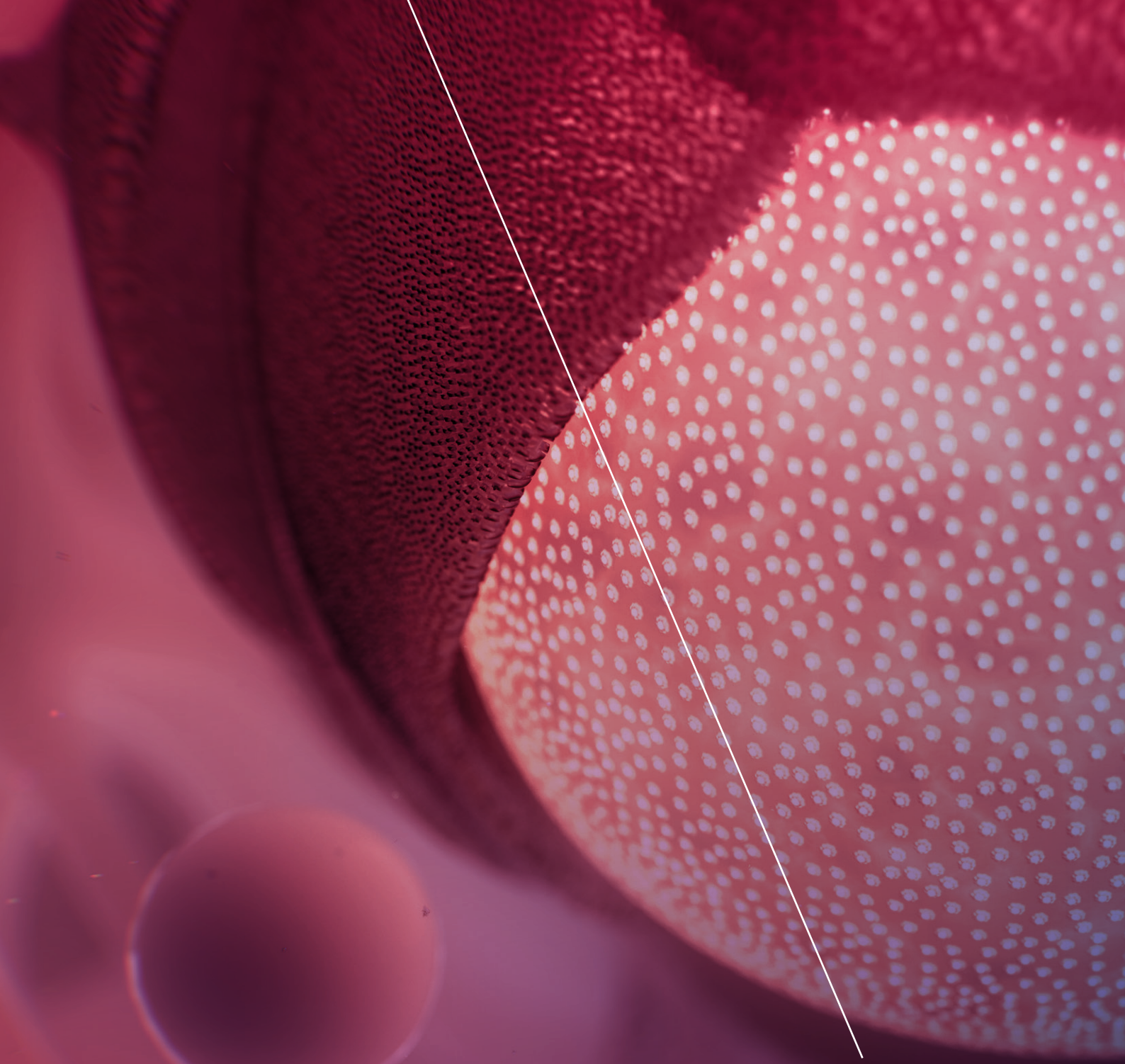
In stage 1 (dose selection), participants were randomised 1:1:1:1 to receive 1 of 3 doses of iPPS or placebo as below, iPPS 1.5mg/kg twice weekly, iPPS 2.0 mg/kg once weekly, iPPS fixed dose once weekly, or Placebo (normal saline) twice weekly for 6 weeks.

During stage 1 of the PARA_OA_002 trial, Paradigm activated 120 clinical trial sites across 7 countries, and completed randomisation of 579 participants in October 2023. Paradigm undertook an interim analysis which was performed by an independent Data Monitoring Committee to review the efficacy of all treatment arms in comparison to placebo in stage 1. This was conducted following reported data from the phase 2 PARA_OA_008 clinical trial demonstrating the once-weekly iPPS dosing regimen was not providing sufficient clinical results to those demonstrated by the 2mg/kg twice-weekly regimen. The interim analysis was performed on 300 patients at Day 56 and which indicated that the iPPS doses included in the dose determination part of the phase 3 did not meet the prespecified performance threshold, which was based on prior efficacy outcomes using the 2mg/kg twice-weekly dosing demonstrated in PARA_005 and PARA_OA_008.

Road Ahead for iPPS in OA

Paradigm's clinical development program has demonstrated significant durable effects with a dose of 2mg/kg iPPS twice weekly for the treatment of knee OA. A revised clinical protocol is being submitted to the Agency for review during Q1 CY2024 and Paradigm expects to commence enrolment activities for the next stage of the phase 3 in Q2 CY2024.

At Day 365, 55% of participants receiving 2mg/kg iPPS twice weekly maintained a clinically meaningful 30% improvement in pain and function compared to baseline.



Improvements

73%

The proportions achieving a clinically meaningful ≥30% and ≥50% improvements in pain at day 56 were 73% and 60% in the iPPS group, respectively.

Day

365

55% of participants maintained a clinically meaningful 30% improvement in pain and function compared to baseline.

Trial sites

120

During stage 1 of the PARA_OA_002 trial, Paradigm activated 120 clinical trial sites across 7 countries, and completed randomisation of 579 participants.

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 2023

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

Donna Skerrett

Amos Meltzer

Helen Fisher

John Gaffney
(Resigned on 20 October 2023)

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 2023 of $48,958,387 (31 December 2022: Loss of $31,867,427).

Review of Operations

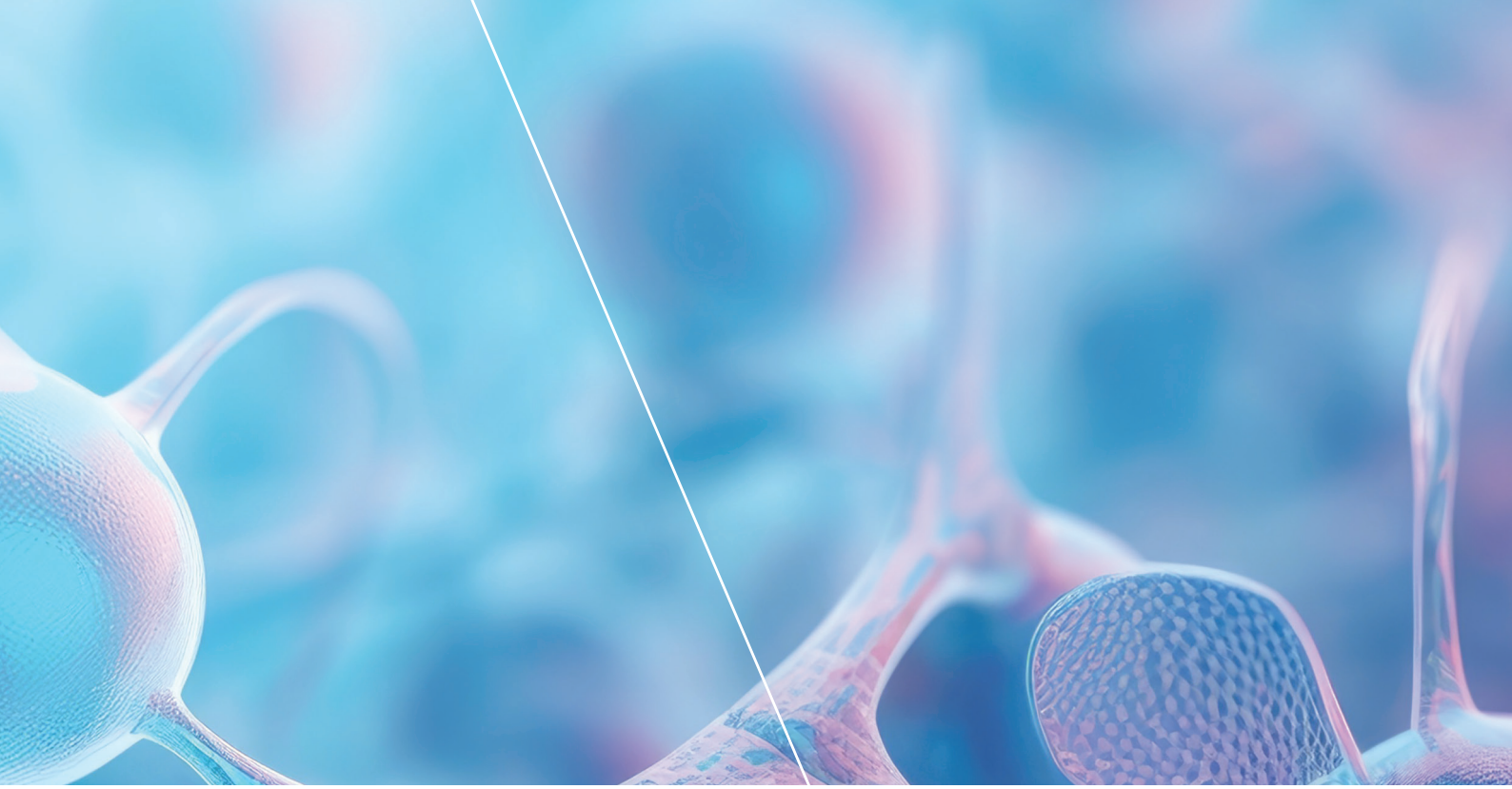
On the 30 October 2023, Paradigm announced a fully-underwritten capital raise of $30.1M, which comprised a fully underwritten $18M institutional placement and a 1 for 10 accelerated non-renounceable entitlement offer of $12.1M, raised at $0.43 per share. The placement received strong participation from domestic and offshore institutional investors. As a part of the capital raise Paradigm issued 3 attaching listed options for every 4 new shares taken up in the capital raise. The options issued under the placement and entitlement have an exercise price of $0.65 and expire on the 30 November 2024. The exercise of options would add additional funding runway to support Paradigm's phase 3 clinical program in osteoarthritis.

On the 10 October 2023 Paradigm reported findings from an interim analysis conducted once the first 300 participants from the PARA_OA_002 clinical trial reached day 56 of the study. The doses (less than 2mg/kg twice weekly) included in the dose determination part of phase 3 trial did not meet the prespecified performance threshold, which was based on prior outcome data produced with the 2mg/kg twice weekly dosing regimen. Following these findings, Paradigm has prepared a new protocol for the next stage of the phase 3 clinical program using the 2mg/kg twice weekly dose regimen of iPPS which has demonstrated consistent positive data in the PARA_OA_008, PARA_005 (previous phase 2b) studies and the TGA Special Access Scheme.

Stage 1 activities for the PARA_OA_002 phase 3 clinical trial concluded during the period with the study completing the randomisation of 579 subjects demonstrating Paradigm's ability to enrol suitable study participants through the many recruitment initiatives implemented for the global phase 3 study.

The PARA_OA_008 phase 2 study completed during the first half of fiscal year 2024. The successful phase 2 provided two major readouts during the period with duration of effect data out to 12 months and new quantitative analysis data from MRI imaging at 6 months reported.

Paradigm reported durable and significant responses in WOMAC scores for pain (p=0.054), function (p=0.048), stiffness and overall (p=0.054) were observed for iPPS twice weekly compared to placebo control through to Day 365. The outstanding results for iPPS compared to placebo were strengthened through the reporting that cumulative rescue pain medication use was over five times higher in the placebo group compared to iPPS group at Day 365. This data is a significant outcome for Paradigm as no OA drug has previously shown durable and meaningful improvements in pain and function at 12 months after a single course of treatment.



$30.1m AUD

Capital raise

On the 30 October 2023, Paradigm announced a fully-underwritten capital raise of $30.1M.

100%

Enrolment target

The additional trial sites activated aided Paradigm to meet the reported 100% enrolment target of June 2023, for stage 1 of the PARA_OA_002 study, which was reported at the beginning of July 2023.

300

Participants

On the 10 October 2023 Paradigm reported findings from an interim analysis conducted once the first 300 participants from the PARA_OA_002 clinical trial reached day 56 of the study.

The Company also reported in October quantitative MRI analysis results at the day 168 follow-up from the phase 2 PARA_OA_008 clinical trial, demonstrated that a single 6-week treatment of iPPS treatment at 2mg/kg twice weekly results in an increase in overall cartilage thickness (p=0.05) and cartilage volume (p=0.07) compared to a decrease in the placebo group. Bone marrow lesions (-17%) and synovitis (-1%) were also decreased in the knee joint following iPPS administration to day 168 compared to small increases in the placebo group.

The successful phase 2 clinical trial achieved its primary endpoint and provide significant evidence demonstrating that iPPS treats both the symptoms of OA and preserves and/or regenerates joint tissues.

In terms of financial performance, Paradigm recorded a loss before tax of $48,958,387 an increase on the prior corresponding period loss before tax of $17,090,960. Paradigm Biopharmaceuticals Ltd. 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 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 iPPS, a potential blockbuster treatment for osteoarthritis.

The increase in loss before tax compared to the prior corresponding period of $17.09M, is mainly driven by research and development costs. The 3 main drivers of the increase in spend related to phase 3 clinical trial activity, in particular, investment into the first stage of the phase 3 clinical program to increase global clinical trial sites, interim analysis conducted on the first 300 participants, and close out activities for the PARA_OA_002 and PARA_OA_006 studies.

Paradigm increased its target clinical trial sites during the period from 80 to 120 clinical trial site activations to support the recruitment increased initiatives undertaken by the Company. The Phase 3 clinical program has activated sites across seven countries, comprising Australia, the US and Canada in North America, and the UK, Belgium, Poland, and Czechia in the EU. The additional trial sites activated aided Paradigm to meet the reported 100% enrolment target of June 2023 which was reported at the beginning of July 2023. The significant one-off upfront investment in the trial setup costs in the stage 1 of the phase 3 trial ensures trial sites are trained and available to commence with next stage of the phase 3 clinical program, thus streamlining the recruitment and enrolment process.

With additional trial sites activated Paradigm was able to increase the recruitment initiatives to increase the pool of potential participants eligible for the study. Through the many initiatives implemented by the Company in stage 1 have enabled identification of potential participants for stage 2 of the phase 3 study.

Paradigm initiated an interim analysis during the first half of the fiscal year to determine the performance of the three iPPS doses in stage 1 of PARA_OA_002 clinical trial against placebo. This was conducted ahead of the schedule following reported data from the phase PARA_OA_008 clinical trial demonstrating the once weekly iPPS dosing regimen was not providing sufficient clinical results to that of the 2mg/kg twice weekly Paradigm previously reported across multiple programs. Costs associated with the interim analysis included Clinical Research Organisation and Data Monitoring Committee costs to analyse data on the first 300 participants who had reached Day 56. The interim analysis provided Paradigm an earlier indication of the optimal dose and aided the preparation of the clinical protocol for the next stage of the phase 3 OA program ahead of schedule.

Following the interim analysis Paradigm conducted important activities to close out both of the PARA_OA_002 and PARA_OA_006 studies, to ensure data was available to be utilised in discussions with the US FDA on the optimal iPPS dose to progress to the next stage of the phase 3 program. Close-out is integral to the quality control of a clinical trial and is designed to ensure quality of the study according to Sponsor requirements and to ensure that all necessary documents are in place should it be necessary for the trial information to be retrieved or inspected, by regulatory agencies, in the future.

Other income is higher for the 6 months to December 2023 mainly due to the $7.36M AUD FY23 R&D tax incentive claim receivable in the first quarter of 2024 being higher than estimated at 30 June 2023. Interest received has decreased due to lower cash levels available for investment. Administration costs decreased compared to the prior corresponding period due to the Company's cost containment program, which is ongoing. Aggressive cost containment measures have been implemented to ensure capital is being directed toward completion of the phase 3 OA clinical trial. Paradigm's financial commitment to the MPS clinical program has completed with a reduced headcount in the MPS clinical team implemented following the completion of the phase 2 studies in MPS I and VI. Paradigm is actively seeking to partner this clinical asset to progress iPPS for treatment of MPS toward commercialisation. Ongoing overheads have been reduced throughout this cost containment phase by over $1M per quarter which will come into effect from January 2024, with further reductions planned over the coming months.

During the period Non-Executive Director, Mr John Gaffney stepped down from the Paradigm board following 9-years of service. Non-Executive Director, Helen Fisher also informed the Paradigm Board during the period that she will be stepping down from the position as Non-Executive Director on the appointment of a replacement Non-Executive Director, to focus on other commitments going forward. The Paradigm Board commenced a search for an Independent Non-Executive Director with commercial experience and financial expertise and an Independent Chair during the December quarter. Paradigm would like to thank Mr Gaffney for his dedication and commitment through the Company's public listing to now a phase 3 Company.

In the second half of FY24, Paradigm expects to deliver several key milestones for the progression of its osteoarthritis program and the development strategy for iPPS. Paradigm's clinical and regulatory teams are preparing for submission of updated nonclinical and clinical data to the Agency ahead of the submission of the clinical protocol to the US FDA during Q3 of this fiscal year. The program has FDA granted Fast-track designation and plans to proceed with the dose of 2mg/kg twice weekly for registration studies. The Company also anticipates to submit the Determination Application which is the next step in the TGA Provisional Approval pathway. Should the TGA consider the determination application eligible, Paradigm plans to file the dossier submission for Provisional Approval by the end of fiscal year 2024. Discussions and progress with potential regional partners aiming to complete at least one agreement by the end of the fiscal year.

The Paradigm Board of Director's would like to thank all Paradigm shareholders for their ongoing support as we navigate this important period to progress iPPS through to commercialisation.

Significant Changes in the State of Affairs

During the period Paradigm conducted a fully underwritten capital raise of $30.1M. In October Paradigm issued approximately 42 million shares via a placement to institutional investors at an issue price of $0.43 to raise approximately $18M. An accelerated non-renounceable entitlement offer of 1 share for every 10 shares held was also offered to eligible Paradigm shareholders raising approximately $12.1M, with the retail component of the entitlement offer closing in November 2023.

Events Subsequent to Reporting Date

No matters or circumstances has arisen since 31 December 2023 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 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.

The 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 and Managing Director

Melbourne, Victoria
28 February 2024

Auditor's Independence Declaration

RSM Australia Partners

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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 2023, 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

Dated: 28 February 2024
Melbourne, Victoria

Consolidated Interim Financial Statements

Contents

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 half-year ended 31 December 2023. 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. Its registered office and principal place of business is:

Level 15, 500 Collins Street
Melbourne VIC 3000

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 28 February 2024.

Consolidated Interim Statement of Profit or Loss and Other Comprehensive Income

for the half-year ended 31 December 2023

	Notes	31 December 2023 $	31 December 2022 $
Revenue		–	4,710
Cost of sales		–	(7,361)
Other income	2	1,273,114	1,184,135
Other gains and (losses)		(78,356)	(284,493)
Research and development expenses		(46,374,458)	(27,729,766)
General and administration expenses		(3,519,024)	(4,563,413)
Commercial expenses		(253,184)	(462,485)
Finance costs		(6,479)	(8,754)
Loss before income tax expense/(benefit)		**(48,958,387)**	**(31,867,427)**
Income tax expense/(benefit)		–	–
Loss after income tax expense/(benefit) attributable to the members of the Consolidated Entity		**(48,958,387)**	**(31,867,427)**
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss			
Foreign currency translation		(29,546)	(54,024)
Other comprehensive loss for the half-year, net of tax		**(29,546)**	**(54,024)**
Total comprehensive loss attributable to members of the Consolidated Entity		**(48,987,933)**	**(31,921,451)**
Loss per share (cents)			
Basic and diluted loss per share	6	(16.33) cents	(11.29) 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 2023

	Notes	31 December 2023 $	30 June 2023 $
ASSETS			
Current assets			
Cash and cash equivalents		33,550,970	56,333,085
Trade and other receivables	3	7,426,855	6,807,301
Prepaid expenses		850,310	599,078
Financial assets held at amortised cost		–	46,200
Total current assets		**41,828,135**	**63,785,664**
Non-current assets			
Intangible assets		2,947,588	2,947,588
Plant and equipment		37,001	42,601
Right-of-use assets		225,994	293,791
Total non-current assets		**3,210,583**	**3,283,980**
Total assets		**45,038,718**	**67,069,644**
LIABILITIES			
Current liabilities			
Trade and other payables		9,986,441	12,161,182
Employee benefits		822,576	776,196
Lease liabilities		113,286	104,971
Total current liabilities		**10,922,303**	**13,042,349**
Non-current liabilities			
Employee benefits		140,171	112,830
Lease liabilities		177,028	236,694
Total non-current liabilities		**317,199**	**349,524**
Total liabilities		**11,239,502**	**13,391,873**
Net assets		**33,799,216**	**53,677,771**
EQUITY			
Issued capital	4	238,113,122	209,833,883
Share-based payments reserve	5	7,898,616	7,786,686
Currency translation reserve		(458,330)	(428,784)
Accumulated losses		(211,754,192)	(163,514,014)
Total equity		**33,799,216**	**53,677,771**

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

Consolidated Interim Statement of Changes in Equity

for the half-year ended 31 December 2023

	Issued Capital $	Share-based Payments Reserve $	Accumulated Losses $	Currency Translation Reserve $	Total $
Balance at 1 July 2022	147,194,772	9,261,765	(114,015,544)	(128,382)	42,312,611
Loss after Income tax expense/(benefit) for the half-year	–	–	(31,867,427)	–	(31,867,427)
Other comprehensive loss for the half-year, net of tax	–	–	–	(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:					
Share-based payments expense	–	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**
Balance at 1 July 2023	209,833,883	7,786,686	(163,514,014)	(428,784)	53,677,771
Loss after Income tax expense/(benefit) for the half-year	–	–	(48,958,387)	–	(48,958,387)
Other comprehensive loss for the half-year, net of tax				(29,546)	(29,546)
Total comprehensive loss for the half-year	–	–	(48,958,387)	(29,546)	(48,987,933)
Transactions with owners in their capacity as owners:					
Share-based payments expense	–	913,482	–	–	913,482
ESP lapsed in the period	–	(801,552)	718,209	–	(83,343)
Shares issued under placement	21,002,894	–	–	–	21,002,894
Shares issued under retail offer	9,113,960	–	–	–	9,113,960
Payment of share issue costs	(1,837,615)	–	–	–	(1,837,615)
Balance at 31 December 2023	**238,113,122**	**7,898,616**	**(211,754,192)**	**(458,330)**	**33,799,216**

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 2023

	Notes	31 December 2023 $	31 December 2022 $
Cash flows from operating activities			
R&D and other tax incentive received		–	7,404,899
Receipts from customers (inclusive of GST)		29,550	23,043
Payments to suppliers and employees (inclusive of GST)		(51,680,965)	(25,329,203)
Interest received		634,982	155,700
Interest repayment of lease liabilities		(6,479)	(8,754)
Net cash outflow from operating activities	7	**(51,022,912)**	**(17,754,315)**
Cash flows from investing activities			
Proceeds for financial assets held at amortised cost		46,200	46,200
Net cash inflow from investing activities		**46,200**	**46,200**
Cash flows from financing activities			
Proceeds from share issue		30,116,854	65,987,681
Payment of share issue costs		(1,763,004)	(3,764,911)
Limited recourse loan repaid under ESP		–	132,090
Principal repayment of lease liabilities		(51,351)	(56,372)
Net cash inflow from financing activities		**28,302,499**	**62,298,488**
Net increase/(decrease) in cash and cash equivalents		**(22,674,213)**	**44,590,373**
Cash and cash equivalents at the beginning of the financial half-year		**56,333,085**	**39,674,413**
Effects of exchange rate changes on cash and cash equivalents		**(107,902)**	**(338,517)**
Cash and cash equivalents at the end of the financial half-year		**33,550,970**	**83,926,269**

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

Notes to Financial Statements

for the half-year ended 31 December 2023

1. Material Accounting Policy Information

These general-purpose financial statements for the interim half-year reporting period ended 31 December 2023 have been prepared in accordance with Australian Accounting Standard AASB 134 'Interim Financial Reporting' and the *Corporations Act 2001*, as appropriate 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 2023 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 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 2023 $	31 December 2022 $
Interest income	211,977	318,837
R&D tax incentive	1,061,137	775,890
Gain on lease modification	–	89,408
	1,273,114	**1,184,135**

3. Trade and Other Receivables

	31 December 2023 $	30 June 2023 $
GST receivable	54,408	43,435
Interest receivable	33,607	456,612
R&D tax incentive receivable	7,327,440	6,266,304
Other receivables	11,400	40,950
	7,426,855	**6,807,301**

4. Issued Capital

	31 December 2023 Number of Shares	30 June 2023 Number of Shares	31 December 2023 $	30 June 2023 $
Ordinary shares – fully paid	**351,495,841**	**281,756,625**	**238,113,122**	**209,833,883**
Movements in ordinary share capital				
Reconciliation and movement	**Shares**		**$**	
Balance as at 1 July 2023	281,756,625		209,833,883	
Shares issued under Placement	48,843,939		21,002,894	
Shares issued under Rights Issue	21,195,277		9,113,960	
Payment of share issue costs	–		(1,837,615)	
ESP shares lapsed	(300,000)		–	
Balance as at 31 December 2023	**351,495,841**		**238,113,122**	

5. Share Based Payment Reserve

	31 December 2023 $
Balance as at 1 July 2023	7,786,686
Share based payment expenses in the period	913,482
ESP options lapsed in the period	(801,552)
Balance as at 31 December 2023	**7,898,616**

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 employee's 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; or
3. By the legal personal representative of the participant, six months after the participant ceases to be an employee or consultant of the company due to their death.

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.

Listed Options – ESP

31 December 2023

Grant Date	Expiry Date	Exercise Price	Balance at the Start of the Half-Year	Granted	Exercised	Expired/ Forfeited	Balance at the End of the Half-Year
7/11/2019	7/11/2024	$2.93	1,128,893	–	–	(300,000)	828,893
10/07/2020	10/07/2025	$3.24	1,365,000	–	–	–	1,365,000
19/11/2020	19/11/2025	$3.05	1,100,000	–	–	–	1,100,000
10/09/2021	10/09/2026	$2.41	1,970,000	–	–	–	1,970,000
25/01/2022	25/01/2027	$1.89	375,000	–	–	–	375,000
			5,938,893	**–**	**–**	**(300,000)**	**5,638,893**

Listed Options – Shareholders/Contractors

31 December 2023

Grant Date	Expiry Date	Exercise Price	Balance at the Start of the Half-Year	Granted	Exercised	Balance at the End of the Half-Year
30/11/2023	30/11/2024	$0.65	–	51,800,629	–	51,800,629
27/11/2023	30/11/2024	$0.65	–	10,100,635	–	10,100,635
			–	**61,901,264**	**–**	**61,901,264**

6. Loss Per Share

	31 December 2023	31 December 2022
Net loss for the period attributable to ordinary shareholders	(48,958,387)	(31,867,427)
	Number	**Number**
Weighted average number of ordinary shares used in calculating basic loss per share	299,789,784	269,213,496
Weighted average number of ordinary shares used in calculation diluted loss per share	**299,789,784**	**269,213,496**
	Cents	**Cents**
Basic loss per share	(16.33)	(11.29)
Diluted loss per share	(16.33)	(11.29)

61,901,264 unexercised options (Period ended 31 December 2022: 825,000) have been excluded from the calculation of the diluted loss per share above as it would have an anti-dilutive impact.

7. Reconciliation of Cash Flows Provided by Operating Activities

	31 December 2023	31 December 2022
Loss for the year	**(48,958,387)**	**(31,867,427)**
AASB 16 Lease gains	–	(89,408)
Depreciation and amortisation	73,397	76,900
Foreign exchange unrealised losses	78,356	284,493
Share-based payment	830,141	919,695
Change in operating assets and liabilities		
(Increase)/decrease in trade receivables	(1,042,559)	6,616,500
(Increase)/decrease in other receivables	423,005	(163,137)
(Increase)/decrease in other assets	(251,232)	(221,697)
Increase/(decrease) in payables	(2,249,354)	6,799,382
Increase/(decrease) in provisions	73,721	(109,616)
Net cash used in operating activities	**(51,022,912)**	**(17,754,315)**

8. Contingent Liabilities

The Consolidated Entity had no contingent liabilities as at the reporting date (30 June 2023: nil).

9. Events Subsequent to Reporting Date

No matter or circumstance has arisen since 31 December 2023 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 periods.

Directors' Declaration

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 2023 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 and Managing Director

Melbourne, Victoria
28 February 2024

Independent Auditor's Review Report

to the members of Paradigm Biopharmaceuticals Limited

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 2023, 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 2023 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 continued

to the members of Paradigm Biopharmaceuticals Limited

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 2023 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

Dated: 28 February 2024
Melbourne, Victoria

Corporate Directory

Directors

Mr Paul Rennie
Chairman and Managing Director

Dr Donna Skerrett
Executive Director

Mr Amos Meltzer
Non-Executive Director

Ms Helen Fisher
Non-Executive Director

Company Secretary

Ms Abby Macnish Niven

Principal Place of Business

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Melbourne VIC 3000

Registered Office

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Melbourne VIC 3000

Auditor

RSM Australia Partners
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Solicitors

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Level 4, The Read Buildings
16 Milligan Street
Perth WA 6000

Share Registry

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Website

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