

**APPENDIX 4E**  
**Preliminary Final Report to the Australian Stock Exchange**

<b>Name of Entity</b>	Paradigm Biopharmaceuticals Limited
<b>ABN</b>	(ABN 94 169 346 963)
<b>Year Ended</b>	30 June 2023
<b>Previous Corresponding Reporting Period</b>	01 July 2021 to 30 June 2022

**1. Results for Announcement to the Market**

	<b>\$</b>	<b>\$ and % increase/(decrease) over previous corresponding period</b>
<b>Revenue from continuing activities</b>	8,580,939	687,374 8.71%
<b>(Loss) from continuing activities after tax attributable to members</b>	(51,910,013)	12,660,429 32.26%
<b>Net (loss) for the period attributable to members</b>	(51,910,013)	12,660,429 32.26%
<b>Dividends (distributions)</b>	<b>Amount per security</b>	<b>Franked amount per security</b>
<b>Final Dividend</b>	N/A	N/A
<b>Interim Dividend</b>	N/A	N/A
<b>Record date for determining entitlements to the dividends (if any)</b>	N/A	
<b>Brief explanation of any of the figures reported above necessary to enable the figures to be understood: N/A</b>		

**2. Key ratios**

	<b>Current Period</b>	<b>Previous corresponding period</b>
<b>Basic earnings per ordinary security</b> (cents per share)	(20.78) cents	(16.87) cents
<b>Diluted earnings per ordinary security</b> (cents per share)	(20.78) cents	(16.87) cents
<b>Net tangible asset backing per ordinary security</b> (cents per share)	18.00 cents	16.92 cents

### 3. Control Gained Over Entities Having Material Effect

Name of entity (or group of entities)	N/A
Date control gained	N/A
Profit / (loss) from ordinary activities after tax of the controlled entity since the date in the current period on which control was acquired.	N/A
Profit / (loss) from ordinary activities after tax of the controlled entity (or group of entities) for the whole of the previous corresponding period.	N/A

### 4. Audit/Review Status

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

### 5. Attachments Forming Part of Appendix 4E

The Annual Report of Paradigm Biopharmaceuticals Limited for the year ended 30 June 2023 is attached.

### 6. Signed

Signed in accordance with a resolution of the Directors.

Signed 

Date: 25 August 2023

Paul Rennie

Managing Director

**People.  
Science.  
Potential.**

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Annual Report 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.

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## Highlights



900+

People treated with Paradigm's iPPS globally since 2015



120

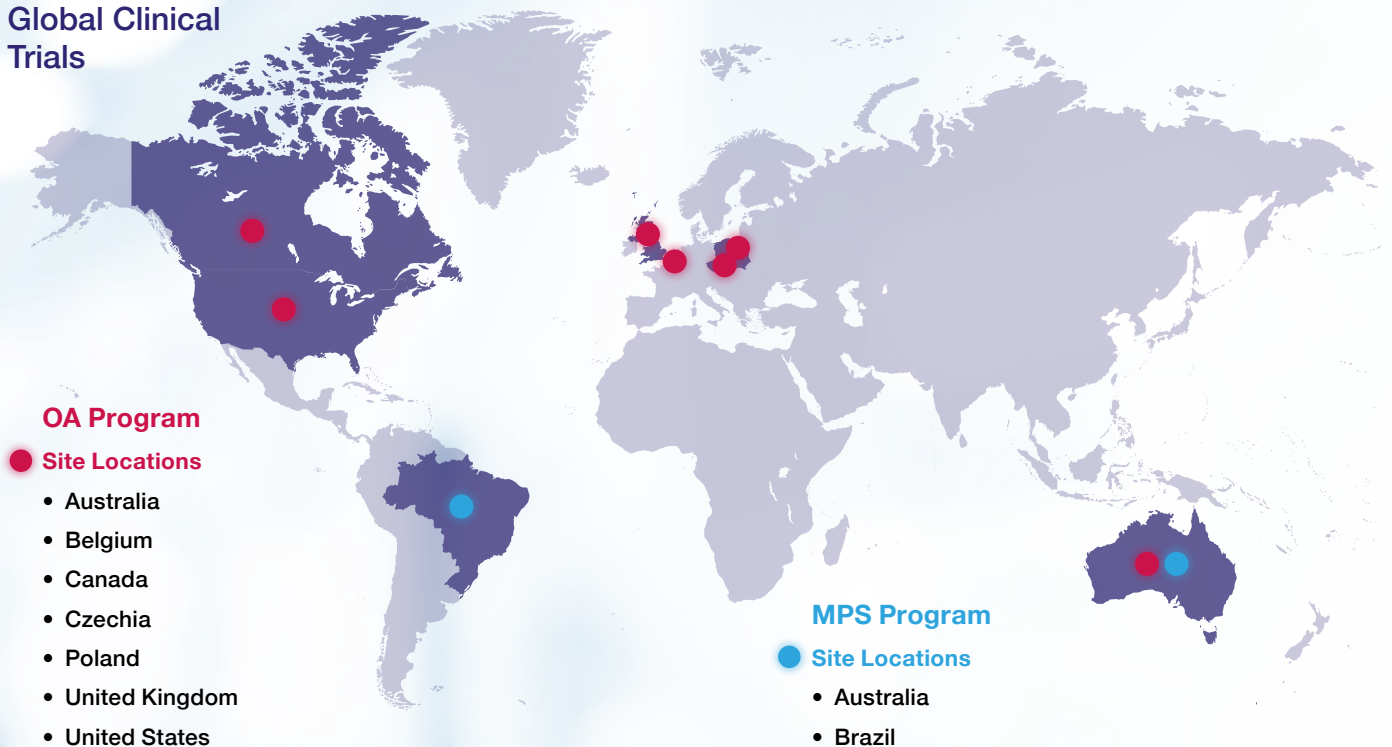
Clinical trial sites recruiting for the phase 3 OA program in 7 countries worldwide



\$7.4m AUD

R&D tax rebate

## Global Clinical Trials



## Key Highlights from FY2023

Paradigm has continued to progress the development of PPS in the two focal clinical programs of osteoarthritis (OA) and the ultra-rare disease mucopolysaccharidosis (MPS). Below are several key successes from financial year 2023.

### > Oct 22

The double-blind, randomised, placebo-controlled phase 2 PARA\_OA\_008 clinical trial achieved its primary endpoint demonstrating changes in the synovial fluid molecular biomarkers from baseline in people with knee OA treated with iPPS compared to placebo.

### > Dec 22, Jun 23

The double-blind, randomised, placebo-controlled phase 3 PARA\_OA\_002 clinical trial underwent two successful formal safety reviews by the data monitoring committee (DMC) with recommendations to proceed without modification.

### > Jun 23

Primary and secondary endpoints met in open-label phase 2 MPS I clinical trial run in Adelaide, Australia. iPPS was well tolerated out to 73 weeks and patients reported meaningful improvements in pain, function, and activities of daily living.

# Chairman and Managing Director's Report



Paul Rennie

Paradigm continues to forge ahead and meet its milestones on the road to registering injectable pentosan polysulfate sodium (iPPS) as a treatment to alleviate pain and improve joint function in both knee osteoarthritis and the ultra-rare diseases of mucopolysaccharidosis types I and VI. As Chair and Managing Director, I'm delighted to share with you these clinical and operational updates as we move towards our goal of filing a New Drug Application (NDA) for iPPS to treat osteoarthritis.

Dear Shareholders,

**I am pleased to report on the progress made by Paradigm Biopharmaceuticals Limited and its controlled entities (Paradigm) during the fiscal year 2023.**

Paradigm Biopharmaceuticals is an Australian-based, global 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 pentosan polysulfate sodium (iPPS or brand name Zilosul®) for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of iPPS.

The immediate commercial focus is for the treatment of pain and joint dysfunction associated with osteoarthritis (OA) and pain and arthropathy in patients with the rare genetic disorder mucopolysaccharidosis types I and VI (MPS).

## OA Clinical Program Highlights

I am pleased to report that the Company has achieved significant progress in the last 12 months in both OA and MPS clinical assets. Paradigm has continued to achieve important milestones as we progress through the phase 3 OA clinical program. In December 2022,

the independent data monitoring committee (DMC) conducted the first formal safety review for the PARA\_OA\_002 phase 3 clinical trial, with a second formal safety review conducted in June 2023. The DMC is responsible for assessing safety risk, benefit, and feasibility during the conduct of Paradigm's PARA\_OA\_002 study, as well as ensuring the validity and scientific merit of the trial. The DMC recommended that the clinical trial proceed without modification.

The Paradigm team worked tirelessly throughout the 12-month period to achieve our goal of activating 120 clinical trial sites to ensure rapid recruitment of the PARA\_OA\_002 study. The global phase 3 clinical trial is now operating in seven countries following regulatory and ethics approvals from the key regulatory agencies in Europe, the United Kingdom (UK), and Canada during FY2023. Paradigm's clinical sites screened participants in Australia, the US and Canada in North America, and the UK, Belgium, Poland, and Czechia in the EU.

The significant progress and milestones achieved in the phase 3 clinical program during fiscal year 2023 have culminated in the identification of all participants needed for stage 1 of the PARA\_OA\_002 clinical trial. Stage 1, enrolling a total of 468 participants, aims to determine the optimal dose of iPPS compared to placebo. This dose

information will then be used to progress through to stage 2 of PARA\_OA\_002 and for the subsequent confirmatory PARA\_OA\_003 clinical trial.

In addition to the phase 3 OA program focusing on the treatment indications of pain and joint dysfunction, we continued to explore the potential disease modifying properties of iPPS with the PARA\_OA\_008 study and in a canine model of naturally occurring OA.

The exploratory phase 2 PARA\_OA\_008 study achieved two positive top-line data readouts at Day 56 and Day 168 during the fiscal year. The primary endpoint—a change in one or more synovial fluid biomarkers associated with OA disease progression—was achieved at Day 56. Pleasingly, significant changes from baseline in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain, function, and stiffness values were also observed at Day 56 following twice-weekly iPPS treatment compared to placebo, despite the small patient groups. Furthermore, this study also produced strong signals of disease modifying potential at Day 168, showing structural improvement as measured by continued positive changes in synovial fluid, serum, and urine biomarkers and positive structural changes to the cartilage, subchondral bone marrow lesions and osteophytes following iPPS treatment versus placebo.



**\$66m** AUD

#### Capital raise

Capital raise in August 2022 comprising \$45.7 million AUD institutional placement and a fully underwritten \$20.3 million AUD entitlement offer.

**7**

#### New hires

In FY2023, Paradigm expanded the employee base with new hires in operational, clinical, commercial, and administrative positions in Australia and the US. Paradigm has balanced gender representation including in senior leadership positions, from the Board to the Executive Leadership Team to employees.

**100+**

#### Patents

As of January 2023, Paradigm owns over 100 granted or pending patent applications related to novel uses for PPS.

### OA Preclinical Program Highlights and OA Program Next Steps

In conjunction with the PARA\_OA\_008 clinical trial, Paradigm also conducted a study in a canine model of naturally occurring OA to further explore the potential disease modifying properties of iPPS and to provide long-term durability data at 26 weeks in dogs, which is equivalent to a three-year period in humans. Data reported from the canine study at 26 weeks demonstrated positive trends with meaningful effect size on subjective measurements of pain, objective functional clinical outcomes, and objective measurements of cartilage volume and molecular biomarkers, following iPPS administration.

The clinical, MRI, and molecular biomarker data produced from the phase 2 PARA\_OA\_008 clinical trial along with the data from the canine OA model will be presented to the US and EU regulatory authorities (FDA and EMA). The aim is to reach agreement on the regulatory pathway for a DMOAD label extension, which would add further commercial value to Paradigm's OA asset.

### MPS Clinical Program Highlights

The development of iPPS for MPS (where Paradigm has achieved designated orphan status for MPS I and MPS VI) continues, with two major phase 2 milestones achieved in FY23.

In April 2023, we announced that Paradigm's MPS VI phase 2 trial based in Brazil had completed enrolment of 13 participants. This placebo-controlled, double-blind, and randomised 24-week study compares iPPS to placebo, where the primary objective is to evaluate the safety and tolerability of iPPS. Secondary endpoints include iPPS effects on pain, function, and glycosaminoglycan (GAG) levels at 6, 12, and 24 weeks. Recruiting 13 participants in this ultra-rare disease is a fantastic achievement for the Company, and we look forward to reporting top-line data later this calendar year.

In June 2023, the Company announced that the phase 2 open-label, single centre pilot study to evaluate iPPS treatment in subjects with MPS I met its primary and secondary endpoints. iPPS was well tolerated out to 73 weeks and subjects reported meaningful improvements in pain, function, and activities of daily living and an overall improvement in quality of life. GAG levels were also reduced with iPPS treatment.

# Chairman and Managing Director's Report continued

I am sure most investors understand that drug development is a complex process, and it takes the dedication and persistence of highly experienced staff to bring a new drug to market. I am pleased to advise shareholders that there is a very professional and productive clinical, safety, and regulatory affairs team in place at Paradigm, and they remain very focused on preparing the necessary data to present to the US Food and Drug Administration and other regulatory agencies.

## Board Initiatives

Following a vote against the Employee Share Plan (ESP) at the 2022 Paradigm AGM, the Board has worked diligently and sought feedback from key stakeholders to produce a new long-term incentive (LTI) plan designed to drive shareholder value and encourage participant behaviour towards achieving business success.

The Plan involves employees being granted 'Performance Rights' each year. Each Performance Right converts to one ordinary share if performance-based vesting conditions are met at the end of a three-year vesting period.

There are three performance hurdles which must be achieved before any performance-based rights can vest. (i) There must be a minimum shareholder return as measured by the compound annual growth rate (CAGR) of the share price, (ii) business goals must be met, and (iii) individual performance as measured by key performance indicators (KPIs) must also be met.

We look forward to presenting the updated LTI plan to all shareholders in the near term. An LTI plan is an important tool for management to ensure Paradigm can continue to attract and retain the best talent necessary to drive the achievement of Company milestones and increase value for all stakeholders.

**I thank Paradigm's independent Directors for the faith and trust they have again bestowed upon me to lead this Company as we navigate the complexities of an extensive clinical program on the way to registering PPS for multiple indications.**

## Key Operational Aspects

Much of the FY23 expenditure was focused on clinical development for the lead programs. Paradigm's cash position was bolstered by a \$66 million capital raise in August 2022. This comprised a \$45.7 million institutional placement supported by existing and new domestic and international institutional investors, and a fully underwritten 1 for 15 pro-rata non renounceable entitlement offer of A\$20.3 million at \$1.30 per share.

Throughout FY23, Paradigm welcomed seven new hires into the organisation to grow Paradigm's global footprint, resulting in equal numbers of staff in Australia and the US. Marco Polizzi was appointed as Paradigm CEO in July 2022, and in November 2022, Marco's employment with Paradigm ceased. The terms of the separation deed are confidential. I thank Paradigm's independent Directors for the faith and trust they have again bestowed upon me to lead this Company as we navigate the complexities of an extensive clinical program on the way to registering PPS for multiple indications. Abby Macnish Niven joined Paradigm as interim CFO and Company Secretary, following the departure of CFO Justin Cahill in March 2023 and after the tragic passing of inaugural Paradigm Company Secretary Kevin Hollingsworth. Kevin was always a passionate contributor to Paradigm, a great friend and colleague.

## The View Ahead

In July 2022, Paradigm engaged Plexus Ventures (USA) to assist with our global partnering activities. Plexus has more than 30 years' experience in structuring and executing transactions and agreements among pharmaceutical and consumer healthcare companies worldwide. The experts from Plexus who are working with Paradigm have direct experience and wide networks within the global pharmaceutical sector. Plexus facilitates Paradigm's discussions with potential partners and advises on deal strategy, timing, value and the strategic fit and capabilities of potential partners for Paradigm's assets. Throughout FY23, Paradigm together with Plexus have attended multiple global conferences including JP Morgan Healthcare Conference, BIO International and BIO-Europe, and held numerous one-on-one meetings with potential global and regional licensing partners to introduce Paradigm and its late-stage assets and pursue discussions with interested parties.

I would like to thank our shareholders for their continued support of Paradigm along our journey to a New Drug Application (NDA). We are extremely grateful for your investment, passion and commitment, which helps drive us to achieve our best. I would also like to thank the staff at Paradigm for their dedication, contributions, and achievements in FY23. I look forward to reporting further significant milestones in FY24.

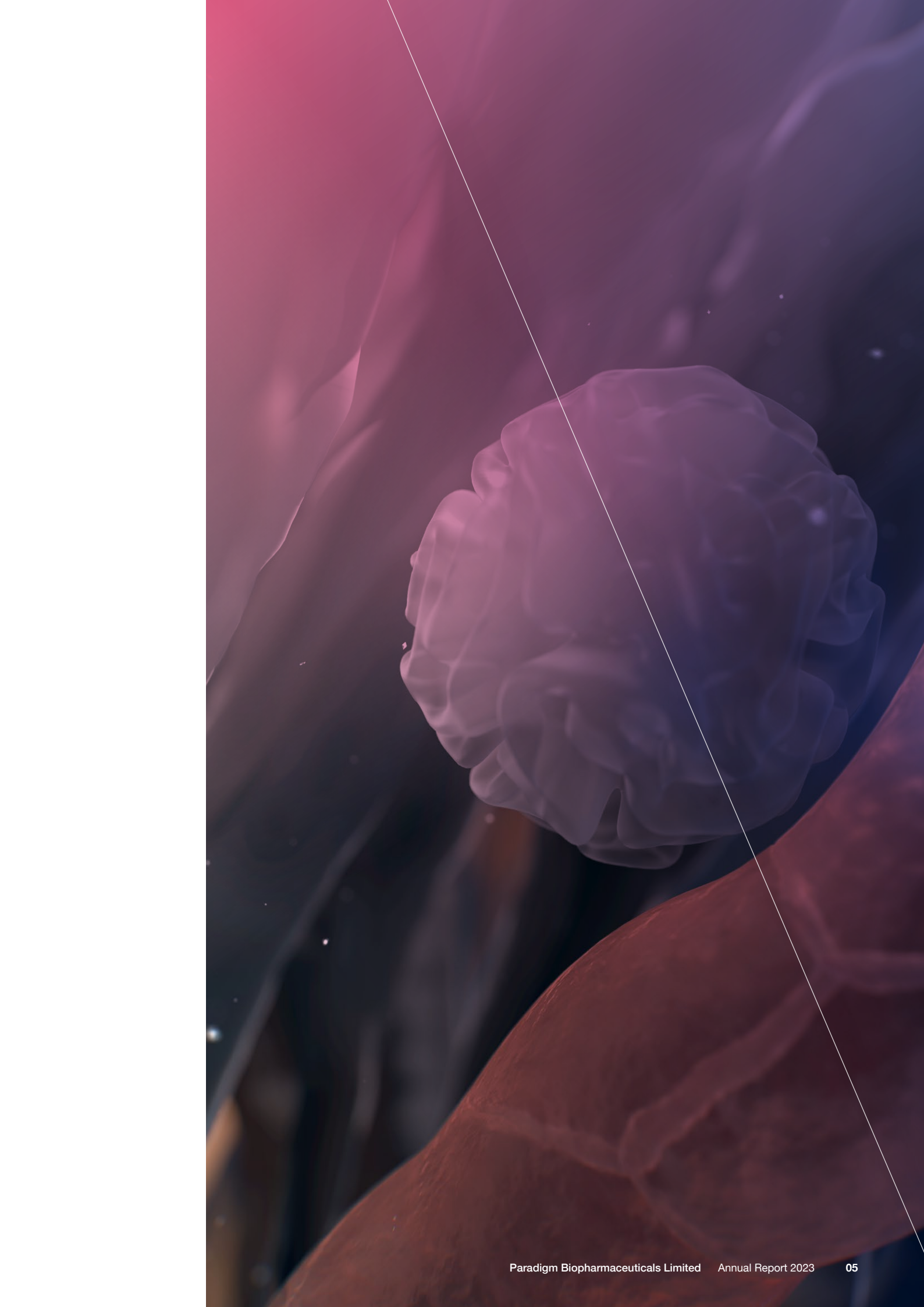
On behalf of the Directors,



**Paul Rennie**  
Chairman and Managing Director

Melbourne, Victoria  
25 August 2023





# Chief Medical Officer's Report



**Donna Skerrett**

This year has seen impressive advances in the Company's two major clinical and scientific programs of osteoarthritis and mucopolysaccharidosis. With these and future upcoming milestones, Paradigm is on track to develop iPPS into a registered product.

Dear Shareholders,

As Paradigm's Chief Medical Officer, I'm pleased to report upon the Company's clinical and scientific progress.

Paradigm's goal is to develop the full potential of underutilised molecules to address many of the unmet medical needs facing millions worldwide suffering from diseases characterised by inflammation. The Company's current primary focus is the clinical development of an injectable version of the semi-synthetic molecule pentosan polysulfate sodium, also known as PPS or iPPS. This molecule has been in use in oral form to treat bladder inflammation in humans for over 25 years.

Based on more recent scientific research, we quickly understood that PPS had the excellent potential to reduce pain and improve function in diseases with strong inflammatory components such as osteoarthritis. This hypothesis was reinforced with early preclinical research results that have translated into highly exciting clinical trial results and real-world evidence from our managed access programs.

Although the road to drug registration is long and complex, we are delighted with our continued progress in our R&D and clinical programs, as emphasised by the FDA Fast Track Designation granted a little over a year ago, and our continuing clinical milestone achievements.

## Navigating Drug Development

Our team of highly skilled clinical, research, medical, regulatory, logistics, and business experts understand that to successfully achieve approval, all facets of a new drug must be beyond reproach. Most importantly, these include clinical effect and safety, which are key metrics used at all stages of a drug development process.

Drug development starts with laboratory and preclinical studies, which can then move into early testing in small groups of volunteers (20-80), known as phase 1 clinical trials. Phase 1 trials are focused on safety with continued checks for side effects (adverse events). Phase 1 studies may also evaluate the kinetics of a drug, i.e., understanding how much drug is in an individual and how long the drug stays in the circulation so a half-life can be calculated.

Phase 2 clinical trials investigate efficacy and continue to monitor safety in larger studies, comparing response and tolerance in the drug-treated group with control subjects. When meaningful signs of efficacy and tolerance are established in phase 2, the program progresses to phase 3 trials, which are powered to demonstrate statistically significant and clinically meaningful treatment effects in treated compared to control subjects and often include hundreds of patients.

Phase 3 trials compare the new investigational drug to an existing medication or the current standard of care if no comparable therapy exists. As with all studies, phase 3 continues to monitor for any adverse effects.

In addition to the safety and efficacy studies, further laboratory or preclinical studies may deepen understanding of the molecular mechanisms of action.

Furthermore, the sponsoring company must ensure that the investigational drug can be manufactured consistently, and quality controlled to all necessary specifications, which means meeting all manufacturing, labelling, transport, and logistical planning requirements necessary to scale up production and deliver consistent drug for human use.

Our team is ensuring that at every stage, we meet and pass all regulatory requirements on this drug development journey, to provide a well planned and executed registration program for commercialising iPPS for osteoarthritis and MPS.

## Clinical Trials – the Cornerstone of our iPPS Development Program

As highlighted by Managing Director Paul Rennie, the last financial year has seen enormous progress in our pivotal phase 3 clinical trial for knee osteoarthritis. This global two-stage, adaptive, double-blinded, placebo-controlled clinical trial is active in seven countries, with over 120 clinical trial sites activated to date. Remotely managing the recruitment process for such a complex trial during the tail end of a global pandemic has been a massive logistical challenge, one that the Company has met with unflagging determination and dedication. We are delighted to report that the PARA\_OA\_002 clinical trial has now identified all patients to be randomised for the first stage.

Multiple different initiatives contributed to this success. The clinical team benefited from the Company's partnership with NFL Alumni Health, resulting in an invitation for our Head of Clinical Osteoarthritis, Dr Mukesh Ahuja, to present at a health symposium during the NFL Draft in Kansas City. Furthermore, Paul Rennie, Dr Ahuja and I were invited to present to several different NFL Alumni chapter presidents, with a resulting positive increase in clinical trial interest.

The Company also engaged the services of two well-respected and effective clinical trial recruitment enterprises, 1nHealth, and SubjectWell, which both use targeted patient-centric technology-enabled approaches to better identify potential participants. In Australia, a targeted radio ad campaign across several states, as well as a focused letterbox drop near clinical trial sites were tested to increase recruitment. Our core internal team works seamlessly and closely with our clinical, safety, and statistical contract research organisation (CRO) partner vendors to manage all aspects of patient care, monitoring, and data management.

PARA\_OA\_002 stage 1 will provide information for selection of the lowest and best tolerated dose for proceeding to stage 2 to complete this phase 3 study, and to initiate the confirmatory phase 3 study. Following dose selection, the above-noted initiatives will support the ongoing recruitment for the subsequent second stage of this pivotal clinical trial, which when complete, will have seen over 900 volunteers randomised for the study.

**Our team is ensuring that at every stage, we meet and pass all regulatory requirements on this drug development journey, to provide a well planned and executed registration program for commercialising iPPS for osteoarthritis and MPS.**



# 7

## Countries

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Number of countries with study trial sites for both OA and MPS clinical programs

# 468

## Patients

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Number of volunteers in the first stage of the double-blind, placebo-controlled, randomised phase 3 PARA\_OA\_002 study

## Chief Medical Officer's Report continued

### Harnessing the Potential Value for DMOAD in OA

Right now, there are no OA treatments available classed as DMOADs—or disease-modifying OA drugs—for people suffering the debilitating effects of progressive OA. Currently available medications and therapies can help manage OA symptoms; however, they are unable to address the underlying bone dysfunction, and cannot slow, stop or reverse the degenerative bone disease process. Furthermore, many OA treatments require prolonged continual administration and are often not tolerated for long periods of administration.

This year, we reported exciting results from two different studies, one aimed to examine the changes that occur in the knee joint space (synovial fluid or synovium) in a canine model that treated family owned dogs with naturally occurring osteoarthritis of the stifle (knee equivalent) and elbow joints. Although only exploratory (small numbers), this study provided a glimpse into the potential longer-term effects of iPPS treatment. This is because the six-month

period that was investigated in the dogs is roughly equivalent to three years of bone deterioration in humans with OA.

Not only were clinical and functional measures showing encouraging effects compared to placebo, but further explorations into changes in the knee joint following iPPS treatment with the assessment of biomarkers, both molecular and structural, provided some evidence that iPPS may slow or halt OA disease progression.

Furthermore, an additional study provided convincing clinical evidence of iPPS DMOAD potential. This exploratory double-blinded, placebo-controlled, randomised controlled phase 2 clinical trial investigated iPPS in 61 people with

moderate to severe knee osteoarthritis at 56 days (two weeks after completing the six-week treatment course) and at 168 days (six-month timepoint). A number of trial participants will also be assessed for pain and function at the one-year timepoint. This PARA\_OA\_008 trial met the primary endpoint of changes in one or more synovial biomarkers at Day 56 and durable effects on pain and function were observed, with rescue medication use four times higher in the placebo group compared to one of the iPPS groups.

These results provide encouraging data supporting DMOAD effects for iPPS. However, as no DMOAD has ever been successfully registered, no established registration pathways for such drugs exist. Given trial results and the Fast

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**Not only were clinical and functional measures showing encouraging effects compared to placebo, but further explorations into changes in the knee joint following iPPS treatment with the assessment of biomarkers, both molecular and structural, provided some evidence that iPPS may slow or halt OA disease progression.**

Track Designation, Paradigm intends to initiate working discussions with the FDA and EMA in order to develop and reach agreement on a novel DMOAD registration pathway.

Paradigm considers DMOAD labelling a strategically valuable goal as independent market research conducted in 2021 demonstrated that physicians would consider Zilosul® much earlier in the therapeutic algorithm if it had a disease modifying indication. Subsequent analysis of US payers found that an annual cost of between \$2,000 to \$3,000 USD would be acceptable for Zilosul® as a therapy to reduce pain and improve function in knee OA, whereas an additional DMOAD label could be valued at \$6,000 USD/year or higher.

### A Brief MPS Update

Our MPS clinical program is a critical pillar in the development of iPPS. Once children born with the ultra-rare forms of lysosomal storage disease known as mucopolysaccharidosis or MPS have been diagnosed, they will be reliant on either bone marrow transplantation and/

or enzyme replacement therapy to keep the worst of the disease effects at bay. Despite these cutting-edge treatments, people with MPS still experience residual joint inflammation and pain, which can severely impact their day-to-day lives.

The Company has progressed to phase 2 clinical trials in both MPS types I and VI. The open-label phase 2 MPS I trial was completed and is currently undergoing analysis. The placebo-controlled, double-blind, randomised phase 2 MPS VI study completed participant enrolment and passed several safety reviews, enabling the inclusion of younger subjects. As analysis continues, we are planning further discussions with regulators to establish regulatory pathways for registration for iPPS for the treatment of this rare disease.

### An Exciting Stage of Development

This year, we've seen our OA clinical trial program progress in leaps and bounds with the continued meeting of targets with the global phase 3 trial and some highly positive phase 2 and nonclinical study

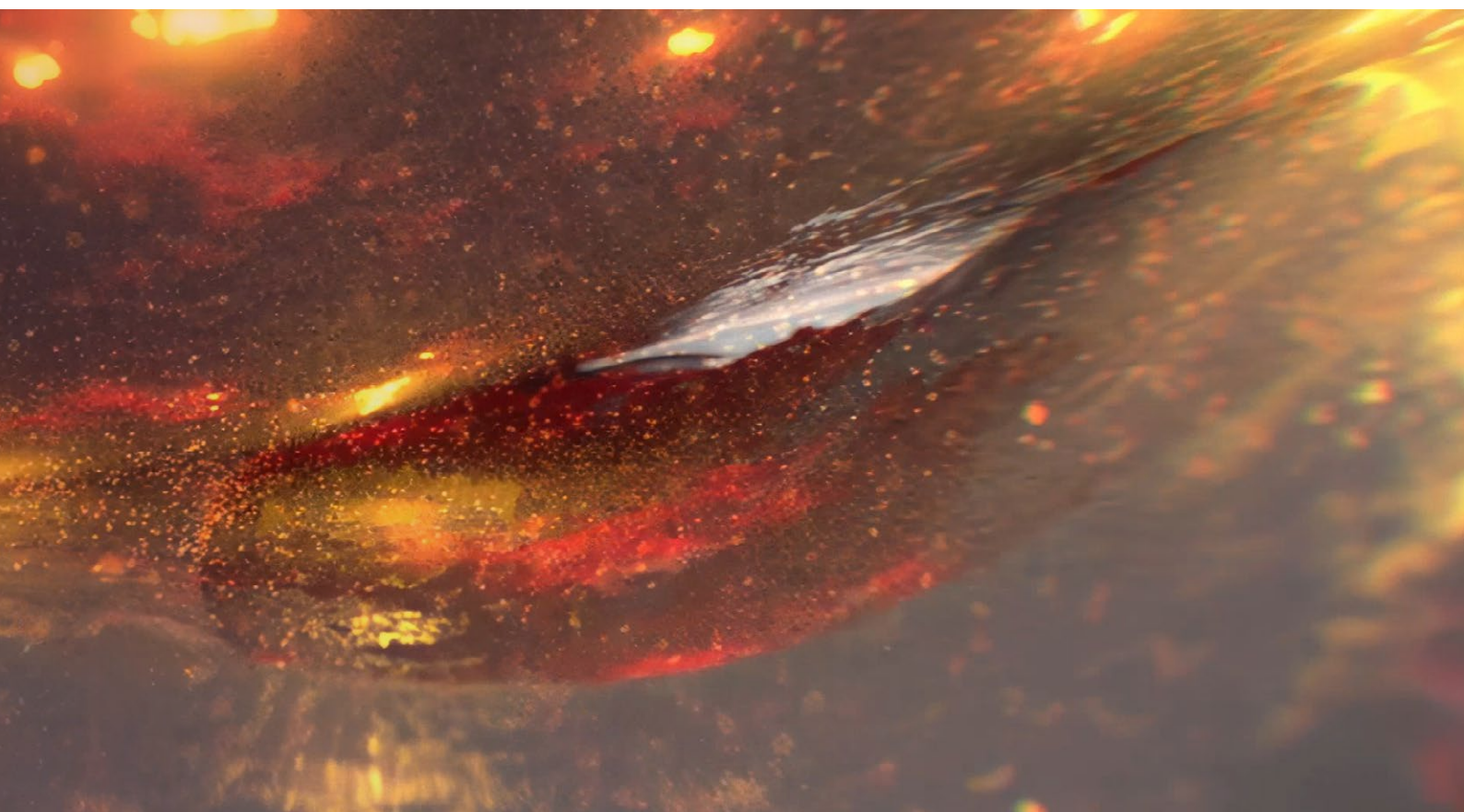
results indicating that DMOAD may well be within reach. Moving from clinically relevant pain relief and improvement in function, to potentially slowing, halting, or even reversing degenerative osteoarthritis will ensure that Zilosul® is at the forefront of decision-makers' minds when considering reimbursement potential.

I would like to personally thank Founder and Managing Director Paul Rennie, and the Board for their continued support throughout the year, as well as the entire dedicated Paradigm team, who have worked tirelessly to achieve excellent results this year, I can't wait to see what the next few years bring.

*Donna Skerrett*

**Donna Skerrett**  
Chief Medical Officer

New York City, New York



# The Unmet Need in Osteoarthritis

In combination with an ageing population, the lack of effective treatments for osteoarthritis is a global issue. Here, we delve into the reasons why developing a novel non-opioid treatment that can alleviate pain and improve mobility in osteoarthritis is so important.

Musculoskeletal disorders—including osteoarthritis—are responsible for more Australian health expenditure than any other group of conditions. This is according to the Australian Institute of Health and Welfare (AIHW) report on the 2019–2020 Australian Burden of Disease Study, which included COVID-19. Musculoskeletal disorders cost Australians a phenomenal \$14.6 billion, compared to \$12.7 billion for cardiovascular diseases or \$12.1 billion for cancer and other neoplasms<sup>1</sup>. Of the musculoskeletal disorders, osteoarthritis is one of the most common, affecting one in five Australians over the age of 45<sup>2</sup>, and rates only look to increase.

This need has only been strengthened with the release of 2021 Census data, confirming a link between ageing and increasing rates of arthritis. The Australian Bureau of Statistics found that 50.4% of baby boomers—those aged 55-74 years—reported a

long-term health condition, equating to a tenth of the Australian population. The condition was more than twice as likely to be arthritis compared to the whole Australian population. Arthritis was also the most commonly reported long-term condition for all Australians living in New South Wales, South Australia, and Tasmania<sup>3</sup>.

Osteoarthritis is a chronic joint disease most often causing pain and stiffness in knees, hips, and hands<sup>4</sup>. In particular, knee osteoarthritis was estimated to affect 913,539 working-age Australians in 2019, where the economic impact due to lost productivity amounted to AU\$424 billion in lost GDP<sup>5</sup>.

There is a scarcity of effective treatments for osteoarthritis, and research has found that four of five osteoarthritis sufferers are dissatisfied with current treatments<sup>6</sup>. Further compounding the issue is the absence of any registered

drugs that can prevent, stop, or slow osteoarthritis progression<sup>7</sup>. Although worldwide research on disease-modifying osteoarthritis drugs—or DMOADs—is ongoing, progress has been slow due to the complexity of this disorder.

In November last year, new research presented at the Radiological Society of North America's annual meeting is calling into question the efficacy of common osteoarthritis treatments such as anti-inflammatories and steroid injections, and even suggesting they could potentially worsen the underlying disease process<sup>8,9</sup>. Although this research is not yet published, such news is potentially concerning to the millions of people relying on these interventions worldwide.

Arthritis Australia—the peak non-profit charitable organisation supporting all types of arthritis sufferers—and the AIHW have highlighted the paucity of

## Paradigm's OA program milestones



**Legend:** DMC = Data Monitoring Committee; EAP = Expanded Access Program (US); EMA = European Medicines Agency; FDA = Food and Drug Administration (US); IND = Investigational New Drug; MHRA = Medicines and Healthcare Products Regulatory Agency (UK); NFL = National Football League; SAS = Special Access Scheme (AU); TGA = Therapeutic Goods Administration (AU).

— Clinical trial — Managed access programs — Regulatory — R&D study — Program development



528 million

Number of people worldwide suffering from OA in 2019<sup>11</sup>.



7

Number of different body zones listed as affected by osteoarthritis in applications for iPPS treatment via the Australian TGA's Special Access Scheme.



81%

Proportion of people suffering from OA that are dissatisfied with current treatments<sup>6</sup>.

research in this area of critical interest to all Australians<sup>10</sup>. Given the lack of effective treatments and growing concerns around current therapies, they are advocating loudly for the government to provide significant funding for arthritis research to prevent future loss of productivity and wellbeing, and to ensure that our health system is not overburdened with arthritis-related disorders, both now and into the future.

Paradigm understands this growing global unmet need, so the team focused its efforts on developing a safe and effective osteoarthritis treatment to reduce pain and improve mobility in people with knee osteoarthritis. Our target drug of interest is pentosan polysulfate sodium (PPS).

PPS was discovered 60 years ago as an anticoagulant and in 1996 was approved as a pill by the US FDA for the management of bladder inflammation.

However, the new formulation, known as iPPS or Zilosul<sup>®</sup> that is being developed for osteoarthritis, only requires a short six-week course of subcutaneous injections rather than daily oral use.

On the path to registration, Paradigm's comprehensive clinical program continues to produce consistent clinical results. In October of 2022, early data from a clinical trial in 61 Australians with moderate to severe knee osteoarthritis demonstrated significant improvements in pain, function, and stiffness in those receiving a six-week treatment course, compared to the control group. Furthermore, certain molecular biomarkers within the knee joint space showed favourable differences in the treated group, thus meeting the study's primary endpoint. Chief Scientific Officer Dr Ravi Krishnan said, "These biomarker changes are highly informative, as they reflect the osteoarthritic disease process and provide information about the

mechanism of action of Zilosul<sup>®</sup> in the knee joints of osteoarthritis sufferers." Managing Director Mr Paul Rennie reinforced their impact, "These results are potentially very exciting to both investigators and investors. If confirmed, they provide tangible evidence that a never-before-seen DMOAD is potentially within reach." Further results from this study were analysed and released in 2023 and demonstrated further bone and cartilage changes via MRI indicative of a potential disease-modifying process.

To further understand the effects iPPS has on the osteoarthritic joint and to gain insight into their duration, the Company completed a focused exploratory study in a canine model of naturally occurring osteoarthritis. Participant dogs with elbow or stifle joint (the knee equivalent in humans) osteoarthritis were screened and recruited as owners brought them in to a Werribee-based veterinary service.



# The Unmet Need in Osteoarthritis continued

Compared to placebo, iPPS-treated dogs showed meaningful improvements in subjective measures of pain, objective functional clinical outcomes, and objective measurements of cartilage volume and molecular biomarkers. Furthermore, positive changes were observed out to 26 weeks, considered to be approximately equivalent to three years in human terms.

In parallel, Paradigm is running a global, adaptive, two-stage, double-blinded, randomised and placebo-controlled clinical trial in which more than 900 participants from over 120 sites in Australia, the US, Canada, the UK,

and Europe will be recruited to determine the minimum effective and safe dose for Zilosul® in knee osteoarthritis sufferers, as well as provide further information on the duration of effects.

Paradigm has collected consistent data throughout its osteoarthritis program with two phase 2 clinical trials conducted in Australia and through real-world evidence via the TGA Special Access Scheme (SAS) and the FDA Expanded Access Program (EAP). To date, the osteoarthritis program has achieved many significant milestones as the Company has progressed into

a globally harmonised and FDA Fast Tracked phase 3 clinical program for knee osteoarthritis.

While osteoarthritis and other musculoskeletal disorders remain a significant burden to sufferers, these promising results in reduction of pain, improvement in function, improvement in overall global impression of change, and signals of molecular and structural improvement provide hope that a better osteoarthritis therapy might be closer to a reality. The over half a billion osteoarthritis sufferers worldwide await further developments with interest.

## What is Zilosul®?

**Injectable pentosan polysulfate sodium (iPPS)—or Zilosul® for the use of treating osteoarthritis—is a semi-synthetic heparin-like drug manufactured from the wood of European beech trees. Extracted glucuronoxylans are then sulphated via a proprietary method to produce a negatively charged product that mimics natural glycosaminoglycans (GAGs). GAGs are complex carbohydrates that play a regulatory role in the body through interacting with proteins involved with inflammation.**

**PPS has several key features including anti-inflammatory activity and pain reduction. The mechanism of action of PPS occurs by reducing the transcription factor NFκB. This reduction then modulates nerve growth factor (NGF) expression, potentially reducing pain signalling<sup>12-14</sup>.**

**The Company's broader focus is therefore to explore the use of PPS in the treatment of a wide spectrum of conditions that begin with and are sustained by inflammation, such as alpha-viral induced arthralgia, heart failure, osteoarthritis (OA), and the ultra-rare disease mucopolysaccharidosis (MPS).**

**Zilosul® is the registered name of injectable PPS when used for the treatment of pain and to improve function in people with osteoarthritis.**

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# Directors' Report

The Directors present their report together with the Financial Report of Paradigm and the entities it controlled at the end of, or during, the year ended 30 June 2023 (referred to hereafter as the 'Consolidated Entity').

## Directors

### Information on Directors

The Directors of Paradigm at any time during or since the end of the financial year are:



#### **Paul Rennie, Managing Director and Executive Chairman (Appointed as Managing Director and ceased as Non-Executive Chairman on 22 November 2022)**

Paul Rennie BSc, MBM, Grad Dip Commercial Law, MSTC, has sales, marketing, business development, operational and IP commercialisation experience in the biopharmaceutical sector. Paul's experience includes working for Boehringer Mannheim (now Roche Diagnostics), Merck KGGA as national sales and marketing manager and Soltec (FH Faulding Ltd) as their Director of business development. Paul also led the commercialisation of Recaldent®, a novel biopharmaceutical arising from research at the dental school, University of Melbourne. Paul took an R&D project from the laboratory bench to a commercial product now marketed globally as an additive to oral care products. More recently Paul worked in a number of positions with Mesoblast Ltd. Paul was the inaugural COO and moved into Executive Vice President New Product Development for the adult stem cell company. Paul is the founder of Paradigm Biopharmaceuticals. Paul is also Non-Executive Chairman and Interim Chief Executive Officer of NeuroScientific Biopharmaceuticals Ltd (ASX:NSB).



#### **Dr Donna Skerrett, Executive Director and Chief Medical Officer (Appointed on 3 July 2020)**

Dr Donna Skerrett, has more than 30 years' experience in transfusion medicine, cellular therapy, and transplantation. She brings a wealth of experience in medical, clinical, and regulatory affairs. Donna served previously as Chief Medical Officer at Mesoblast. She was Director of Transfusion Medicine and Cellular Therapy at Weill Cornell Medical Center in New York (2004 – 2011), and prior to that was Associate Director of Transfusion Medicine and Director of Stem Cell Facilities at Columbia University's New York-Presbyterian Hospital. She has previously chaired the New York State Council on Blood and Transfusion Services, and served on the Board of Directors of the Fox Chase Cancer Center in Philadelphia, PA, and is currently a member of the Board of Visitors of Lewis Katz School of Medicine at Temple University.



#### **John Gaffney, Non-Executive Director (Appointed on 30 September 2014)**

John Gaffney LL.M is a lawyer with over 30 years' experience and has undertaken the AICD Company Directors qualification. He brings to the Board a compliance and corporate governance background and is experienced in financial services compliance. John also has corporate and commercial experience having worked with a major national law firm as a senior lawyer and also practised as a Barrister at the Victorian Bar. Previously John has been a Non-Executive Director of a US-based biotechnology company and SelfWealth Ltd (ASX:SWF). John is Chair of the Remuneration and Nomination Committee and is a member of the Audit and Risk Management Committee.



#### **Amos Meltzer, Non-Executive Director (Appointed on 9 December 2020)**

Amos Meltzer is a scientist and an intellectual property lawyer with over 25 years of experience in international trade and in commercialising technologies, principally in the life sciences sector. He has presided over life science research and product development projects clinical trials as well as the commercialisation of life sciences assets through both licensing and the sale and marketing of a pharmaceutical product. Previously Amos served as General Counsel and IP director at two Nasdaq-listed companies, Compugen and Gilat, as a Non-Executive Director of a biotechnology company Evogene, and as VP of Business Development and then CEO of an ASX-listed biopharmaceutical company Immuron. Amos currently serves as Chief Legal Officer of neuro-medical device company Synchron, chairman of the Board of surgeons' education services company Vasculab, and as a legal adviser to a number of ASX listed and private life science companies. Amos is a member of the Remuneration and Nomination Committee and a member of the Audit and Risk Management Committee.



#### **Helen Fisher, Non-Executive Director (Appointed on 23 February 2021)**

Helen Fisher, BSc, LLB (Hons), LLM, MCom, is Chief Executive Officer and Managing Director of Bio Capital Impact Fund (BCIF) and Non-Executive Director and Chair of the Audit and Risk Management Committee of Calix Limited (ASX:CXL), a company with a platform technology with applications in climate change, water management, biotech, and pharmaceutical areas. Prior to establishing BCIF, Helen was a partner of Deloitte for over ten years and led Deloitte's life science practice in Australia for five years, having had many years' experience in the life sciences and healthcare sector. Helen is Chair of the Audit and Risk Management Committee and a member of the Remuneration and Nomination Committee.

# Directors' Report continued

## Company Secretary

### Kevin Hollingsworth, Company Secretary (Appointed on 2 May 2014 and ceased on 30 August 2022)

Kevin Hollingsworth, FCPA, FCMA, CGMA, in addition to his duties at Paradigm, served as Principal of Hollingsworth Financial Services. Prior to that he served as Chief Financial Officer and Company Secretary of Mesoblast Limited (ASX:MSB). At Alpha Technologies Corporation Limited (ASX:ASU), Kevin served as a Non-Executive Director. He has served as National President of CIMA Australia, State Councillor for CPA Australia and Chairman of the National and Victorian Industry and Commerce Accountants Committees. He is a Chartered Global Management Accountant and Fellow of CPA Australia and Chartered Management Accountants. Kevin Hollingsworth passed away in August 2022.

### Abby Macnish Niven, Company Secretary (Appointed on 30 August 2022)

Abby Macnish Niven (BComm, Bsc, CFA, GAICD) has over 20 years' experience in wealth management in Australia. She holds a Bachelor of Commerce degree with a double major in Commerce and Science, is a CFA Charterholder and is a member of the Australian Institute of Company Directors. She has also completed the Certificate in Governance Practice. Abby has also held the role of Company Secretary and Chief Financial Officer of NeuroScientific Biopharmaceuticals Ltd (ASX:NSB) since April 2020.

## Directorships in Other Listed Entities

Directorships of other listed entities held by Directors of Paradigm during the last three years immediately before the end of the financial year are as follows:

Director	Company	Period of Directorship	
		From	To
John Gaffney	SelfWealth Ltd	23-Nov-17	30-Sep-19
Paul Rennie	NeuroScientific Biopharmaceuticals Ltd	22-Jun-21	Current
Helen Fisher	Calix Limited	22-Sep-20	Current
	Sienna Cancer Diagnostics Limited	28-Mar-18	28-Jul-20
	BARD1 Life Sciences Limited	28-Jul-20	25-Nov-20

## Directors' Meetings

The number of Directors' meetings (including meetings of committees of Directors) and the number of meetings attended by each of the Directors of Paradigm during the financial year are:

Director	Board		Nomination & Remuneration Committee		Audit & Risk Committee	
	Held	Attended	Held	Attended	Held	Attended
Paul Rennie	12	12	–	–	–	–
John Gaffney	12	12	1	1	2	2
Donna Skerrett	12	12	–	–	–	–
Amos Meltzer	12	12	1	1	2	2
Helen Fisher	12	12	1	1	2	2

In addition to the formal meetings identified in the table above, the committee members and the Board members each convened on many occasions including for the purpose of, in the case of the committees, preparing recommendations to present to the Board and, in the case of the Board, to attend to matters discussed at formal Board meetings and ensure that the Board decisions are implemented, and action items acted upon.

## Committee Membership

As at the date of the report, Paradigm had a Remuneration and Nomination Committee and an Audit and Risk Management Committee of the Board of Directors. Members acting on the committees of the Board during the financial year were:

Remuneration & Nomination Committee	Audit & Risk Management Committee
John Gaffney (Chair)	Helen Fisher (Chair)
Amos Meltzer	John Gaffney
Helen Fisher	Amos Meltzer

## Principal Activities

The principal activities of Paradigm are researching and developing therapeutic products for human use.

## Operating Review

Paradigm made a loss of \$51,910,013 (2022: \$39,249,584) for the financial year ended 30 June 2023, an increase of \$12,660,429 on the prior year. Given Paradigm is a late-stage clinical development company, it is likely that NPAT losses can be expected in future years as the clinical development of Zilosul<sup>®</sup> continues towards marketing approval.

Revenue from continuing operations of \$46,760 (2022: \$79,224) decreased compared to the prior corresponding period by \$32,464. This revenue is related to the TGA approved Special Access Scheme (**SAS**). Under the SAS program, Zilosul<sup>®</sup> has been made available to selected physicians to treat patients experiencing chronic arthralgia from Ross River Virus (**RRV**) infection, previous SAS patients seeking re-treatment, and other subjects that do not qualify for recruitment in the PARA\_OA\_002 or PARA\_OA\_008 clinical studies. The pay-for-use SAS program was launched late in FY21, with Paradigm supplying product to prescribing doctors experienced with iPPS and who had the ability to provide the safety monitoring necessary for this program. Subject monitoring is of a standard consistent with those in the PARA\_OA\_002 and PARA\_OA\_008 studies, which does add further cost to the SAS program. Paradigm is willing to continue to provide SAS for subjects who meet strict participation criteria, knowing that this provides a therapy option for those that have participated in SAS previously or who are ineligible for participating in open recruiting studies. Due to the strict monitoring guidelines and reporting procedures, Paradigm has determined that whilst the Company is conducting its global phase 3 program, it is necessary to provide access only to prescribing doctors who have considerable experience with iPPS. Due to this we expect continued modest uptake of the SAS program into FY24.

Other income of \$8,534,179 (2022: \$7,814,341) is higher than the prior corresponding period by \$719,838. The main reason for this increase is the interest received during the year was much higher than FY22 by \$1,350,833 due to increased cash on term deposits as well as the impact of higher interest rates in FY23.

Expenditure on research and development increased on the prior corresponding period by \$13,667,206 to \$52,679,197. Most of the increased spend is directly related to the clinical development program for Zilosul<sup>®</sup>, a phase 3 asset in treating pain and joint function associated with knee osteoarthritis. Paradigm reported in FY23 regulatory and ethics approvals for the PARA\_OA\_002 study in Europe, Canada, and the UK, enabling site activation and patient recruitment in these countries. During FY23, over 60 sites across the US, Australia, Canada, Europe, and the UK were activated for the PARA\_OA\_002 study. Paradigm staff, in conjunction with our Clinical Research Organisation (CRO) partner, Premier, coordinated the set-up of the now 120 activated sites, including training, system development, coordination of lab tests, and start up support as each site commenced screening of subjects. Paradigm recently reported all subjects have been identified for stage 1 of the two-stage adaptive PARA\_OA\_002 phase 2 clinical trial. In addition to the PARA\_OA\_002 study, expenditure increased in the PARA\_OA\_008 study. This study focused on examining biomarker data on synovial fluid of the knee, whilst also collecting important pain, function, and MRI data at various timepoints to inform the Company of the potential for Zilosul<sup>®</sup> to be developed as a DMOAD for knee osteoarthritis. During the financial year, Paradigm reported complete enrolment of this phase 2 study as well as top-line data from both the Day 56 time point where the primary endpoint was achieved and further significant top-line data at Day 168 demonstrating the potential of iPPS to slow the progression of osteoarthritis.

General and administrative costs of \$6,564,548 (2022: \$7,934,179) were lower than the prior corresponding period by \$1,369,631. The reduced costs in FY23 are the result of our targeted cost reduction programs during FY23.

Commercial expenses of \$822,695 (2022: \$918,860) were lower than the prior corresponding period by \$96,165. The decrease in spend relates primarily to our cost reduction program, whilst still ensuring the delivery of targeted stakeholder engagement and communication programs to continue raising the external global profile of Paradigm's clinical programs.

The impairment loss during the period was Nil (2022: Nil).

Basic and diluted net loss per share increased to 20.78 cents (2022: 16.87 cents as restated) due to the greater loss attributable to the number of shares.

On the 15th of August 2022 Paradigm announced a capital raise of approximately \$66 million at \$1.30 per share. The raise comprised a \$45.7 million institutional placement under Paradigm's existing LR7.1 capacity and a 1:15 pro rata non renounceable entitlement offer of \$20.3 million. The use of funds was focused on:

- Continuation of phase 3 clinical development and new drug application (**NDA**) related activities for Zilosul<sup>®</sup>,
- Business development related activities
- Product development related activities (auto injector, for example)
- Working capital.

# Directors' Report continued

## Environmental Regulation

Paradigm's operations are not regulated by any significant environmental law of the Commonwealth or of a state or territory of Australia.

## Risk Statement

### Clinical Development

Clinical trials are inherently very risky and may prove unsuccessful or non-efficacious, impracticable or costly – which may impact on the prospect of completion. Failure or negative or inconclusive results can occur at many stages in development and the results of earlier clinical trials are not necessarily predictive of future results. In addition, data obtained from trials is susceptible to varying interpretations, and regulators may not interpret the data as favourably as Paradigm, which may delay, limit or prevent regulatory approval.

### Research and Development Activities

Paradigm's future success is dependent on the performance of Paradigm in clinical trials and whether its therapeutic product candidate proves to be a safe and effective treatment. Paradigm's lead product is an experimental product in clinical development and product commercialisation resulting in potential product sales and revenues is likely to still be a few years away, and there is no guarantee that, even when commercialised, it will be successful. It requires additional research and development, including ongoing clinical evaluation of safety and efficacy in clinical trials and regulatory approval, prior to marketing authorisation. Drug development is associated with a high failure rate and, until Paradigm is able to provide further clinical evidence of the ability of Paradigm's product to improve outcomes in patients, the future success of the product in development remains speculative. Research and development risks include uncertainty of the outcome of results, difficulties or delays in development and generally the uncertainty that surrounds the scientific development of pharmaceutical products.

### Regulatory Approval

Paradigm operates within a highly regulated industry, relating to the manufacture, distribution and supply of pharmaceutical products. There is no guarantee that Paradigm will obtain the required approvals, licences and registrations from all relevant regulatory authorities in all jurisdictions in which it operates. The commencement of clinical trials may be delayed and Paradigm may incur further costs if the Food and Drug Administration (**FDA**) and other regulatory agencies observe deficiencies that require resolution or request additional studies be conducted in addition to those that are currently planned. A change in regulation may also adversely affect Paradigm's ability to commercialise and manufacture its treatments.

### Intellectual Property Risks

Securing rights in technology and patents is an integral part of securing potential product value in the outcomes of biotechnology research and development. Competition in retaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes. Paradigm's success depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. Because the patent position of biotechnology companies can be highly uncertain and frequently involves complex legal and factual questions, neither the breadth of claims allowed in biotechnology patents nor their enforceability can be predicted. There can be no assurance that any patents which Paradigm may own, access or control will afford Paradigm commercially significant protection of its technology or its products or have commercial application or that access to these patents will mean that Paradigm will be free to commercialise its drug candidates. The granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology or products to avoid Paradigm's patented technology. Paradigm's current patenting strategies do not cover all countries, which may lead to generic competition arising in those markets.

### Competition

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change, both in Australia and internationally, and there are no guarantees about Paradigm's ability to successfully compete. Paradigm's products may compete with existing alternative treatments that are already available to customers. In addition, a number of companies, both in Australia and internationally, are pursuing the development of competing products. Some of these companies may have, or may develop, technologies superior to Paradigm's own technology. Some competitors of Paradigm may have substantially greater financial, technical and human resources than Paradigm does, as well as broader product offerings and greater market and brand presence. Paradigm's services, expertise or products may be rendered obsolete or uneconomical or decrease in attractiveness or value by advances or entirely different approaches developed by either Paradigm or its competitors.

## Commercial Risk

Paradigm may, from time to time, consider acquisition, licensing, partnership or other corporate opportunities for Paradigm's product development programs. There can be no assurance that any such acquisition, licensing, partnership or corporate opportunities can be concluded on terms that are, or are believed by Paradigm to be, commercially acceptable. In the case of licensing and partnership opportunities, even if such terms are agreed there is a risk that the performance of distributors and the delivery of contracted outcomes by collaborators will not occur due to a range of unforeseen factors relating to environment, technology and market conditions.

## Market Penetration

Where Paradigm does obtain regulatory approval, future success will also depend on Paradigm's ability to achieve market acceptance and attract and retain customers, which includes convincing potential consumers and partners of the efficacy of Paradigm's products and Paradigm's ability to manufacture a sufficient quantity and quality of products at a satisfactory price.

## Manufacturing

There is a risk that scale-up of manufacturing of pentosan polysulfate sodium (PPS) for commercial supply may present certain difficulties. Any unforeseen difficulty relating to manufacturing or supply of commercial GMP quantities of PPS may negatively impact Paradigm's ability to generate profit in future.

## Reliance on Key Personnel

Paradigm is reliant on key personnel employed or engaged by Paradigm. Loss of such personnel may have a material adverse impact on the performance of Paradigm. In addition, recruiting qualified personnel is critical to Paradigm's success. As Paradigm's business grows, it may require additional key financial, administrative, investor and public relations personnel as well as additional staff for operations. While Paradigm believes that it will be successful in attracting and retaining qualified personnel, there can be no assurance of such success. The loss of key personnel or the inability to attract suitably qualified additional personnel could have a material adverse effect on Paradigm's financial performance.

## Insurance and Uninsured Risks

Although Paradigm maintains insurance to protect against certain risks in such amounts as it considers to be reasonable, its insurance will not cover all the potential risks associated with its operations and insurance coverage may not continue to be available or may not be adequate to cover any resulting liability. It is not always possible to obtain insurance against all such risks and Paradigm may decide not to insure against certain risks because of high premiums or other reasons.

## Product Safety and Efficacy

Serious or unexpected health, safety or efficacy concerns with Paradigm's (or similar third party) products may expose Paradigm to reputational harm or reduced market acceptance of its products, and lead to product recalls and/or product liability claims and resulting liability, and increased regulatory reporting. There can be no guarantee that unforeseen adverse events or manufacturing defects will not occur. Paradigm will seek to obtain adequate product liability insurance at the appropriate time in order to minimise its liability to such claims however, there can be no assurance that adequate insurance coverage will be available at an acceptable cost. Any health, safety or efficacy concerns are likely to lead to reduced customer demand and impact on potential future profits of Paradigm.

## Litigation

In the ordinary course of conducting its business, Paradigm is exposed to potential litigation and other proceedings, including through claims of breach of agreements, intellectual property infringement or in relation to employees (through personal injuries, occupational health and safety or otherwise). If such proceedings were brought against Paradigm, it would incur considerable defence costs (even if successful), with the potential for damages and costs awards against Paradigm if it were unsuccessful, which could have a significant negative financial effect on Paradigm's business. Changes in laws can also heighten litigation risk (for example, antitrust and intellectual property). Circumstances may also arise in which Paradigm, having received legal advice, considers that it is reasonable or necessary to initiate litigation or other proceedings, including, for example, to protect its intellectual property rights. There has been substantial litigation and other proceedings in the pharmaceutical industry, including class actions from purchasers and end users of pharmaceutical products.

# Directors' Report continued

## Share Price Fluctuations

The market price of Paradigm shares will fluctuate due to various factors, many of which are non-specific to Paradigm, including recommendations by brokers and analysts, Australian and international general economic conditions, inflation rates, interest rates, changes in government, fiscal, monetary and regulatory policies, global geo-political events and hostilities and acts of terrorism, and investor perceptions. Fluctuations such as these may adversely affect the market price of Paradigm shares. Neither Paradigm nor the Directors warrant the future performance of Paradigm or any return on investment in Paradigm.

## Dilution Risk

Eligible shareholders that do not take up all or part of their entitlements will be diluted by not participating to the full extent in the Entitlement Offer and by the Institutional Placement, but will not be exposed to future increases or decreases in Paradigm's share price in respect of those shares which would have been issued to them had they taken up all of their entitlement.

## Economic Risks

Paradigm is exposed to economic factors in the ordinary course of business. A number of economic factors/conditions, both domestic and global, affect the performance of financial markets generally, which could affect the price at which Paradigm Shares trade on ASX. Among other things, adverse changes in macroeconomic conditions, including movements on international and domestic stock markets, interest rates, exchange rates, cost and availability of credit, general consumption and consumer spending, input costs, employment rates and industrial disruptions, inflation and inflationary expectations and overall economic conditions, economic cycles, investor sentiment, political events and levels of economic growth, both domestically and internationally, as well as government taxation, fiscal, monetary, regulatory and other policy changes may affect the demand for, and price of, Paradigm Shares and adversely impact Paradigm's business, financial position and operating results. Trading prices can be volatile and volatility can be caused by general market risks such as those that have been mentioned. Shares in Paradigm may trade at or below the price at which they are currently trading on ASX including as a result of any of the factors that have been mentioned, and factors such as those mentioned may also affect the income, expenses and liquidity of Paradigm. Additionally, the stock market can experience price and volume fluctuations that may be unrelated or disproportionate to the operating performance of Paradigm.

## Dividend Guidance

No assurances can be given in relation to the payment of future dividends. Future determinations as to the payment of dividends by Paradigm will be at the discretion of Paradigm and will depend upon the availability of profits, the operating results and financial conditions of Paradigm, future capital requirements, covenants in relevant financing agreements, general business and financial conditions and other factors considered relevant by Paradigm. No assurance can be given in relation to the level of tax deferral of future dividends. Tax deferred capacity will depend upon the amount of capital allowances available and other factors.

## Forward-looking Statements

There can be no guarantee that the assumptions and contingencies on which any forward-looking statements, opinions and estimates contained in materials published by Paradigm are based will ultimately prove to be valid or accurate. The forward-looking statements, opinions and estimates depend on various factors, including known and unknown risks, many of which are outside the control of Paradigm. Actual performance of Paradigm may materially differ from forecast performance.

## Significant Changes in the State of Affairs

There have been no significant changes in the state of affairs of the entities in Paradigm during the year. Please refer to information on the share capital raise in the Operating Review section above.

## Dividends

No dividends were declared or paid since the start of the financial year. No recommendation for payment of dividends has been made.

## Matters Subsequent to the End of the Financial Year

No matters or circumstance has arisen since 30 June 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 years.

## Likely Developments and Expected Results of Operations

Paradigm will continue to progress its clinical development program for Zilosul<sup>®</sup>, a potential blockbuster treatment for OA of the knee. Approximately 120 sites have been activated in the US, UK, Canada, Europe and in Australia for the PARA\_OA\_002 study. Paradigm has identified all of the subjects required for stage 1 of the PARA\_OA\_002 study. Once all participants in this stage have reached day 84, the independent data monitoring committee will review the data and recommend the optimal dose to progress through to stage 2 of PARA\_OA\_002 and for the subsequent confirmatory PARA\_OA\_003 clinical trial. The PARA\_OA\_006 extension study continues to enrol participants as they complete the PARA\_OA\_002 clinical trial. Top-line data from the 12-month timepoint of the PARA\_OA\_008 study is expected to be available in Q3 CY 2023. These milestones, along with other important NDA activity, will progress in FY24.

## Corporate Governance

The Corporate Governance Statement appears on Paradigm's website at:

<https://paradigmbiopharma.com/about-paradigm/#corporate-governance>

## Directors' Interests

The relevant interest of each Director in the shares and options issued by Paradigm at the date of this report is as follows:

Director	Ordinary Shares
Paul Rennie	20,512,805
John Gaffney	587,555
Donna Skerrett	1,094,284
Amos Meltzer	–
Helen Fisher	10,204

## Indemnification and Insurance of Officers

### Indemnification

Paradigm has agreed to indemnify the current Directors of Paradigm against all liabilities to another person (other than Paradigm or a related body corporate) that may arise from their position as Directors of Paradigm, except where the liability arises out of conduct involving a lack of good faith.

The agreement stipulates that Paradigm will meet to the maximum extent permitted by law, the full amount of any such liabilities, including costs and expenses.

### Insurance Premiums

Paradigm paid a premium during the year in respect of a Director and Officer liability insurance policy, insuring the Directors of Paradigm, the Company Secretary, and all Executive Officers of Paradigm against a liability incurred as such a Director, Secretary or Executive Officer to the extent permitted by the *Corporations Act 2001*. The Directors have not included details of the nature of the liabilities covered or the amount of the premium paid in respect of the Directors' and Officers' liability and legal expenses insurance contracts, as such disclosure is prohibited under the terms of the contract.

## Directors' Report continued

### Proceedings on Behalf of Paradigm

No person has applied to the Court under section 237 of the *Corporations Act 2001* for leave to bring proceedings on behalf of Paradigm, or to intervene in any proceedings to which Paradigm is a party for the purpose of taking responsibility on behalf of Paradigm for all or part of those proceedings.

### Officers of Paradigm Who are Former Partners of RSM Australia

There are no Officers of Paradigm who are former partners of RSM Australia.

### Auditor's Independence Declaration

The Auditor's Independence Declaration as required under section 307C of the *Corporations Act 2001* is set out on page 28 of the Annual Report.

### Auditor

RSM Australia Partners continues in office in accordance with section 327 of the *Corporations Act 2001*.



# Remuneration Report

## Audited Remuneration Report

This Remuneration Report outlines the Director and Executive Remuneration arrangements of Paradigm in accordance with the requirements of the *Corporations Act 2001* and the *Corporations Regulations 2001*.

For the purposes of this report, Key Management Personnel (**KMP**) of Paradigm are defined as those persons having authority and responsibility for planning, directing and controlling the major activities of Paradigm, directly or indirectly, including any Director (whether executive or otherwise) of Paradigm.

## Remuneration Report

The following were KMP of Paradigm at any time during the year and unless otherwise indicated, were KMP for the entire year:

Name	Position held	Date appointed	Date ceased
Paul Rennie	Managing & Executive Director	22 November 2022	
Paul Rennie	Non-Executive Chairman	22 November 2021	22 November 2022
Marco Polizzi	Chief Executive Officer	1 July 2022	20 February 2023
John Gaffney	Non-Executive Director	30 September 2014	
Donna Skerrett	Executive Director	3 July 2020	
Amos Meltzer	Non-Executive Director	9 December 2020	
Helen Fisher	Non-Executive Director	23 February 2021	

## Remuneration and Nomination Committee

The Remuneration and Nomination Committee is comprised of three Independent Non-Executive Directors and advises the Board on remuneration policies and practices, consistent with those of a late-stage development, pre-commercial revenue pharma company. The Remuneration and Nomination Committee proposes candidates for Director and senior Company executive appointments for the Board's consideration, reviews the fees payable to senior Company executives and to Non-Executive Directors and reviews and advises the Board in relation to succession planning for the Board. The Remuneration and Nomination Committee has the authority to consult any independent professional adviser it considers appropriate to assist it in meeting its responsibilities.

During FY23, after appointing Mr Marco Polizzi as CEO on 1 July 2022, Mr Polizzi's employment with Paradigm ceased on 22 November 2022. Mr Paul Rennie, Paradigm's founder and Non-Executive Chairman of the Board, was appointed as Managing Director.

The Remuneration and Nomination Committee is a committee of the Board and is established in accordance with the authority provided in Paradigm's constitution.

The Board is responsible to shareholders for ensuring that Paradigm:

- has coherent remuneration policies and practices, which are observed, and which enable it to attract and retain Executives and Directors who will create value for shareholders;
- fairly and responsibly rewards Executives having regard to the performance of Paradigm, the performance of the Executive and the general pay environment;
- provides disclosure in relation to Paradigm's remuneration policies to enable investors to understand the costs and benefits of those policies and the link between remuneration paid to Directors and key Executives and corporate performance; and
- complies with the provisions of the ASX Listing Rules and the *Corporations Act 2001*.

# Remuneration Report continued

## Principles of Remuneration

The objectives of the Company's remuneration policies are to align Directors and KMP to the Company's and shareholders' long-term interests and to ensure that remuneration structure is fair and competitive.

Paradigm has developed a remuneration philosophy that seeks to combine elements of Fixed Remuneration, Short-Term Incentive (STI) and Long-Term Incentive (LTI), noting that the proposed LTI plan is pending shareholder approval, that aims to ensure its remuneration strategy successfully aligns the interests of its executives and employees with those of its shareholders. Paradigm is a late-stage development, pre-commercial revenue pharma company, with less than 50 employees across the US and Australia. The Board maintains a simple remuneration structure and performance review process that comprises:

- Fixed Remuneration that allows the organisation to attract and retain individuals with the necessary skills and experience to execute on the Company's strategy;
- STI that is linked to individual and Company performance, payable upon achieving individual KPIs and on execution of the Company's strategy that will grow shareholder value; and
- LTI that is aimed at long-term retention of staff and rewards staff in a manner that is aligned with the growth in shareholder value.

During FY23, following a vote against the existing LTI plan, the Board has worked diligently and sought feedback from key stakeholders to produce a new LTI plan designed to drive shareholder value, and encourage participant behaviours towards achieving business success. The Plan involves employees each year being granted 'Performance Rights'. Each Performance Right converts to one ordinary share if performance-based vesting conditions are met at the end of a three-year vesting period.

## Remuneration Framework Review

The Board adopted the Remuneration Committee's recommendations that the process of awarding STIs needs to be based on pre-determined KPIs that are objectively measurable and that the award of LTIs needs to be aligned with value created by the Company for the Company's shareholders.

The award of STIs to the KMP is reviewed by the Remuneration Committee that then provides its recommendation to the Board. In preparing its recommendation to the Board, the Remuneration Committee considers the KMPs' respective KPIs, and a formal performance evaluation takes place annually, where each KMP's actual performance is measured against that KMP's KPIs. STIs are measured principally based on objectively measurable KPIs and there is generally a small element of discretion that the Remuneration Committee is required to exercise. The CEO performs the evaluations of the Company's other senior executives. This too occurs annually.

To ensure that the value of the LTIs is aligned with value created for the Company's shareholders, the proposed vesting conditions for the new LTI plan, which is subject to shareholder approval, include the Company attaining value inflection milestones. If the vesting conditions are not met, LTIs do not vest and Company employees to whom LTIs are awarded are not able to realise any of the potential value of the LTIs. Based on the principles that the Remuneration Committee has formulated, the Board continues to devise remuneration policies that benchmark Paradigm's framework with its peers and is able to effectively attract and retain the best KMP to manage the Company and continue to create value for the Company's shareholders.

## Non-Executive Director Remuneration

The Constitution and the ASX Listing Rules specify that the aggregate remuneration of Non-Executive Directors shall be determined from time to time by a general meeting of shareholders. Remuneration of Non-Executive Directors is determined in maximum aggregate amount of \$500,000 by the shareholders and is allocated by the Board on the recommendation of the Remuneration Committee. The Remuneration Committee will take independent advice in respect to Directors' fees on an as needed basis.

There is no payment made for attendance at Board committee meetings or participation in other Board activities beyond the global remuneration payable to the Directors that is described above.

Directors are not required to hold shares in Paradigm as part of their appointment.

There is to be no plan to provide remuneration, reward or other benefits to Non-Executive Directors upon the cessation of them holding office as a Director.

## Executive Remuneration

Executive Directors receive no extra remuneration for their service on the Board beyond their executive salary package.

KMP remuneration is compared against similar positions across the industry peers to ensure that remuneration levels and structures remain consistent with roles of comparable skill, experience and responsibility levels.

For FY 2023, the Board resolved to apply a 60% reduction of the available STIs across the entire Company, in view of the prevailing market conditions and the performance of the Company's share price and the biotechnology sector generally. As a result, in FY 2023, each Company's employee maximum entitlement to STIs was 40% of the STIs resolved to be available for FY 2023. With this limit applying, the Remuneration Committee recommended the awarding of STIs to employees whose performance met or exceeded their KPIs for their respective roles and extended their efforts beyond their respective roles' responsibilities.

The award of an STI to Mr Paul Rennie recognises the contribution he has made to the Company's management, business development efforts, and fund-raising activities since being appointed Managing Director in November 2022. Based on his performance, Mr Rennie was awarded STI in the form of a cash bonus equivalent to 7% of his fixed salary (or 40% of his eligible STI payout). Mr Rennie is eligible under his employment agreement to a maximum of 30% of his base salary and this amount has then been reduced by the 60% described in the previous paragraph, and also represents a pro-rata amount to align with Mr Rennie having served as the Company's Managing Director only for 8 months of FY 2023.

The award of an STI to Dr Donna Skerrett, Paradigm's Chief Medical Officer, recognises the contribution Dr Skerrett made to the Company's research program during FY 2023. Based on her performance, Dr Skerrett was awarded STI in the form of a cash bonus equivalent to 12% of her fixed salary (or 40% of her eligible STI payout).

## Movement in Shares

The movement during the reporting period in the number of ordinary shares in Paradigm held directly, indirectly or beneficially by each Director and KMP, including their related entities, is as follows:

<b>Directors &amp; Key Management Persons</b>	<b>Held at year opening</b>	<b>Purchases</b>	<b>Disposals</b>	<b>Issued via ESP</b>	<b>Held at year end</b>
Paul Rennie	20,157,389	355,416	–	–	20,512,805
John Gaffney	587,555	–	–	–	587,555
Donna Skerrett	1,094,284	–	–	–	1,094,284
Amos Meltzer	–	–	–	–	–
Helen Fisher	–	10,204	–	–	10,204

# Remuneration Report continued

## Employment Agreements

The Board has reviewed the remuneration package for the Chief Executive Officer in November 2022. The Remuneration and other terms of employment for the Chief Executive Officer is formalised in a service agreement. Details of this agreement are as follows:

<b>Name:</b>	Paul Rennie
<b>Title:</b>	Managing Director and Chief Executive Officer
<b>Agreement commenced:</b>	22 November 2022
<b>Term of agreement:</b>	Commence on the Commencement Date and will continue until terminated in accordance with this Agreement.
<b>Details:</b>	Base annual package*, STI** and LTI***, subject to annual performance review, six-month termination notice by either party, three to 12-month non-solicitation clause after termination depending on the area. Paradigm may terminate the agreement with cause in certain circumstances such as gross misconduct.

\* Base annual package for financial year 2022/23 – \$1,060,000 gross per annum inclusive of superannuation, to be reviewed annually by the Remuneration and Nomination Committee.

\*\* STI to be paid in cash up to a maximum of 30% of the Base Salary (excluding superannuation), provided KPIs agreed with the Board have been met. For financial year 2022/23, Mr Rennie has been awarded an STI of \$72,000 which is a pro-rata amount commencing from appointment as Managing Director.

\*\*\* LTI via invitation to participate in Paradigm's LTI plan, which is subject to shareholder approval.

The Board has reviewed the remuneration package for the Chief Medical Officer on 17 August 2022. The Remuneration and other terms of employment for the Chief Medical Officer from 1 July 2022 to 30 June 2023 are formalised in a service agreement. Details of this agreement are as follows:

<b>Name:</b>	Donna Skerrett
<b>Title:</b>	Chief Medical Officer
<b>Agreement commenced:</b>	1 September 2019
<b>Term of agreement:</b>	Role is ongoing
<b>Details:</b>	Base annual package*, STI** and LTI***, subject to annual performance review, three-month termination notice by either party, three to 12-month non-solicitation clause after termination depending on the area. Paradigm may terminate the agreement with cause in certain circumstances such as gross misconduct.

\* Base annual package for financial year 2023 – US\$674,170 per annum plus 401K contribution of 6%, to be reviewed annually by the Remuneration and Nomination Committee.

\*\* STI to be paid in cash up to a maximum of 30% of the Base Salary, provided KPIs agreed with the Board have been met. For FY23, Dr Skerrett has been awarded an STI of 11% of the base salary (US\$80,900), which is 40% of the maximum available STI.

\*\*\* LTI via invitation to participate in Paradigm's LTI plan, which is subject to shareholder approval.

## Remuneration of Key Management Personnel

Details of the nature and amount of each major element of the remuneration of each Key Management Personnel of Paradigm for the year ended 30 June 2023 are:

Directors & Key Management Personnel	Short-term		Post-employment	Long-term	Share-based payments	Total	Proportion of remuneration performance related %	Value of options as proportion of remuneration %	
	Salary & fees \$	Annual leave \$	Cash bonus \$	Super-annuation and benefits \$	Long service leave \$				Options \$
<b>Non-Executive</b>									
Paul Rennie	83,333	–	–	8,750	–	–	92,083	0.0%	0.00%
John Gaffney	80,000	–	–	8,400	–	–	88,400	0.0%	0.00%
Amos Meltzer	80,000	–	–	8,400	–	–	88,400	0.0%	0.00%
Helen Fisher	80,000	–	–	8,400	–	–	88,400	0.0%	0.00%
<b>Executive</b>									
Paul Rennie <sup>1</sup>	601,791	46,349	72,000	16,542	–	194,513	931,195	7.73%	20.89%
Donna Skerrett <sup>2,3</sup>	1,001,144	45,375	120,137	92,604	–	255,596	1,514,856	7.93%	16.87%
Marco Polizzi <sup>4</sup>	662,349	34,650	–	297,686	–	–	994,685	0.00%	0.00%
<b>Total</b>	<b>2,588,617</b>	<b>126,374</b>	<b>192,137</b>	<b>440,782</b>	<b>–</b>	<b>450,109</b>	<b>3,798,019</b>	<b>5.06%</b>	<b>11.85%</b>

1. Share-based payments represents valuation of shares awarded in November 2020 in line with the Company's accounting policy for accounting for share-based payments.

2. Share-based payments represents valuation of shares awarded in November 2020 and January 2022 in line with the Company's accounting policy for accounting for share-based payments.

3. Dr Donna Skerrett is paid in USD, remuneration figures have been translated to AUD at a conversion rate of 0.6734.

4. Mr Marco Polizzi is paid in USD, remuneration figures have been translated to AUD at a conversion rate of 0.6734.

## Remuneration and awards for financial year ended 30 June 2023

### Board of Directors Remuneration

The Remuneration and Nomination Committee of the Board is responsible for establishing remuneration of Directors.

Non-Executive Director fees were unchanged in FY23. Non-Executive Chair fees were set at \$200,000, plus superannuation.

### KMP Remuneration

Following the company performance review, the Remuneration and Nominations Committee has resolved that there will be an increase of 3–6% applied to gross salaries in FY23. Performance outcomes for KMP are as follows:

During FY23, the Company achieved many milestones, including those which are critical for the registration and commercialisation of Zilosul®. Paradigm achieved its target of activating 120 clinical trial sites for the PARA\_OA\_002 phase 3 clinical trial. This was made possible through a significant effort to ensure the phase 3 clinical protocol received feedback and approval in multiple jurisdictions to ensure a globally harmonised clinical trial to achieve registration in these jurisdictions. The PARA\_OA\_002 clinical trial has regulatory and ethics approval in seven countries including Australia, the US, the UK, Europe, and Canada. Immediately following the close of FY23, Paradigm reported that all participants required for stage 1 of the PARA\_OA\_002 study had been identified, a significant achievement for the Company. The financial year also produced strong data readouts in the PARA\_OA\_008 phase 2 study, with top-line data readouts at Days 56 and 168 (~6 months) demonstrating the potential of Zilosul® to slow the progression of osteoarthritis as witnessed through reduction of key biomarkers within the synovial fluid at both timepoints and through MRI imaging at the Day 168 timepoint. The Company has also continued to progress the rare disease asset of MPS with two clinical studies conducted during the year. The MPS I open-label study produced a strong top-line data readout at Week 73, meeting the study's primary endpoint of safety and tolerability and secondary endpoints of meaningful improvements in pain, function, and quality of life. The randomised double-blinded phase 2 study in MPS VI completed recruitment of 13 participants in Brazil during the period, with data available toward the end of this calendar year.

## Remuneration Report continued

Following review of FY23 performance against strategic objectives, the Board has decided to award STIs to Mr Paul Rennie and Dr Donna Skerrett of 40% of their fixed salary (or 12% of their eligible STI payout). Whilst many of the Board-approved strategic objectives were met and, in some cases, exceeded, which has created value for the organisation, this value creation has not yet been reflected in the Company share price. Therefore, the Board resolved that the reduction in shareholder value over FY23 materialised by a softer share price has resulted in reduced STI awards relating to FY23 performance.

Details of the nature and amount of each major element of the remuneration of each Key Management Personnel of Paradigm for the year ended 30 June 2022 are:

Directors & Key Management Personnel	Short-term		Post-employment	Long-term	Share-based payments	Total	Proportion of remuneration performance related %	Value of options as proportion of remuneration %	
	Salary & fees \$	Annual leave \$	Cash bonus \$	Super-annuation and benefits \$	Long service leave \$				Options \$
<b>Non-Executive</b>									
Paul Rennie	116,667	–	–	11,667	–	–	128,334	0.0%	0.00%
John Gaffney	80,000	–	–	8,000	–	–	88,000	0.0%	0.00%
Amos Meltzer	80,000	–	–	8,000	–	–	88,000	0.0%	0.00%
Helen Fisher	80,000	–	–	8,000	–	–	88,000	0.0%	0.00%
<b>Executive</b>									
Paul Rennie <sup>1</sup>	218,875	267,689	–	51,699	30,428	440,485	1,009,176	0.00%	43.65%
Donna Skerrett <sup>2,3</sup>	853,385	67,238	89,745	92,236	–	465,000	1,567,604	5.72%	29.66%
<b>Total</b>	<b>1,428,927</b>	<b>334,927</b>	<b>89,745</b>	<b>179,602</b>	<b>30,428</b>	<b>905,485</b>	<b>2,969,114</b>	<b>3.02%</b>	<b>30.50%</b>

- Share-based payments represents valuation of shares awarded in November 2020 in line with the Company's accounting policy for accounting for share-based payments.
- Share-based payments represents valuation of shares awarded in November 2020 and January 2022 in line with the Company's accounting policy for accounting for share-based payments.
- Dr Donna Skerrett is paid in USD, remuneration figures have been translated to AUD at a conversion rate of 0.7258.

The proportion of remuneration linked to performance and the fixed proportion are as follows:

Name	Fixed remuneration		At risk – STI		At risk – LTI	
	2023	2022	2023	2022	2023	2022
<b>Non-Executive</b>						
Paul Rennie	100.00%	100.00%	–	–	–	–
John Gaffney	100.00%	100.00%	–	–	–	–
Amos Meltzer	100.00%	100.00%	–	–	–	–
Helen Fisher	100.00%	100.00%	–	–	–	–
<b>Executive</b>						
Paul Rennie	71.38%	56.35%	7.73%	–	20.89%	43.65%
Donna Skerrett	75.20%	64.61%	7.93%	5.72%	16.87%	29.66%
Marco Polizzi	100.00%	100.00%	–	–	–	–

The proportion of the cash bonus paid/payable or forfeited is as follows:

Name	STI paid/payable		STI forfeited	
	2023	2022	2023	2022
<b>Non-Executive</b>				
John Gaffney	–	–	–	–
Amos Meltzer	–	–	–	–
Helen Fisher	–	–	–	–
<b>Executive</b>				
Paul Rennie	40.00%	–	60.00%	100.00%
Donna Skerrett	40.00%	33.33%	60.00%	66.67%
Marco Polizzi	–	–	–	–

### Additional Information

The earnings of Paradigm for the five years to 30 June 2023 are summarised below:

	2023 \$	2022 \$	2021 \$	2020 \$	2019 \$	2018 \$
Income	8,580,939	8,787,830	8,941,647	4,695,494	3,245,628	2,736,400
Loss after income tax	(51,910,013)	(39,249,584)	(34,297,184)	(12,298,887)	(15,627,544)	(6,190,232)

The factors that are considered to affect total shareholders return (TSR) are summarised below:

	2023	2022	2021	2020	2019	2018
Share price at financial year end (\$)	0.99	0.97	2.10	3.15	1.40	0.65
Total dividends declared (cents per share)	–	–	–	–	–	–
Basic earnings per share (cents per share)	(20.78)	(16.87)	(14.92)	(6.12)	(10.93)	(5.46)

**This is the end of the audited Remuneration Report.**

Dated at Melbourne, Victoria this 25th day of August 2023.

Signed in accordance with a resolution of the Directors, pursuant to section 298(2)(a) of the *Corporations Act 2001*:



**Paul Rennie**  
Managing Director

# Auditor's Independence Declaration



## RSM Australia Partners

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## AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the audit of the financial report of Paradigm Biopharmaceuticals Limited for the year ended 30 June 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 audit; and
- (ii) any applicable code of professional conduct in relation to the audit.

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

**RSM AUSTRALIA PARTNERS**

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

**R J MORILLO MALDONADO**  
Partner

Date: 25 August 2023  
Melbourne, Victoria

**THE POWER OF BEING UNDERSTOOD**  
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# Consolidated Statement of Profit or Loss and Other Comprehensive Income

for the year ended 30 June 2023

	Notes	Year ended 30-Jun-23 \$	Year ended 30-Jun-22 \$
Revenue from continuing operations		46,760	79,224
Cost of sales		(18,827)	(143,751)
Other income	2	8,534,179	7,814,341
Other gains and losses	3	(389,269)	894,265
Research and development expenses		(52,679,197)	(39,011,991)
General and administration expenses		(6,564,548)	(7,934,179)
Commercial expenses		(822,695)	(918,860)
Finance costs		(16,416)	(28,633)
<b>Loss before income tax</b>		<b>(51,910,013)</b>	<b>(39,249,584)</b>
Income tax expense/(benefit)		–	–
<b>Loss for the year</b>		<b>(51,910,013)</b>	<b>(39,249,584)</b>
<b>Other comprehensive loss</b>			
<i>Items that may be reclassified subsequently to profit or loss</i>			
Foreign currency translation		(300,402)	(186,416)
<b>Other comprehensive loss for the year, net of tax</b>		<b>(300,402)</b>	<b>(186,416)</b>
<b>Total comprehensive loss attributable to members of the Consolidated Entity</b>		<b>(52,210,415)</b>	<b>(39,436,000)</b>
<b>Earnings per share – loss (cents)</b>			
<i>Basic and diluted loss per share</i>	21	(20.78) cents	(16.87) cents

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

# Consolidated Statement of Financial Position

as at 30 June 2023

	Notes	2023 \$	2022 \$
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents	5	56,333,085	39,674,413
Trade and other receivables	6	6,807,301	6,718,798
Prepaid expenses	7	599,078	730,715
Financial assets held at amortised cost		46,200	46,200
<b>Total current assets</b>		<b>63,785,664</b>	<b>47,170,126</b>
<b>Non-current assets</b>			
Intangible assets	8	2,947,588	2,947,588
Plant and equipment	9	42,601	60,657
Right-of-use assets	10	293,791	510,498
<b>Total non-current assets</b>		<b>3,283,980</b>	<b>3,518,743</b>
<b>Total assets</b>		<b>67,069,644</b>	<b>50,688,869</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables	11	12,161,182	7,088,279
Employee benefits	12	776,196	594,955
Lease liabilities	13	104,971	147,758
<b>Total current liabilities</b>		<b>13,042,349</b>	<b>7,830,992</b>
<b>Non-current liabilities</b>			
Employee benefits	14	112,830	76,355
Lease liabilities and others	15	236,694	468,911
<b>Total non-current liabilities</b>		<b>349,524</b>	<b>545,266</b>
<b>Total liabilities</b>		<b>13,391,873</b>	<b>8,376,258</b>
<b>Net assets</b>		<b>53,677,771</b>	<b>42,312,611</b>
<b>EQUITY</b>			
Issued capital	16	209,833,883	147,194,772
Share-based payments reserve	17	7,786,686	9,261,765
Currency translation reserve		(428,784)	(128,382)
Accumulated losses	18	(163,514,014)	(114,015,544)
<b>Total equity</b>		<b>53,677,771</b>	<b>42,312,611</b>

The consolidated statement of financial position is to be read in conjunction with the accompanying notes.

# Consolidated Statement of Cash Flows

for the year ended 30 June 2023

	Notes	Year ended 30-Jun-23 \$	Year ended 30-Jun-22 \$
<b>Cash flows from operating activities</b>			
Research and development and other tax incentive received		7,404,899	9,525,710
Receipts from customers		23,043	81,441
Payments to suppliers and employees (Inclusive of GST)		(53,548,260)	(41,831,716)
Interest received		950,455	47,932
Interest repayment of lease liabilities		(16,416)	(28,633)
<b>Net cash outflow from operating activities</b>	26	<b>(45,186,279)</b>	<b>(32,205,266)</b>
<b>Cash flows from investing activities</b>			
Proceeds for financial assets held at amortised cost		–	–
<b>Net cash inflow from investing activities</b>		<b>–</b>	<b>–</b>
<b>Cash flows from financing activities</b>			
Proceeds from issue of shares		65,987,641	–
Payment of share issue costs		(3,764,871)	–
Limited recourse loan repaid under ESP		416,341	205,288
Principal repayment of lease liabilities		(104,489)	(135,172)
<b>Net cash inflow from financing activities</b>		<b>62,534,622</b>	<b>70,116</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>17,348,343</b>	<b>(32,135,150)</b>
<b>Cash at the beginning of the financial year</b>		<b>39,674,413</b>	<b>71,034,983</b>
<b>Net effect of cash flows on foreign exchange</b>		<b>(689,671)</b>	<b>774,579</b>
<b>Cash at the end of the financial year</b>		<b>56,333,085</b>	<b>39,674,413</b>

The consolidated statement of cash flows is to be read in conjunction with the accompanying notes.

# Consolidated Statement of Changes in Equity

for the year ended 30 June 2023

	Issued capital \$	Share option reserve \$	Accumulated losses \$	Currency translation reserve \$	Total \$
<b>Balance at 30 June 2021</b>	<b>146,989,484</b>	<b>6,453,995</b>	<b>(75,228,227)</b>	<b>58,034</b>	<b>78,273,286</b>
Loss for the period	–	–	(39,249,584)	–	(39,249,584)
Other comprehensive (loss)	–	–	–	(186,416)	(186,416)
Total comprehensive (loss) for the year ended 30 June 2022	–	–	(39,249,584)	(186,416)	(39,436,000)
Transactions with owners in their capacity as owners:					
Share based payment expenses for the year (Note 17)	–	3,270,037	–	–	3,270,037
ESP lapsed in the period	–	(335,705)	335,705	–	–
Transfer from share-based payments reserve on exercise of options	–	(126,562)	126,562	–	–
Shares issued relating to repayment of limited recourse loan for ESP	205,288	–	–	–	205,288
<b>Balance at 30 June 2022</b>	<b>147,194,772</b>	<b>9,261,765</b>	<b>(114,015,544)</b>	<b>(128,382)</b>	<b>42,312,611</b>
Loss for the period	–	–	(51,910,013)	–	(51,910,013)
Other comprehensive (loss)	–	–	–	(300,402)	(300,402)
Total comprehensive (loss) for the year ended 30 June 2023	–	–	(51,910,013)	(300,402)	(52,210,415)
Transactions with owners in their capacity as owners:					
Shares issued	65,987,641	–	–	–	65,987,641
Costs in relation to shares issued	(3,764,871)	–	–	–	(3,764,871)
Share based payments expense for the year (Note 17)	–	1,447,590	–	–	1,447,590
ESP lapsed in the period	–	(1,914,909)	1,403,783	–	(511,126)
Unlisted options lapsed in the period	–	(786,568)	786,568	–	–
Transfer from share-based payments reserve on exercise of options	–	(221,192)	221,192	–	–
Shares issued relating to repayment of limited recourse loan for ESP	416,341	–	–	–	416,341
<b>Balance at 30 June 2023</b>	<b>209,833,883</b>	<b>7,786,686</b>	<b>(163,514,014)</b>	<b>(428,784)</b>	<b>53,677,771</b>

The consolidated statement of changes in equity is to be read in conjunction with the accompanying notes.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

## 1. Summary of Significant Accounting Policies

The principal accounting policies adopted in the preparation of the Financial Statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

### (a) Reporting Entity

Paradigm Biopharmaceuticals Limited (the 'Consolidated Entity') is a company incorporated and domiciled in Australia. Paradigm Biopharmaceuticals Limited is a company limited by shares which are publicly traded on the Australian Securities Exchange from 19 August 2015. The Consolidated Financial Report of the Consolidated Entity for the year ended 30 June 2023 comprises the Company and controlled entities (together referred to as the 'Consolidated Entity').

The nature of the operations and principal activities of the Consolidated Entity are described in the Directors' Report.

For the purposes of preparing the Financial Statements the Consolidated Entity is a for-profit entity.

### (b) Basis of Preparation

#### Statement of Compliance

This Financial Report is a general-purpose Financial Report prepared in accordance with the Australian Accounting Standards ('AASs') (including Australian Accounting Interpretations) adopted by the Australian Accounting Standards Board and the *Corporations Act 2001*. This Consolidated Financial Report complies with the International Financial Reporting Standards ('IFRSs') and interpretations adopted by the International Accounting Standards Board (**IASB**).

#### Basis of Measurement

##### *Historical Cost Convention*

The Financial Statements have been prepared under the historical cost convention, except for, where applicable, the revaluation of available-for-sale financial assets, financial assets and liabilities at fair value through profit or loss, investment properties, certain classes of plant and equipment and derivative financial instruments.

##### *Critical Accounting Estimates*

The preparation of the Financial Statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Consolidated Entity's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the Financial Statements, are disclosed in Note 1 (c).

#### Significant Accounting Policies

The accounting policies set out below have been applied consistently by the Consolidated Entity to all periods presented in these Financial Statements.

#### New, Revised or Amending Accounting Standards and Interpretations Adopted

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

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

#### Rounding of Amounts

The Company is of a kind referred to in Corporations Instrument 2016/191, issued by the Australian Securities and Investment Commission, relating to 'rounding off'. Amounts in this report have been rounded off in accordance with that Corporations Instrument to the nearest dollar.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 1. Summary of Significant Accounting Policies *continued*

### Foreign Currency Translation

The Financial Statements are presented in Australian dollars, which is Paradigm Biopharmaceutical Limited's functional and presentation currency.

### Foreign Currency Transactions

Foreign currency transactions are translated into Australian dollars using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at financial year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in profit or loss.

### Foreign Operations

The assets and liabilities of foreign operations are translated into Australian dollars using the exchange rates at the reporting date. The revenues and expenses of foreign operations are translated into Australian dollars using the average exchange rates, which approximate the rates at the dates of the transactions, for the period. All resulting foreign exchange differences are recognised in other comprehensive income through the foreign currency reserve in equity.

## (c) Significant Accounting Estimates, Assumptions and Judgements

The preparation of the Financial Statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the Financial Statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements and estimates on historical experience and on various other factors it believes to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal the related actual results. The judgements, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities (refer to the respective notes) within the next financial year are discussed below.

### Share-based Payment Transactions

The Consolidated Entity measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using either the Binomial or Black-Scholes model, taking into account the terms and conditions upon which the instruments were granted. The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity.

### R&D Expenditure

The Company's research and development activities are eligible under the Australian R&D Tax Incentive. The Company has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. The Company has assessed that all research and development expenditure to date does not meet the requirements for capitalisation as an intangible asset because it is not yet probable that the expected future economic benefits that are attributable to the asset will flow.

### Impairment of Non-financial Assets Other Than Goodwill and Other Indefinite Life Intangible Assets

The Consolidated Entity assesses impairment of non-financial assets other than goodwill and other indefinite life intangible assets at each reporting date by evaluating conditions specific to the Consolidated Entity and to the particular asset that may lead to impairment. If an impairment trigger exists, the recoverable amount of the asset is determined. This involves fair value less costs of disposal or value-in-use calculations, which incorporate a number of key estimates and assumptions.

### Other Indefinite Life Intangible Assets

The Consolidated Entity tests annually, or more frequently if events or changes in circumstances indicate impairment, whether other indefinite life intangible assets have suffered any impairment, in accordance with the accounting policy stated in Note 1. The recoverable amounts of cash-generating units have been determined based on value-in-use calculations. These calculations require the use of assumptions, including estimated discount rates based on the current cost of capital and growth rates of the estimated future cash flows. Refer to Note 8 for further information.

## Employee Benefits Provision

As discussed in Note 1, the liability for employee benefits expected to be settled more than 12 months from the reporting date are recognised and measured at the present value of the estimated future cash flows to be made in respect of all employees at the reporting date. In determining the present value of the liability, estimates of attrition rates and pay increases through promotion and inflation have been considered.

## Lease Term

The lease term is a significant component in the measurement of both the right-of-use asset and lease liability. Judgement is exercised in determining whether there is reasonable certainty that an option to extend the lease or purchase the underlying asset will be exercised, or an option to terminate the lease will not be exercised, when ascertaining the periods to be included in the lease term. In determining the lease term, all facts and circumstances that create an economical incentive to exercise an extension option, or not to exercise a termination option, are considered at the lease commencement date. Factors considered may include the importance of the asset to the consolidated entity's operations; comparison of terms and conditions to prevailing market rates; incurrence of significant penalties; existence of significant leasehold improvements; and the costs and disruption to replace the asset. The consolidated entity reassesses whether it is reasonably certain to exercise an extension option, or not exercise a termination option, if there is a significant event or significant change in circumstances.

## Incremental Borrowing Rate

Where the interest rate implicit in a lease cannot be readily determined, an incremental borrowing rate is estimated to discount future lease payments to measure the present value of the lease liability at the lease commencement date. Such a rate is based on what the Consolidated Entity estimates it would have to pay a third party to borrow the funds necessary to obtain an asset of a similar value to the right-of-use asset, with similar terms, security and economic environment.

## Lease Make Good Provision

A provision has been made for the present value of anticipated costs for future restoration of leased premises. The provision includes future cost estimates associated with closure of the premises. The calculation of this provision requires assumptions such as application of closure dates and cost estimates. The provision recognised for each site is periodically reviewed and updated based on the facts and circumstances available at the time. Changes to the estimated future costs for sites are recognised in the statement of financial position by adjusting the asset and the provision. Reductions in the provision that exceed the carrying amount of the asset will be recognised in profit or loss.

## (d) Summary of Significant Accounting Policies

### (i) Basis of Consolidation

#### *Parent Entity*

In accordance with the *Corporations Act 2001*, these Financial Statements present the results of the Consolidated Entity only. Supplementary information about the parent entity is disclosed in Note 25.

#### *Subsidiaries*

The consolidated Financial Statements comprise those of the Consolidated Entity, and the entities it controlled at the end of, or during, the financial year. The balances and effects of transactions between entities in the Consolidated Entity included in the Financial Statements have been eliminated. Where an entity either began or ceased to be controlled during the year, the results are included only from the date control commenced or up to the date control ceased.

Subsidiaries are entities controlled by the Consolidated Entity. Control exists when the Consolidated Entity is exposed to or has rights to variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. The Financial Statements of subsidiaries are included in the consolidated Financial Statements from the date control is transferred to the Consolidated Entity until the date that control ceases.

#### *Transactions Eliminated on Consolidation*

Intra-company balances and all gains and losses or income and expenses arising from intra-company transactions are eliminated in preparing the consolidated Financial Statements.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 1. Summary of Significant Accounting Policies *continued*

### (ii) Cash and Cash Equivalents

Cash and cash equivalents in the statement of financial position comprise cash at bank and in hand and short-term deposits with an original maturity of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

For the purpose of the statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above but also include as a component of cash and cash equivalents bank overdrafts (if any), which are included as borrowings on the statement of financial position.

### (iii) Trade and Other Receivables

Trade receivables are initially recognised at fair value and subsequently measured at amortised cost using the effective interest method, less any allowance for expected credit losses. Trade receivables are generally due for settlement within 30 days.

The Consolidated Entity has applied the simplified approach to measuring expected credit losses, which uses a lifetime expected loss allowance. To measure the expected credit losses, trade receivables have been grouped based on days overdue.

Other receivables are recognised at amortised cost, less any provision for impairment.

### (iv) Investments

Investments are initially measured at cost. Transaction costs are included as part of the initial measurement. They are subsequently measured at either amortised cost or fair value depending on their classification. Classification is determined based on the purpose of the acquisition and subsequent reclassification to other categories is restricted.

### (v) Intangible Assets

Intangible assets acquired as part of a business combination, other than goodwill, are initially measured at their fair value at the date of the acquisition. Intangible assets acquired separately are initially recognised at cost. Indefinite life intangible assets are not amortised and are subsequently measured at cost less any impairment. Finite life intangible assets are subsequently measured at cost less amortisation and any impairment. The gains or losses recognised in profit or loss arising from the derecognition of intangible assets are measured as the difference between net disposal proceeds and the carrying amount of the intangible asset. The method and useful lives of finite life intangible assets are reviewed annually. Changes in the expected pattern of consumption or useful life are accounted for prospectively by changing the amortisation method or period.

#### (a) Patents and Trademarks

Patents have a finite useful life and are carried at cost less accumulated amortisation and impairment losses once the patents are considered held ready for use. Intellectual property and licences are amortised on a systematic basis matched to the future economic benefits over the useful life of the project once the patents are considered held ready for use.

Significant costs associated with trademarks are capitalised and amortised on a straight-line basis over the period of their expected benefit, being their finite life of 10 years.

#### (b) Research and Development

Expenditure during the research phase of a project is recognised as an expense when incurred. Development costs are capitalised only when technical feasibility studies identify that the project will deliver future economic benefits and these benefits can be measured reliably.



#### (vi) Impairment

At the end of each reporting period, the Consolidated Entity assesses whether there is any indication that an asset may be impaired. The assessment will include considering external sources of information and internal sources of information. If such an indication exists, an impairment test is carried out on the asset by comparing the recoverable amount of the asset, being the higher of the asset's fair value less costs to sell and value-in-use, to the asset's carrying value. Any excess of the asset's carrying value over its recoverable amount is expensed to the statement of comprehensive income.

Where it is not possible to estimate the recoverable amount of an individual asset, the Consolidated Entity estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Impairment testing is performed annually for goodwill and intangible assets with indefinite lives.

In assessing value-in-use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of the money and risks specific to the asset. In determining fair value less costs of disposal, recent market transactions are taken into account. If no such transactions can be identified, an appropriate valuation model is used. These calculations are corroborated by valuation multiples, quoted share prices for publicly traded companies or other available fair value indicators.

The Consolidated Entity bases its impairment calculation on detailed budgets and forecast calculations, which are prepared separately for each of the Consolidated Entity's projects to which the individual assets are allocated. These budgets and forecast calculations generally cover a period of five years.

Impairment losses of continuing operations are recognised in the statement of profit or loss in expense categories consistent with the function of the impaired asset.

#### (vii) Plant and Equipment

Plant and equipment is stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Depreciation is calculated on a straight-line basis to write off the net cost of each item of plant and equipment over their expected useful lives of two to 15 years.

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each reporting date.

Leasehold improvements and plant and equipment under lease are depreciated over the unexpired period of the lease or the estimated useful life of the assets, whichever is shorter.

An item of plant and equipment is derecognised upon disposal or when there is no future economic benefit to the Consolidated Entity. Gains and losses between the carrying amount and the disposal proceeds are taken to profit or loss. Any revaluation surplus reserve relating to the item disposed of is transferred directly to retained profits.

#### (viii) Right-of-use Assets

A right-of-use asset is recognised at the commencement date of a lease. The right-of-use asset is measured at cost, which comprises the initial amount of the lease liability, adjusted for, as applicable, any lease payments made at or before the commencement date net of any lease incentives received, any initial direct costs incurred, and, except where included in the cost of inventories, an estimate of costs expected to be incurred for dismantling and removing the underlying asset, and restoring the site or asset.

Right-of-use assets are depreciated on a straight-line basis over the unexpired period of the lease or the estimated useful life of the asset, whichever is the shorter. Where the consolidated entity expects to obtain ownership of the leased asset at the end of the lease term, the depreciation is over its estimated useful life. Right-of-use assets are subject to impairment or adjusted for any remeasurement of lease liabilities.

The consolidated entity has elected not to recognise a right-of-use asset and corresponding lease liability for short-term leases with terms of 12 months or less and leases of low-value assets. Lease payments on these assets are expensed to profit or loss as incurred.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 1. Summary of Significant Accounting Policies *continued*

### (ix) Trade and Other Payables

Trade and other payables represent the liability outstanding at the end of the reporting period for goods and services received by the entity during the reporting period which remain unpaid. The balance is recognised as a current liability with the amounts normally paid within the requisite terms specified by the supplier.

### (x) Share Capital

Ordinary and preference shares are classified as equity.

Any incremental costs directly attributable to the issue of new shares or options are recognised in equity as a deduction, net of tax, from the proceeds.

### (xi) Provisions

Provisions are recognised when the Consolidated Entity has a present (legal or constructive) obligation as a result of a past event, it is probable the Consolidated Entity will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation. The amount recognised as a provision is the best estimate of the consideration required to settle the present obligation at the reporting date, taking into account the risks and uncertainties surrounding the obligation. If the time value of money is material, provisions are discounted using a current pre-tax rate specific to the liability. The increase in the provision resulting from the passage of time is recognised as a finance cost.

### (xii) Revenue

#### *Interest Income*

Interest income is recognised on a time proportion basis using the effective interest rate method.

#### *Other Revenue*

Other revenue is recognised when it is received or when the right to receive payment is established.

#### *Government Grants*

Grants that compensate the Consolidated Entity for expenditures incurred are recognised in profit or loss on a systematic basis in the periods in which the expenditures are recognised. R&D tax offset receivables will be recognised in profit before tax (in EBIT) over the periods necessary to match the benefit of the credit with the costs for which it is intended to compensate. Such periods will depend on whether the R&D costs are capitalised or expensed as incurred.

### (xiii) Employee Benefits

#### *Wages and Salaries, Cash Bonus, Annual Leave and Long Service Leave*

Provision is made for benefits accruing to employees in respect of wages and salaries, annual leave and long service leave when it is probable that settlement will be required, and they are capable of being measured reliably. Provisions made in respect of employee benefits are measured based on an assessment of the existing benefits to determine the appropriate classification under the definition of short-term and long-term benefits, placing emphasis on when the benefit is expected to be settled.

Short-term benefits provisions that are expected to be settled within 12 months are measured at their nominal values using the remuneration rate expected to apply at the time of settlement.

Long-term benefits provisions that are not expected to be settled within 12 months and are measured as the present value of the estimated future cash outflows to be made by the Consolidated Entity in respect of services provided by employees up to reporting date. Consideration is given to the expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date to estimate the future cash flows at a pre-tax rate that reflects current market assessments of the time value of money.

Regardless of the expected timing of settlement, provisions made in respect of employee benefits are classified as a current liability unless there is an unconditional right to defer the settlement of the liability for at least 12 months after the reporting date, in which case it would be classified as a non-current liability. Provisions made for annual leave and unconditional long service leave are classified as a current liability where the employee has a present entitlement to the benefit. Provisions for conditional long service are classified as a non-current liability.

### *Share-based Payments*

The Consolidated Entity operates an incentive scheme to provide these benefits, known as the Paradigm Biopharmaceuticals Limited Employee Share Plan ('**ESP**') approved on 22 October 2014. Issues of shares to employees with limited recourse loans under the ESP are share-based payments in the form of options.

The fair value of options granted under the ESP is recognised as an employee benefit expense with a corresponding increase in equity. The fair value is measured at grant date and recognised over the period during which the employees become unconditionally entitled to the options. The fair value at grant date is determined using a binomial pricing model that takes into account the exercise price, the term of the option, the vesting and performance criteria, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the limited recourse loan. In valuing share-based payment transactions, no account is taken of any non-market performance conditions.

The Consolidated Entity provides benefits to employees (including Directors) of the Consolidated Entity in the form of share-based payment transactions, whereby employees render services in exchange for shares or rights over shares.

The cost of share-based payment transactions is recognised, together with a corresponding increase in equity, over the period in which the performance conditions are fulfilled, ending on the date on which the relevant employees become fully entitled to the award ('vesting date'). The cumulative expense recognised for equity-settled transactions at each reporting date until vesting date reflects (i) the extent to which the vesting period has expired, and (ii) the number of awards that, in the opinion of the Directors of the Consolidated Entity, will ultimately vest. This opinion is formed based on the best available information at balance date. No adjustment is made for the likelihood of market performance conditions being met as the effect of these conditions is included in the determination of fair value at grant date.

No expense is recognised for awards that do not ultimately vest, except for awards where vesting is conditional upon a market condition.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified. In addition, an expense is recognised for any increase in the value of the transaction as a result of the modification, as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. However, if a new award is substituted for the cancelled award, and designated as a replacement award on the date that it is granted, the cancelled and new award are treated as if they were a modification of the original award, as described in the previous paragraph.

### *(xiv) Lease Liabilities*

A lease liability is recognised at the commencement date of a lease. The lease liability is initially recognised at the present value of the lease payments to be made over the term of the lease, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Consolidated Entity's incremental borrowing rate. Lease payments comprise of fixed payments less any lease incentives receivable, variable lease payments that depend on an index or a rate, amounts expected to be paid under residual value guarantees, exercise price of a purchase option when the exercise of the option is reasonably certain to occur, and any anticipated termination penalties. The variable lease payments that do not depend on an index or a rate are expensed in the period in which they are incurred.

Lease liabilities are measured at amortised cost using the effective interest method. The carrying amounts are remeasured if there is a change in the following: future lease payments arising from a change in an index or a rate used; residual guarantee; lease term; certainty of a purchase option and termination penalties. When a lease liability is remeasured, an adjustment is made to the corresponding right-of-use asset, or to profit or loss if the carrying amount of the right-of-use asset is fully written down.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 1. Summary of Significant Accounting Policies *continued*

### (xv) Income Tax

The income tax expense or benefit for the period is the tax payable on that period's taxable income based on the applicable income tax rate for each jurisdiction, adjusted by the changes in deferred tax assets and liabilities attributable to temporary differences, unused tax losses and the adjustment recognised for prior periods, where applicable.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to be applied when the assets are recovered or liabilities are settled, based on those tax rates that are enacted or substantively enacted, except for:

- when the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or
- when the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

The carrying amount of recognised and unrecognised deferred tax assets are reviewed at each reporting date. Deferred tax assets recognised are reduced to the extent that it is no longer probable that future taxable profits will be available for the carrying amount to be recovered. Previously unrecognised deferred tax assets are recognised to the extent that it is probable that there are future taxable profits available to recover the asset.

Deferred tax assets and liabilities are offset only where there is a legally enforceable right to offset current tax assets against current tax liabilities and deferred tax assets against deferred tax liabilities; and they relate to the same taxable authority on either the same taxable entity or different taxable entities which intend to settle simultaneously.

The Consolidated Entity and its wholly-owned Australian resident entities are part of a tax-consolidated entity. As a consequence, all members of the tax-consolidated entity are taxed as a single entity. The head entity within the tax-consolidated entity is Paradigm Biopharmaceuticals Limited.

Current tax expense/income, deferred tax liabilities and deferred tax assets arising from temporary differences of the members of the tax-consolidated entity are recognised in the separate Financial Statements of the members of the tax-consolidated entity using the 'separate taxpayer within Consolidated Entity' approach by reference to the carrying amount of assets and liabilities in the separate Financial Statements of each entity and the tax values applying under tax consolidation.

Any current tax liabilities (or assets) and deferred tax assets arising from unused tax losses of the subsidiaries are assumed by the head entity in the tax-consolidated entity. Any difference between these amounts is recognised by the Consolidated Entity as an equity contribution or distribution.

Any subsequent period adjustments to deferred tax assets arising from unused tax losses as a result of revised assessments of the probability of recoverability are recognised by the head entity only.

Assets or liabilities arising under tax funding agreements with the tax-consolidated entities are recognised as amounts receivable from or payable to other entities in the tax consolidated group. The tax funding arrangement ensures that the intercompany charge equals the current tax liability or benefit of each tax consolidated group member, resulting in neither a contribution by the head entity to the subsidiaries nor a distribution by the subsidiaries to the head entity.

### (xvi) Current and Non-current Classification

Assets and liabilities are presented in the statement of financial position based on current and non-current classification.

An asset is classified as current when: it is either expected to be realised or intended to be sold or consumed in the Consolidated Entity's normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is classified as current when: it is either expected to be settled in the Consolidated Entity's normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current.

#### (xvii) Goods and Services Tax

Revenues, expenses and assets are recognised net of the amount of goods and services tax (GST), except where the amount of GST incurred is not recoverable from the Australian Taxation Office (ATO). In these circumstances the GST is recognised as part of the cost of acquisition of the asset or as part of an item of the expense.

Receivables and payables are stated with the amount of GST included.

The net amount of GST recoverable from, or payable to, the ATO is included as a current asset or liability in the statement of financial position.

Cash flows are included in the statement of cash flows at their nominal value inclusive of GST.

#### (xviii) Earnings (Loss) Per Share

The Consolidated Entity presents basic and, when applicable, diluted earnings per share ('**EPS**') data for its ordinary shares.

Basic EPS is calculated by dividing the profit or loss attributable to the ordinary shareholders of the Consolidated Entity by the weighted average number of ordinary shares outstanding during the period.

Diluted EPS is calculated by adjusting basic earnings for the impact of the after-tax effect of costs associated with dilutive ordinary shares and the weighted average number of additional ordinary shares that would be outstanding assuming the conversion of all dilutive potential ordinary shares. The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share.

#### (xix) Fair Value Measurement

When an asset or liability, financial or non-financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either: in the principal market; or in the absence of a principal market, in the most advantageous market.

Fair value is measured using the assumptions that market participants would use when pricing the asset or liability, assuming they act in their economic best interests. For non-financial assets, the fair value measurement is based on its highest and best use. Valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, are used, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

Assets and liabilities measured at fair value are classified into three levels, using a fair value hierarchy that reflects the significance of the inputs used in making the measurements. Classifications are reviewed at each reporting date and transfers between levels are determined based on a reassessment of the lowest level of input that is significant to the fair value measurement.

For recurring and non-recurring fair value measurements, external valuers may be used when internal expertise is either not available or when the valuation is deemed to be significant. External valuers are selected based on market knowledge and reputation. Where there is a significant change in fair value of an asset or liability from one period to another, an analysis is undertaken, which includes a verification of the major inputs applied in the latest valuation and a comparison, where applicable, with external sources of data. There are no assets held at fair value on a recurring or non-recurring basis.

The Consolidated Entity does not have any assets or liabilities held at fair value on a recurring or non-recurring basis.

#### (xx) Operating Segment

##### *Identification of Reportable Operating Segments*

The Consolidated Entity is organised into one operating segment based on the research and development of pharmaceutical drugs. The operating segment is based on the internal reports that are reviewed and used by the Board of Directors (who are identified as the Chief Operating Decision Makers ('**CODM**')) in assessing performance and in determining the allocation of resources.

The CODM reviews EBITDA (earnings before interest, tax, depreciation and amortisation). The accounting policies adopted for internal reporting to the CODM are consistent with those adopted in the financial statements.

The information reported to the CODM is on a monthly basis.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 1. Summary of Significant Accounting Policies *continued*

### New Standards and Interpretations Not Yet Effective or Early Adopted

Australian Accounting Standards and Interpretations that have recently been issued or amended but are not yet mandatory, have not been early adopted by the Consolidated Entity for the annual reporting period ended 30 June 2023. The Consolidated Entity has not yet assessed the impact of these new or amended Accounting Standards and Interpretations.

## 2. Other Income

	2023 \$	2022 \$
R&D tax incentive	7,042,194	7,762,597
Interest received	1,402,577	51,744
Gain on lease modification	89,408	–
	<b>8,534,179</b>	<b>7,814,341</b>

## 3. Other Gains and Losses

	2023 \$	2022 \$
Realised currency gains/(losses)	(116,860)	(81,752)
Unrealised currency gains/(losses)	(272,409)	976,017
	<b>(389,269)</b>	<b>894,265</b>

## 4. Expenses

Loss before income tax from continuing operations includes the following specific expenses:

	2023 \$	2022 \$
Short-term leases	71,421	94,719
Superannuation	619,700	516,107
Share-based payment expenses	936,462	3,270,037
	<b>1,627,583</b>	<b>3,880,863</b>

The Company has elected to show a functional view of its profit and loss. Total wages and salaries for 2023 is \$9,877,486 (2022: \$5,271,782), including superannuation.

## 5. Cash and Cash Equivalents

	2023 \$	2022 \$
Cash at bank and in hand	56,333,085	39,674,413
	<b>56,333,085</b>	<b>39,674,413</b>

## 6. Trade and Other Receivables

	2023 \$	2022 \$
GST receivable	43,435	66,965
Interest receivable	456,612	4,491
R&D tax incentive receivable	6,266,304	6,629,009
Other receivables	40,950	18,333
	<b>6,807,301</b>	<b>6,718,798</b>

## 7. Prepaid Expenses

	2023 \$	2022 \$
Prepaid insurance	248,362	242,715
Other prepaid expenses	350,717	488,000
	<b>599,078</b>	<b>730,715</b>

## 8. Intangible Assets

	2023 \$	2022 \$
Patents	9,926,366	9,926,366
Less: Accumulated amortisation	(6,978,778)	(6,978,778)
	<b>2,947,588</b>	<b>2,947,588</b>
<b>Reconciliation</b>		
Carrying amount at the beginning of the period	2,947,588	2,947,588
Additions during the period	–	–
Disposals	–	–
Amortisation expense	–	–
Impairment loss	–	–
<b>Balance at the end of the financial year</b>	<b>2,947,588</b>	<b>2,947,588</b>

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 8. Intangible Assets *continued*

The Consolidated Entity performed its annual impairment test in June 2023. The Consolidated Entity remains committed to its respiratory intangible asset. Investigating the use of iPPS as a potential therapy for Hay Fever, Asthma or Chronic Obstructive Pulmonary Disease (COPD) remains part of the Company's development pipeline. Further consideration is being given around delivery mechanism and developing the formulation to effectively deliver the therapy to treat patients suffering from these illnesses before further development costs are committed.

### Respiratory Patent

The respiratory patent covers the use of PPS for treating allergic rhinitis, allergic asthma and COPD. The respiratory patent is now granted in Australia, New Zealand, China, Canada and Europe.

The recoverable amount of the respiratory patent as at 30 June 2023 has been determined based on a value-in-use calculation using a five-year cash flow projection approved by senior management. The after-tax discount rate applied to cash flow projections is in the range of 25-30%. It was concluded that the risk adjusted value-in-use exceeds the carrying amount of the cash-generating unit by \$11,340,407. As a result of this analysis, management has not recognised an impairment charge.

### Key Assumptions Used in Value-in-use Calculations and Sensitivity to Changes in Assumptions

The calculation of value-in-use for both respiratory and anti-inflammatory/autoimmune patents is most sensitive to the following assumptions:

- projected milestone revenue;
- projected development costs; and
- discount rate.

Projected revenue has been forecast based on projected partnering income associated with the development of the respiratory asset. The milestone income assumptions in the value-in-use calculation are comparable to other global partnering arrangements with an estimated gross profit of \$81 m from FY2024 to FY2027. The value-in-use calculation does not include royalty from product sales, as this is seen to be outside of the five-year period of the calculation. In terms of development costs used in the value-in-use calculation, there are broad assumptions made, which as Paradigm continues to refine its approach to this asset, may see development costs reduce (i.e., once Paradigm determines the delivery mechanism, formulation of therapy and dose regimen, development costs will become clearer and will be reflected in the model).

An after-tax discount rate of between 25-30% has been applied to the projected free cash flow of the cash-generating unit. The discount rate reflects the Consolidated Entity's estimated cost of capital based on the risk-free rate, market risk premium, volatility of the share price relative to market movements, Company-specific risk factors and some allowance for probability of success adjustment in the interest rate.



## 9. Plant and Equipment

	2023 \$	2022 \$
Computer equipment	104,522	104,522
Less: Accumulated depreciation	(96,665)	(88,489)
	<b>7,857</b>	<b>16,033</b>
<b>Reconciliation</b>		
Carrying amount at the beginning of the period	16,033	33,994
Additions during the period	–	–
Disposals	–	–
Depreciation expense	(8,176)	(17,961)
<b>Balance at the end of the financial year</b>	<b>7,857</b>	<b>16,033</b>
Clinical trial equipment	9,419	9,419
Less: Accumulated depreciation	(8,962)	(8,719)
	<b>457</b>	<b>700</b>
<b>Reconciliation</b>		
Carrying amount at the beginning of the period	700	1,077
Additions during the period	–	–
Disposals	–	–
Depreciation expense	(243)	(377)
<b>Balance at the end of the financial year</b>	<b>457</b>	<b>700</b>
Office equipment	78,038	78,038
Less: Accumulated depreciation	(47,897)	(40,333)
	<b>30,141</b>	<b>37,705</b>
<b>Reconciliation</b>		
Carrying amount at the beginning of the period	37,705	48,297
Additions during the period	–	–
Disposals	–	–
Depreciation expense	(7,564)	(10,592)
<b>Balance at the end of the financial year</b>	<b>30,141</b>	<b>37,705</b>
Leasehold improvements	20,431	20,431
Less: Accumulated amortisation	(16,285)	(14,212)
	<b>4,146</b>	<b>6,219</b>
<b>Reconciliation</b>		
Carrying amount at the beginning of the period	6,219	9,328
Additions during the period	–	–
Disposals	–	–
Amortisation expense	(2,073)	(3,109)
<b>Balance at the end of the financial year</b>	<b>4,146</b>	<b>6,219</b>
	<b>42,601</b>	<b>60,657</b>

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 10. Right-of-use Assets

	2023 \$	2022 \$
Land and buildings – right-of-use	813,579	967,258
Less: Accumulated depreciation	(519,788)	(456,760)
	<b>293,791</b>	<b>510,498</b>

The Consolidated Entity leases land and buildings for its office under agreement of three years with option to extend (an additional two years). On renewal, the extension will be on the same conditions as this lease subject to the terms applicable to extension. The Consolidated Entity has renewed the lease in August 2022. This was treated as a lease modification and \$89,408 was recognised as a gain in Other Income (Note 2).

The Consolidated Entity has a sub-tenancy agreement for one year. This is short term and has been expensed as incurred and not capitalised as the right-of-use asset.

There have been no additions to right-of-use assets in the current financial year.

## 11. Trade and Other Payables

	2023 \$	2022 \$
Trade and other creditors	12,161,182	7,088,279
	<b>12,161,182</b>	<b>7,088,279</b>

## 12. Employee Benefits

	2023 \$	2022 \$
Annual leave and on-costs	776,196	594,955
	<b>776,196</b>	<b>594,955</b>

The current provision for employee benefits includes all unconditional entitlements where employees have completed the required period of service and also those where employees are entitled to pro-rate payments in certain circumstances. The entire amount is presented as current since the Consolidated Entity does not have an unconditional right to defer settlement.

## 13. Current Liabilities – Lease Liabilities

	2023 \$	2022 \$
Lease liabilities	104,971	147,758
	<b>104,971</b>	<b>147,758</b>

## 14. Non-current Liability – Employee Benefits

	2023 \$	2022 \$
Long service leave provision	112,830	76,355
	<b>112,830</b>	<b>76,355</b>

## 15. Non-current Liability – Lease Liabilities and Others

	2023 \$	2022 \$
Lease liabilities	139,776	374,560
Make good provision	96,918	94,351
	<b>236,694</b>	<b>468,911</b>

### Make Good Provision

The provision represents the present value of the estimated costs to make good the premises leased by the Consolidated Entity at the end of the respective lease terms.

### Movements in Provisions

Movements in each class of provision during the current financial year, other than employee benefits, are set out below:

	Lease make good 2023 \$	Lease make good 2022 \$
<b>Consolidated</b>		
Carrying amount at the start of the year	94,351	91,853
Unwinding of discount	2,567	2,498
<b>Carrying amount at the end of the year</b>	<b>96,918</b>	<b>94,351</b>

## 16. Issued Capital

	2023 Number of shares	2022 Number of shares	2023 \$	2022 \$
Ordinary shares fully paid	281,756,625	232,680,798	209,833,883	147,194,772

The following movements in issued capital occurred during the year:

	2023 Number of shares	2022 Number of shares	2023 \$	2022 \$
<b>Ordinary shares</b>				
Balance as at the beginning of the period	232,680,798	229,905,798	147,194,772	146,989,484
Ordinary shares issued	50,759,724	–	65,987,641	–
Ordinary shares issue costs (net of GST)	–	–	(3,764,871)	–
Shares issued under ESP	2,000,000	3,075,000	–	–
ESP shares lapsed/buy-back in the period	(3,683,897)	(300,000)	–	–
Limited recourse loan repaid under ESP	–	–	416,341	205,288
<b>Balance as at the end of the period</b>	<b>281,756,625</b>	<b>232,680,798</b>	<b>209,833,883</b>	<b>147,194,772</b>

### Ordinary Shares

Ordinary shares entitle the holder to participate in dividends and the proceeds on the winding up of the Consolidated Entity in proportion to the number of and amounts paid on the shares held. The fully paid ordinary shares have no par value and the Consolidated Entity does not have a limited amount of authorised capital.

On a show of hands every member present at a meeting in person or by proxy shall have one vote and upon a poll each share shall have one vote.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 16. Issued Capital *continued*

### Capital Risk Management

The Consolidated Entity's objectives when managing capital is to safeguard its ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders and to maintain an optimum capital structure to reduce the cost of capital.

Capital is regarded as total equity, as recognised in the statement of financial position, plus net debt. Net debt is calculated as total borrowings less cash and cash equivalents.

In order to maintain or adjust the capital structure, the Consolidated Entity may adjust the number of dividends paid to shareholders, return capital to shareholders, issue new shares or sell assets to reduce debt.

The Consolidated Entity would look to raise capital when an opportunity to invest in a business or company was seen as value adding relative to the current Consolidated Entity's share price at the time of the investment. The Consolidated Entity is not actively pursuing additional investments in the short term as it continues to integrate and grow its existing businesses in order to maximise synergies.

The Consolidated Entity is subject to certain financing arrangements covenants and meeting these is given priority in all capital risk management decisions. There have been no events of default on the financing arrangements during the financial year.

The capital risk management policy remains unchanged from the 30 June 2022 Annual Report.

## 17. Share Based Payment Reserve

	2023 \$	2022 \$
Balance as at the beginning of the period	9,261,765	6,453,995
Share based payment expenses in the period	1,447,590	3,270,037
ESP options lapsed in the period	(1,914,909)	(335,705)
Unlisted options lapsed in the period	(786,568)	–
Transfer from share reserve on exercise of options	(221,192)	(126,562)
	<b>7,786,686</b>	<b>9,261,765</b>

Once approved by the Board, monies are loaned by the Consolidated Entity interest free and on a non-recourse basis to participants to finance the purchase of shares in the Company. The ESP shares are registered in the name of participants but are subject to a restriction on disposal for a period of five years (from date of issue) and for further periods whilst they remain financed. On cessation of employment, the entitlement to any shares held for less than three years is pro-rated.

On 7 July 2022, an invitation of ESP shares of 2,000,000 was approved and issued at a price of \$0.96 per share to Mr Marco Polizzi. These shares were issued on vesting conditions. Each tranche of shares were to vest in 12 months, 24 months and 36 months. However, the total number of shares were cancelled in relation to the cessation of employment.

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.

The weighted average share price during the financial year was \$1.2746 (30 June 2022: \$1.63).

Set out below are summaries of options granted under the Employee Share Plan:

ESP shares	Grant date	Vesting condition	Number
Jul-22	7/07/2022	666,667 shares are vested on 7 July 2023, 666,667 shares are vested on 7 July 2024 and 666,666 shares are vested on 7 July 2025	2,000,000

**30-Jun-23**

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Expired/ forfeited	Balance at the end of the year
7/11/2019	7/11/2024	\$2.93	2,245,890	–	(713,100)	(403,897)	1,128,893
10/07/2020	10/07/2025	\$3.24	1,915,000	–	–	(550,000)	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	2,700,000	–	–	(730,000)	1,970,000
25/01/2022	25/01/2027	\$1.89	375,000	–	–	–	375,000
7/07/2022	7/07/2027	\$0.96	–	2,000,000	–	(2,000,000)	–
			<b>8,335,890</b>	<b>2,000,000</b>	<b>(713,100)</b>	<b>(3,683,897)</b>	<b>5,938,893</b>

**30-Jun-22**

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Expired/ forfeited	Balance at the end of the year
7/11/2019	7/11/2024	\$2.93	2,685,890	–	(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
			<b>6,000,890</b>	<b>3,075,000</b>	<b>(440,000)</b>	<b>(300,000)</b>	<b>8,335,890</b>

In addition, the following unlisted options were expired:

- (i) 275,000 unlisted options exercisable at \$1.75 each on or before 28 February 2023 in accordance with existing corporate services mandate; and
- (ii) 550,000 unlisted options exercisable at \$1.75 each on or before 24 March 2023 in accordance with existing corporate services mandate.

**Unlisted Options****30-Jun-23**

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

**30-Jun-22**

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
18/05/2018	18/05/2021	\$0.65	861,250	–	(861,250)	–
16/11/2017	15/11/2020	\$0.31	35,000	–	(35,000)	–
27/09/2017	27/09/2020	\$0.45	1,000,000	–	(1,000,000)	–
			<b>2,721,250</b>	<b>–</b>	<b>(1,896,250)</b>	<b>825,000</b>

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 18. Accumulated Losses

	2023 \$	2022 \$
Balance as at the beginning of the period	(114,015,544)	(75,228,227)
Loss for the accounting period	(51,910,013)	(39,249,584)
ESP options lapsed in the period	1,403,783	335,705
Unlisted options lapsed in the period	786,568	–
Transfer from share reserve on exercise of options	221,192	126,562
	<b>(163,514,014)</b>	<b>(114,015,544)</b>

## 19. Commitments

The Consolidated Entity had no capital commitments as at 30 June 2023 and 30 June 2022.

## 20. Contingencies

The Consolidated Entity had no contingent liabilities as at 30 June 2023 and 30 June 2022.

## 21. Loss Per Share

	2023 \$	2022 \$
<b>Net loss for the year attributable to ordinary shareholders</b>	<b>(51,910,013)</b>	<b>(39,249,584)</b>

	Number	Number
Weighted average number of ordinary shares used in calculating basic loss per share	281,756,625	232,680,798
Adjustments for calculation of diluted loss per share:		
Options over ordinary shares	–	825,000
Weighted average number of ordinary shares used in calculating diluted loss per share	281,756,625	233,505,798

	Cents	Cents
Basic loss per share	(0.2078)	(0.1687)
Diluted loss per share	(0.2078)	(0.1687)

## 22. Financial Instruments Disclosure

The Consolidated Entity's financial instruments consist mainly of deposits with banks, short-term investments, accounts receivable and accounts payable.

The totals for each category of financial instruments, measured in accordance with AASB 9 as detailed in the accounting policies of these Financial Statements, are as follows:

	2023 \$	2022 \$
<b>Financial assets</b>		
<b>Current</b>		
Cash and cash equivalents	56,333,085	39,674,413
Other receivables	540,997	89,789
Term deposits	46,200	46,200
	<b>56,920,282</b>	<b>39,810,402</b>
<b>Financial liabilities</b>		
<b>Current</b>		
Trade and other payables at amortised cost	12,161,182	7,088,279
Lease liabilities	104,971	147,758
	<b>12,266,153</b>	<b>7,236,037</b>
<b>Non-current</b>		
Lease liabilities	139,776	374,560
	<b>139,776</b>	<b>374,560</b>

### Financial Risk Management Objectives

The Consolidated Entity's activities expose it to a variety of financial risks: market risk (including foreign currency risk), credit risk and liquidity risk. The Consolidated Entity's overall risk management program focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the financial performance of the Consolidated Entity. The Consolidated Entity uses different methods to measure different types of risk to which it is exposed. These methods include sensitivity analysis in the case of interest rate, foreign exchange and other price risks, and ageing analysis for credit risk.

Risk management is carried out by senior finance executives (finance team) under policies approved by the Board. These policies include identification and analysis of the risk exposure of the Consolidated Entity and appropriate procedures, controls and risk limits. The finance team identifies, evaluates and hedges financial risks within the Consolidated Entity's operating units and reports to the Board on a monthly basis.

### Market Risk

Market risk is the risk that changes in market prices, such as foreign currency fluctuations, interest rates and equity prices will affect the Consolidated Entity's income and expenses or the value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimising the return.

### Equity Price Risk

The Consolidated Entity is currently not subject to equity price risk movement.

### Interest Rate Risk

Interest rate risk is the risk that the value of a financial instrument or cash flows associated with the instrument will fluctuate due to changes in market interest rates. Interest rate risk arises from fluctuations in interest-bearing financial assets and liabilities that the Consolidated Entity uses. Interest-bearing assets comprise cash and cash equivalents which are considered to be short-term liquid assets and investment decisions are governed by the monetary policy.

During the year, the Consolidated Entity had no variable rate interest bearing liability.

It is the Consolidated Entity's policy to settle trade payables within the credit terms allowed and therefore not incur interest on overdue balances.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 22. Financial Instruments Disclosure *continued*

### Foreign Currency Risk

The carrying amount of the Consolidated Entity's foreign currency denominated financial assets and financial liabilities at the reporting date were as follows:

Consolidated	Assets		Liabilities	
	2023 \$	2022 \$	2023 \$	2022 \$
US dollars	135,617	343,015	372,716	609,350
	<b>135,617</b>	<b>343,015</b>	<b>372,716</b>	<b>609,350</b>

The Consolidated Entity's main currency exposure is the AUD:USD pair, with much of the Company's clinical development costs being denominated in USD. The Company reviews its currency needs and uses a combination of sourcing currency at spot or via forward contracts to manage USD flows.

The consolidated entity had net liabilities denominated in foreign currencies of US\$237K as at 30 June 2023 (2022: US\$266K net liabilities). Based on this exposure, had the Australian dollar weakened by 10% / strengthened by 10% against these foreign currencies with all other variables held constant, the Consolidated Entity's profit before tax for the year would have been \$26K lower/higher (2022: \$43K lower/\$35K higher). The percentage change is illustrative of overall volatility of the significant currencies, which is based on management's assessment of reasonable possible fluctuations taking into consideration movements over the last 6 months each year and the spot rate at each reporting date. The actual unrealised foreign exchange loss for the year ended 30 June 2023 was \$389K (2022: gain of \$894K).

### Credit Risk

Credit risk is the risk of financial loss to the Consolidated Entity if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Consolidated Entity's receivables from customers and investment securities.

The Consolidated Entity does not presently have customers and consequently does not have credit exposure to outstanding receivables. Trade and other receivables represent GST refundable from the Australian Taxation Office and R&D tax incentive claims. Trade and other receivables are neither past due nor impaired.

Credit risk of the Consolidated Entity is low because the majority financial instruments are cash in bank.

### Liquidity Risk

Liquidity risk is the risk that the Consolidated Entity will not be able to meet its financial obligations as they fall due. The Consolidated Entity's approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet its liabilities when due, under both normal and stressed conditions, without incurring unacceptable losses or risking damage to the Consolidated Entity's reputation.

The Consolidated Entity's objective is to maintain a balance between continuity of funding and flexibility. The Consolidated Entity's exposure to financial obligations relating to corporate administration and projects expenditure is subject to budgeting and reporting controls, to ensure that such obligations do not exceed cash held and known cash inflows for a period of at least one year.

### Remaining Contractual Maturities

The following tables detail the Consolidated Entity's remaining contractual maturity for its financial instrument liabilities. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the financial liabilities are required to be paid. The tables include both interest and principal cash flows disclosed as remaining contractual maturities and therefore these totals may differ from their carrying amount in the statement of financial position.



<b>Consolidated – 2023</b>	<b>Weighted average interest rate %</b>	<b>1 year or less \$</b>	<b>Between 1 and 2 years \$</b>	<b>Between 2 and 5 years \$</b>	<b>Over 5 years \$</b>	<b>Remaining contractual maturities \$</b>
Non-derivatives						
Non-interest bearing						
Trade payables	–	12,161,182	–	–	–	12,161,182
Other payables	–	–	–	–	–	–
<i>Interest-bearing – fixed rate</i>						
Lease liability	4.70%	116,706	123,172	20,709	–	260,587
<b>Total non-derivatives</b>		<b>12,277,888</b>	<b>123,172</b>	<b>20,709</b>	<b>–</b>	<b>12,421,769</b>

<b>Consolidated – 2022</b>	<b>Weighted average interest rate %</b>	<b>1 year or less \$</b>	<b>Between 1 and 2 years \$</b>	<b>Between 2 and 5 years \$</b>	<b>Over 5 years \$</b>	<b>Remaining contractual maturities \$</b>
Non-derivatives						
Non-interest bearing						
Trade payables	–	7,088,279	–	–	–	7,088,279
Other payables	–	–	–	–	–	–
<i>Interest-bearing – fixed rate</i>						
Lease liability	4.70%	155,861	178,172	216,382	–	550,415
<b>Total non-derivatives</b>		<b>7,244,140</b>	<b>178,172</b>	<b>216,382</b>	<b>–</b>	<b>7,638,694</b>

#### Fair Value of Financial Assets and Liabilities

The fair value of cash and cash equivalents and non-interest-bearing financial assets and financial liabilities of the Consolidated Entity is equal to their carrying value.

## 23. Related Parties

### Receivable From and Payable to Related Parties

The following transactions occurred with related parties:

	<b>Consolidated</b>	
	<b>2023</b>	<b>2022</b>
	<b>\$</b>	<b>\$</b>
Payments for legal services provided by BioMeltzer, which Amos Meltzer is also a Director of	31,680	31,284
Payments for membership subscription to AusBiotech Ltd; Helen Fisher is the Chair of the Victorian State Committee	5,768	2,436
	<b>37,448</b>	<b>33,720</b>

	<b>Consolidated</b>	
	<b>2023</b>	<b>2022</b>
	<b>\$</b>	<b>\$</b>
<b>Current payables</b>		
Trade payables – BioMeltzer	–	3,564
	<b>–</b>	<b>3,564</b>

Loans to or from related parties:

There were no loans to or from related parties at the time of current and previous reporting dates.

Terms and conditions:

All transactions were made on normal commercial terms and conditions and at market rates.

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 23. Related Parties *continued*

### Parent Entity

The Parent Entity is Paradigm Biopharmaceuticals Limited.

### Controlled Entities

Interests in controlled entities are outlined in Note 24.

In the Financial Statements of the Consolidated Entity, investments in subsidiaries are measured at cost. All entity interests held are fully paid ordinary shares or units.

The consolidated financial statements incorporate the assets, liabilities and results of the following wholly-owned subsidiaries in accordance with the accounting policy described in Note 1.

## 24. Controlled Entities

Name	Principal place of business	Ownership interest	
		2023 %	2022 %
Paradigm Health Sciences Pty Ltd	Australia	100.00%	100.00%
Xosoma Pty Ltd	Australia	100.00%	100.00%
C4M Pharmaceuticals Pty Ltd	Australia	100.00%	100.00%
Paradigm Biopharmaceuticals (Ireland) Limited	Ireland	100.00%	100.00%
Paradigm Biopharmaceuticals (USA) Inc.	USA	100.00%	100.00%

### Subsidiaries

An inter-company loan exists between Paradigm Biopharmaceuticals Limited (Parent) and Paradigm Health Sciences (Subsidiary) of amounts owing to Paradigm Biopharmaceuticals Limited \$334,061 (2022: \$334,061).

## 25. Parent Entity Disclosures

Set out below is the supplementary information about the parent entity

	2023 \$	2022 \$
<i>Statement of profit or loss and other comprehensive income</i>		
Loss after income tax	(17,296,643)	(18,902,012)
<i>Statement of financial position</i>		
Total current assets	61,465,176	45,947,940
<b>Total assets</b>	<b>123,084,610</b>	<b>79,360,014</b>
Total current liabilities	2,620,168	4,978,762
<b>Total liabilities</b>	<b>2,969,692</b>	<b>5,524,028</b>
<b>Total equity</b>	<b>120,114,918</b>	<b>73,835,986</b>

There are no guarantees entered into by the parent entity in relation to the debts of its subsidiaries.

### Contingent Liabilities

The parent entity had no contingent liabilities as at 30 June 2023 and 30 June 2022.

### Capital Commitments

The parent entity had no capital commitments as at 30 June 2023 and 30 June 2022.

### Significant Accounting Policies

The accounting policies of the parent entity are consistent with those of the Consolidated Entity.

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

	2023 \$	2022 \$
<b>Loss for the year</b>	<b>(51,910,013)</b>	<b>(39,249,584)</b>
Gain on lease modification	(89,408)	
Depreciation and amortisation	153,656	193,250
Foreign exchange unrealised gains/(losses)	389,272	(858,379)
Share based payment expenses	936,462	3,270,037
Change in operating assets and liabilities		
(Increase)/decrease in trade receivables	363,619	1,792,655
(Increase)/decrease in other receivables	(452,122)	(3,812)
Decrease in other assets	131,637	658,033
Increase in payables	5,072,903	2,101,838
Increase/(decrease) in provisions	217,716	(109,302)
<b>Net cash used in operating activities</b>	<b>(45,186,279)</b>	<b>(32,205,266)</b>

## 27. Non-cash Investing and Financing Activities

	2023 \$	2022 \$
Shares issued/to be issued under Employee Share Plan	1,447,590	3,270,037
	<b>1,447,590</b>	<b>3,270,037</b>

## 28. Events Subsequent to Reporting Date

No matters or circumstance has arisen since 30 June 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 years.

## 29. Key Management Personnel Remuneration Disclosures

The aggregate remuneration made to directors and other members of key management personnel of the Consolidated Entity is set out below:

	2023 \$	2022 \$
Short-term employee benefits	2,907,128	1,853,599
Post-employment benefits	440,782	179,602
Long-term employee benefits	–	30,428
Share-based payments	450,109	905,485
	<b>3,798,019</b>	<b>2,969,114</b>

# Notes to the Consolidated Financial Statements

for the year ended 30 June 2023

continued

## 30. Auditor's Remuneration Note

During the financial year the following fees were paid or payable for services provided by RSM Australia Partners, the auditor of the Company.

	2023 \$	2022 \$
<i>Audit services</i>		
Audit or review of the financial statements	79,000	78,000
	<b>79,000</b>	<b>78,000</b>
<i>Other services</i>		
Preparation of the tax return and other tax matters	–	25,520
R&D tax incentive claim	–	93,012
<i>Other services network firms</i>		
Provision of Ireland Registered Office and corporation services	3,535	–
	3,535	118,532
	<b>82,535</b>	<b>196,532</b>

In addition, RSM Ireland provided services tax and secretarial services for Paradigm. Since July 2023, services in relation to preparing income tax returns and R&D tax incentive claims for Paradigm are no longer performed by RSM.

## 31. Income Tax Expenses

	2023 \$	2022 \$
Numerical reconciliation of income tax expense and tax at the statutory rate		
Loss before income tax expense	(51,910,013)	(39,249,584)
Tax at the statutory tax rate of 25%	(12,977,503)	(9,812,396)
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Depreciation and amortisation	38,414	48,312
Entertainment expenses	3,143	1,491
Share-based payment	234,115	817,509
Employee benefits	54,429	(27,326)
Foreign exchange gains	95,624	26,037
Differences in tax rate from different jurisdictions	(1,384,501)	(825,089)
Current year tax losses not recognised	(13,936,278)	(9,771,462)
Income tax expense	–	–
Tax losses not recognised		
Unrecognised deferred tax assets in relation to tax losses	29,921,538	15,985,260

## Directors' Declaration

In the Directors' opinion:

- (a) the Financial Statements and notes thereto and the Remuneration Report contained in the Directors' Report are in accordance with the *Corporations Act 2001* and other mandatory professional reporting requirements;
- (b) the attached Financial Statements and notes comply with International Financial Reporting Standards as issued by the International Accounting Standards Board as described in Note 1(b) to the Financial Statements;
- (c) the attached Financial Statements and notes give a true and fair view of the Consolidated Entity financial position as at 30 June 2023 and of its performance for the financial year ended on that date; and
- (d) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

The Directors have been given the declarations required by Section 295A of the *Corporations Act 2001* for the financial year ended on 30 June 2023.

Signed in accordance with a resolution of the Directors made pursuant to section 295(5)(a) of the *Corporations Act 2001*.

On behalf of the Directors



**Paul Rennie**  
Managing Director

Dated at Melbourne, Victoria this 25th day of August 2023.

# Independent Audit Report



## RSM Australia Partners

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## INDEPENDENT AUDITOR'S REPORT To the Members of Paradigm Biopharmaceuticals Limited

### Opinion

We have audited the financial report of Paradigm Biopharmaceuticals Limited ('the Company'), and its subsidiaries (together 'the Consolidated entity'), which comprises the consolidated statement of financial position as at 30 June 2023, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion the accompanying financial report of the Consolidated entity is in accordance with the *Corporations Act 2001*, including:

- (i) giving a true and fair view of the Consolidated entity's financial position as at 30 June 2023 and of its financial performance for the year then ended; and
- (ii) complying with Australian Accounting Standards and the Corporations Regulations 2001.

### Basis for Opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit 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* (the Code) that are relevant to our audit of the 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 the Company, would be in the same terms if given to the directors as at the time of this auditor's report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

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### Key Audit Matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report of the current period. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Key Audit Matter	How our audit addressed this matter
<p><b>Research and development expenses</b> Refer to Note 1 (d) (v) in the financial statements</p>	
<p>The Consolidated entity incurred in expenditure amounting to \$52.7m in relation to Research and development expenses of ongoing projects, primarily for the phase 3 clinical trials of the osteoarthritis project.</p> <p>These activities are the primary business of Paradigm and deemed to be still in 'research phase'. Accordingly, these expenses have been recognised in the profit or loss as incurred in line with AASB 138 <i>Intangible Assets</i> ('AASB 138').</p> <p>We considered the accounting of Research and development expenses to be a key audit matter because it is the Consolidated entity main business activity and represents its most significant expense. In addition, management is required to exercise significant judgment to determine whether a particular project is categorised to be in 'research' or 'development' phase, which then dictates the appropriate accounting treatment in the financial statements.</p>	<p>Our audit procedures in relation to this matter included:</p> <ul style="list-style-type: none"> <li>• Holding discussions with management regarding the current status of each project to gather an understanding of management's conclusion that the projects are still being in the 'research phase' as defined by AASB 138;</li> <li>• Gathering an understanding the entity level of controls (in particular regarding control activities relevant to procurement, payables and payments). This procedure included an evaluation of the effectiveness of the design of the controls in place;</li> <li>• Obtaining third party confirmation from key service providers in relation to the level of expense incurred during the year and the amount payables held at the reporting date; and</li> <li>• Performing substantive detail testing by agreeing a sample of expenses to supporting documentation to understand the nature of the expenditure incurred and to verify the accuracy and existence of the recorded expenses.</li> </ul>



## Key Audit Matters (continued)

Key Audit Matter	How our audit addressed this matter
<p><b>Impairment of Intangible Assets</b> Refer to Note 8 in the financial statements</p>	
<p>As at 30 June 2023, the Consolidated entity's Intangible asset amounted to \$2.9m. This Intangible asset relates to Patent costs for ongoing respiratory projects in the development of numerous biopharmaceutical drugs.</p> <p>The Consolidated entity's Intangible asset is subject to an annual impairment test.</p> <p>We identified this area as a key audit matter due to the size of the intangible assets balance and because the directors' assessment of the 'value in use' of the cash generating unit ("CGU") involves judgements about the future underlying cash flows of the business and the discount rates applied to them.</p> <p>For the year ended 30 June 2023, management has performed an impairment assessment over the intangible assets balance by:</p> <ul style="list-style-type: none"> <li>Assessing for each related project the success to date in line with agreed milestones including any clinical trial data; and other statistical test results;</li> <li>Estimating the additional funding required on the projects and the plan going forward including the use of the Patent for other purposes;</li> <li>Calculating the value in use for the respiratory project using a discounted cash flow model. The model included estimated cash flows for the project for 5 years. These cash flows were then discounted to net present value using the Consolidated entity's weighted average cost of capital (WACC); and</li> <li>Comparing the determined value in use against the carrying value of the Intangible assets.</li> </ul>	<p>Our audit procedures in relation to this matter included:</p> <ul style="list-style-type: none"> <li>Assessing management's determination that the respiratory asset should be allocated to a single CGU based on the nature of the Consolidated entity's business;</li> <li>Assessing the overall valuation methodology used to determine the value in use;</li> <li>Challenging the reasonableness of key assumptions, including the cash flow projections, revenue growth rates, discount rates, and sensitives used;</li> <li>Checking the mathematical accuracy of the cash flow model, and reconciling input data to supporting evidence and considering the reasonableness the supporting documentation;</li> <li>Reviewing the appropriateness and accuracy of disclosures of critical estimates and assumptions in the financial statements in relation to the valuation methodologies; and</li> <li>Reviewing announcements to date in relation to the details of current developments and results of the respiratory projects.</li> </ul>

## Other Information

The directors are responsible for the other information. The other information comprises the information included in the Consolidated entity's annual report for the year ended 30 June 2023; but does not include the financial report and the auditor's report thereon.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report, or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.





### **Responsibilities of the Directors for the Financial Report**

The directors of the Company are responsible for the preparation of the 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 financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the directors are responsible for assessing the ability of the Consolidated entity to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Consolidated entity or to cease operations, or have no realistic alternative but to do so.

### **Auditor's Responsibilities for the Audit of the Financial Report**

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance; but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: [https://www.auasb.gov.au/admin/file/content102/c3/ar2\\_2020.pdf](https://www.auasb.gov.au/admin/file/content102/c3/ar2_2020.pdf). This description forms part of our auditor's report.

### **Report on the Remuneration Report**

#### *Opinion on the Remuneration Report*

We have audited the Remuneration Report included in pages 21 to 27 of the directors' report for the year ended 30 June 2023.

In our opinion, the Remuneration Report of Paradigm Biopharmaceuticals Limited, for the year ended 30 June 2023, complies with section 300A of the *Corporations Act 2001*.

#### *Responsibilities*

The directors of the Company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

**RSM AUSTRALIA PARTNERS**

**R J MORILLO MALDONADO**  
Partner

Dated: 25 August 2023  
Melbourne, Victoria

# Shareholder Information

Details of shares and options as at 14 August 2023:

## Top Holders

The 20 largest holders of each class of equity security as at 14 August 2023 were:

### Fully Paid Ordinary Shares

Name	Number of shares	%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	19,967,193	7.09%
CITICORP NOMINEES PTY LIMITED	15,408,992	5.47%
KZEE PTY LTD <KZEE SUPERANNUATION FUND A/C>	10,914,902	3.87%
MR PAUL JOHN RENNIE	8,500,548	3.02%
J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	7,907,224	2.81%
NETWEALTH INVESTMENTS LIMITED <WRAP SERVICES A/C>	7,199,417	2.56%
BNP PARIBAS NOMS PTY LTD <DRP>	6,307,738	2.24%
BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT DRP>	5,724,948	2.03%
WACC PTY LTD <PROGRESSIVE GLOBAL FUND A/C>	3,959,480	1.41%
NANCY EDITH WILSON-GHOSH <GHOSH FAMILY A/C>	3,475,835	1.23%
MR EVAN PHILIP CLUCAS + MS LEANNE JANE WESTON <KURANGA NURSERY SUPER A/C>	3,207,913	1.14%
BNP PARIBAS NOMINEES PTY LTD HUB24 CUSTODIAL SERV LTD <DRP A/C>	2,616,142	0.93%
MR BRETT LANGAN	2,303,432	0.82%
V REDFORD PTY LTD <REDFORD S/F A/C>	2,228,500	0.79%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	1,666,793	0.59%
AUSTRALIAN EXECUTOR TRUSTEES LIMITED <NO 1 ACCOUNT>	1,603,641	0.57%
UBS NOMINEES PTY LTD	1,539,064	0.55%
39KP PTY LTD <ROSS FAMILY A/C>	1,468,994	0.52%
MS LENNA YU LING TYE	1,441,631	0.51%
FLINDERS MEDICAL CENTRE FOUNDATION	1,420,000	0.50%
<b>Totals: Top 20 holders of ordinary fully paid shares</b>	<b>108,862,387</b>	<b>38.64%</b>
<b>Total remaining holders' balance</b>	<b>172,894,238</b>	<b>61.36%</b>
<b>Total no. of shares</b>	<b>281,756,625</b>	

## Distribution Schedules

A distribution of each class of equity security as at 12 August 2023:

### Fully Paid Ordinary Shares

Range	Total holders	Units	% of issued capital
1 – 1,000	4,641	2,483,043	0.88
1,001 – 10,000	6,737	26,328,684	9.34
10,001 – 100,000	2,401	70,999,535	25.20
100,001 – 500,000	243	49,238,835	17.48
500,001 – 1,000,000	23	16,243,038	5.76
1,000,001 – 20,000,000	27	116,463,490	41.33
20,000,001 and over	0	0	0.00
Rounding			0.01
<b>Total</b>	<b>14,072</b>	<b>281,756,625</b>	<b>100.00</b>

## Substantial Shareholders

The names of substantial shareholders and the number of shares to which each substantial shareholder and their associates have a relevant interest, as disclosed in substantial shareholding notices given to the Consolidated Entity, are set out below:

<b>Substantial shareholder</b>	<b>Number of shares</b>
PAUL RENNIE AND RELATED COMPANIES	20,512,805
ALLIANZ SE AND RELATED ENTITIES	20,215,330

## Unmarketable Parcels

Holdings less than a marketable parcel of ordinary shares (being 562 shares at 14 August 2023):

<b>Holders</b>	<b>Units</b>
2,673	842,453

## Voting Rights

The voting rights attaching to ordinary shares are:

- On a show of hands every member present in person or by proxy shall have one vote and upon a poll each share shall have one vote.
- Options do not carry any voting rights.

## On-market Buy-back

There is no current on-market buy-back.

# Corporate Governance Statement

The Board and management of Paradigm Biopharmaceuticals Limited (Consolidated Entity) are committed to conducting the business of the Consolidated Entity in an ethical manner and in accordance with the highest standards of corporate governance. The Consolidated Entity has adopted and has substantially complied with the ASX Corporate Governance Principles and Recommendations (Fourth Edition) to the extent appropriate to the size and nature of the Consolidated Entity's operations.

This Corporate Governance Statement is accurate and up to date as at 30 June 2023 and has been approved by the Board on 30 December 2022.

The Corporate Governance Statement is available on the Consolidated Entity's website at:

<http://www.paradigmbiopharma.com/investors/corporate-governance>

# Corporate Directory

## Directors

### Mr Paul Rennie

Managing & Executive Director  
(Appointed on 22 November 2022)

### Mr Paul Rennie

Non-Executive Chairman  
(Ceased on 22 November 2022)

### 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

Mr Kevin Hollingsworth  
(Ceased on 30 August 2022)

Ms Abby Macnish Niven  
(Appointed on 30 August 2022)

## Principal Place of Business

Level 15, 500 Collins Street  
Melbourne VIC 3000

## Registered Office

Level 15, 500 Collins Street  
Melbourne VIC 3000

## Auditor

RSM Australia Partners  
Level 21, 55 Collins Street  
Melbourne VIC 3000

## Solicitors

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

## Share Registry

Computershare Limited  
Yarra Falls, 452 Johnston Street  
Abbotsford VIC 3067  
Telephone: (61-3) 1300 137 328

## Bankers

Commonwealth Bank  
Level 20, Tower One,  
Collins Square  
727 Collins Street  
Melbourne VIC 3008

## Stock Exchange

ASX Limited  
Level 4, North Tower  
525 Collins Street  
Melbourne VIC 3000

ASX Code: **PAR**

## Website

<https://paradigmbiopharma.com/>

