

Appendix 4D: Preliminary Financial Report

under ASX Listing Rule 4.2A

Current reporting period: Half-year ended 31 December 2023

Prior corresponding period: Half-year ended 31 December 2022

Results for announcement to the market

				\$'000
Revenue from continuing operations (Appendix 4D item 2.1)	Up (increase)	399%	to	\$8,025
Adjusted Revenue* (excluding Mundipharma settlement)	Down (decrease)	8%	to	\$1,472
Loss from continuing operations after tax attributable to members (Appendix 4D item 2.2)	Down (decrease)	88%	to	\$1,034
Loss for the period attributable to members (Appendix 4D item 2.3)	Down (decrease)	88%	to	\$1,034
Adjusted Loss* (excluding Mundipharma settlement)	Down (decrease)	8%	to	\$7,587

*Adjusted Revenue is calculated as Revenue (\$8,025,000) from continuing operations less nonrecurring revenue of \$6,553,000 relating to the commercial settlement and termination of the VivaGel® BV license and supply agreement with Mundipharma in August 2023. Adjusted Loss likewise subtracts the above nonrecurring revenue from the Loss for the period.

Dividends (Appendix 4D items 2.4 and 2.5)

No dividends have been paid or declared by the entity since the beginning of the current reporting period. No dividends were paid for the previous corresponding period. No record date for determining entitlements to dividends has been declared.

Explanation of Revenue (Appendix 4D item 2.6)

Revenue of \$8,025,000 (31 December 2022: \$1,607,000) for the half-year includes product sales, royalty and license, and research revenue from commercial partners of \$7,197,000 (31 December 2022: \$1,086,000), and interest income on cash invested in term deposits of \$828,000 (31 December 2022: \$521,000). Revenue included a nonrecurring \$6,553,000 from the commercial settlement of the VivaGel® BV license and supply agreement with Mundipharma in August 2023. Excluding the Mundipharma settlement, half-year adjusted revenue was \$1,471,000, an 8% decrease on prior corresponding period revenues, with lower product sales in the current period.

For further details, refer to the Interim Report which follows this announcement.



Explanation of Loss (*Appendix 4D item 2.6*)

The loss after tax was \$1,034,000 (31 December 2022: \$8,277,000 loss) and includes nonrecurring revenue of \$6,553,000 from the Mundipharma commercial settlement. The half-year includes research and product development expense of \$5,263,000 (31 December 2022: \$5,599,000) net of the Australian Government's R&D tax incentive. Research expenditures are primarily associated with the internal DEP[®] drug delivery programs including DEP[®] docetaxel, DEP[®] cabazitaxel, DEP[®] irinotecan, DEP[®] ADCs and DEP[®] radiotheranostics, and the VIRALEZE™ post-market study.

For further details, refer to the Interim Report which follows this announcement.

Net Tangible Asset Backing (*Appendix 4D item 3*)

Net tangible asset (NTA) backing per ordinary share at 31 December 2023 is \$0.08 (31 December 2022: \$0.10).

The above NTA backing calculation is considered a non-IFRS value and has not been audited or reviewed in accordance with Australian Accounting Standards.

Appendix 4D items 4,5,6,7,8,9 are not applicable.

This report is based on the consolidated 2023 half-year financial statements which have been reviewed by PricewaterhouseCoopers (the Company's auditor) with the Independent Auditor's Review Report included within the 31 December 2023 half-year financial statements.

This information should be read in conjunction with the 30 June 2023 Annual Report and any public announcements made by Starpharma Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001.

Interim Report and Half-Year Financial Results

- *Strong cash position with \$32.1M as at 31 December 2023. Reported half-year revenue of \$8M (H1 FY23 \$1.6M), including \$6.6M VivaGel[®] BV settlement from Mundipharma. The reported loss for the period was \$1.0M (H1 FY23 \$8.3M).*
 - *Phase 2 clinical trials of DEP[®] cabazitaxel, DEP[®] docetaxel, and DEP[®] irinotecan showed positive results in treating multiple cancer types, providing further clinical validation of the DEP[®] platform and highlighting its value proposition in repurposing and enhancing the therapeutic and commercial utility of widely used cancer therapies.*
 - *The DEP[®] platform showed imaging benefits in targeted radio diagnostic approaches. Specifically, DEP[®] HER2-zirconium demonstrated a favourable biodistribution profile, rapid uptake, and high levels of tumour accumulation in a HER2+ breast cancer model.*
 - *Results from the Viraleze[™] post-market study in participants with COVID-19 showed antiviral efficacy, with effects more pronounced in the older patient cohorts. Viraleze[™] achieved a statistically significant reduction in SARS-CoV-2 viral load in the cohort of participants aged 45 and over. The clinical evidence generated by the Viraleze[™] post-market study will support ongoing commercial and regulatory activities.*
 - *Following Starpharma's successful commercial settlement agreement with Mundipharma for VivaGel[®] BV and the subsequent reversion of territorial rights over the product, Starpharma signed a regional sales and distribution agreement for VivaGel[®] BV with ITROM Pharmaceutical Group, covering 13 countries across the Middle East and North Africa (MENA) region.*
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Melbourne, Australia; 28 February 2024: Starpharma (ASX: SPL, OTCQX: SPHRY) today releases its Interim Report and Half-Year Financial Results for the period ended 31 December 2023 (H1 FY24).

Starpharma's Chief Executive Officer, Cheryl Maley, commented:

"Starpharma has made important progress towards achieving its objectives during this half. This includes completing and reporting the results from the Phase 2 clinical trials of its DEP[®] candidates and the clinical study of Viraleze[™]. The Company also presented the DEP[®] platform at multiple industry conferences and executed a new VivaGel[®] BV partnership in the Middle East and North Africa region.

"Starpharma is focused on advancing its DEP[®] platform towards commercialisation and building partnerships and collaborations. The DEP[®] platform is highly versatile and can be applied to a wide range of novel therapeutics, including but not limited to Antibody-Drug Conjugates (ADCs) and radiotheranostics, offering a range of therapeutic and commercial benefits. This is supported by the Phase 2 proof-of-concept clinical trial results and the early data in ADCs and radiotheranostics.

"In parallel, Starpharma is committed to leveraging the existing approvals of VivaGel[®] BV and Viraleze[™] to expand their brand recognition and sales.

"With a strong cash balance of \$32.1 million (at 31 December 2023), Starpharma is well-positioned to move forward with its pipeline and will allocate its resources in line with its strategic priorities."



DEP® Programs

The final results from the Phase 2 clinical trial programs of DEP® cabazitaxel and DEP® docetaxel were reported. Recruitment for the Phase 2 clinical trial of DEP® irinotecan was completed, and interim results were reported. Multiple scientific posters highlighting the DEP® platform were also accepted for presentation at international cancer research conferences.

The **DEP® cabazitaxel** Phase 2 clinical trial met its objectives, with endpoints demonstrating anti-tumour efficacy in advanced, metastatic castration-resistant prostate cancer, platinum-resistant ovarian cancer, and gastro-oesophageal cancers. The trial also confirmed the safety and tolerability of DEP® cabazitaxel.

The key results from the Phase 2 trial of DEP® cabazitaxel in patients with advanced gastro-oesophageal cancers were presented at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium in the US in January 2024.

The **DEP® docetaxel** Phase 2 clinical program demonstrated encouraging anti-tumour activity in multiple advanced, metastatic cancers, including pancreatic cancer, gastro-oesophageal cancer, non-small cell lung cancer, and cholangiocarcinoma. The safety and tolerability of DEP® docetaxel were also confirmed. These results were demonstrated in the monotherapy and combination arms, where DEP® docetaxel was administered either as a monotherapy or combination therapy with other anti-cancer agents, nintedanib or gemcitabine.

The interim clinical data on **DEP® irinotecan** showed durable anti-tumour responses in advanced colorectal cancer and platinum-resistant/refractory ovarian cancer and good tolerability across the study. Enrolment has been completed for both the monotherapy and combination arms. Several patients with advanced cancers, including ovarian and colorectal cancers, are continuing therapy and are experiencing prolonged responses to treatment and significant clinical benefits.

These interim data on DEP® irinotecan were presented at the International Conference on Molecular Targets and Cancer Therapeutics, co-hosted by the American Association of Cancer Research (AACR), National Cancer Institute (NCI), and the European Organisation for Research and Treatment of Cancer (EORTC) in the US in October 2023. Additional nonclinical data on DEP® irinotecan in combination with immuno-oncology agents were also presented at this conference.

The **DEP® radiotheranostics** program made progress, with Starpharma's HER2-targeted radiodiagnostic candidate, **DEP® HER2-zirconium**, demonstrating a favourable biodistribution profile with excellent imaging contrast between tumour and normal tissues, as well as rapid uptake and high levels of tumour accumulation in a HER2-positive (HER2+) breast cancer model. These data were also presented at the AACR-NCI-EORTC Conference in the US in October 2023.

The application, versatility, and benefits of the DEP® platform for targeted delivery of radiotheranostics, including an overview of Starpharma's two DEP® HER2-targeted radiotheranostic products, DEP® HER2-zirconium and DEP® HER2-lutetium, were also presented at the Targeted Radiopharmaceuticals Summit in Berlin in December 2023.

On 31 July 2023, following communication from AstraZeneca on 28 July 2023 and the subsequent release of their H1 and Q2 2023 results announcement that day, Starpharma reported that AstraZeneca had made the decision to discontinue the development of AZD0466 after an internal review prompted by a small number of asymptomatic adverse events that were unrelated to Starpharma's dendrimer drug delivery technology.

Starpharma's in-house preclinical **DEP® Antibody-Drug Conjugates** (ADCs) programs continued progressing alongside our partnered programs, including MSD and Genentech. The Company's partner programs involve a number of therapeutic areas, including ADCs.

A key focus for Starpharma is advancing its DEP® platform and assets towards commercialisation through partnerships and licensing. The Company is actively supporting its existing partners and, in parallel, is seeking and targeting new partnerships to leverage its dendrimer technology.



Viraleze™ and VivaGel® BV

The results of the post-market clinical study of **Viraleze™ nasal spray** in participants with COVID-19 were reported in January 2024. Viraleze™ achieved a statistically significant reduction in SARS-CoV-2 viral load in the cohort of participants aged 45 and over. Other antiviral effects were also observed, including increased viral clearance rate from the nose, reduced time to negative PCR¹ test and improvement in key symptoms, including recovery from loss of smell. As seen in a previously announced trial in healthy volunteers, Viraleze™ was well-tolerated.

The results from the Viraleze™ clinical study provide significant clinical evidence of the performance of Viraleze™ that will support regulatory processes for the transition to the new European Medical Device Regulations (MDR), which will come into full effect in 2029. The data will also support ongoing marketing and commercial activities for the product.

Starpharma continues to market Viraleze™ online through Amazon and dedicated product websites. Starpharma also has commercial partners in several international markets, where the product is distributed online and in retail outlets, including pharmacies.

Viraleze™ is not approved for use or supply in Australia, where the review by the Therapeutic Goods Administration (TGA) for the SPL7013 nasal spray as a medical device is ongoing.

In February 2024, Starpharma completed the formal dispute resolution process with the US Food and Drug Administration (FDA) in relation to **VivaGel® BV**. The FDA maintained its position that they require additional clinical efficacy data to be generated for the regulatory approval of VivaGel® BV for bacterial vaginosis (BV) in the US. Starpharma is not planning to pursue additional clinical studies for VivaGel® BV on its own at this time but remains committed to leveraging the VivaGel® BV development program and will work to maximise the commercial potential for VivaGel® BV in the more than 45 markets where it is already approved. The decision by the FDA does not alter the approval status in the countries where VivaGel® BV is already registered.

In January 2024, Starpharma partnered with ITROM Pharmaceutical Group for the sales and distribution of VivaGel® BV across 13 countries in the Middle East and North Africa region. ITROM has a strong presence throughout the region's public and private health sectors, maintaining strong relationships with key opinion leaders, specialist physicians, hospital chains and retail outlets.

This new partnership with ITROM followed the reversion of VivaGel® BV rights to Starpharma under a settlement agreement with Mundipharma in August 2023. Under the settlement, Starpharma received a \$6.6M cash payment from Mundipharma in August 2023, and the VivaGel® BV commercial rights reverted to Starpharma.

Starpharma's partner, Aspen, continues to market VivaGel® BV in Australia and New Zealand. In Australia, VivaGel® BV is the number 1 topical brand by sales for the treatment of BV and prevention of BV recurrence.

The Company continues pursuing additional commercial opportunities for the Viraleze™ and VivaGel® BV products.

Starpharma and Okamoto signed a contract extension for the **VivaGel® Condom** product. This agreement covers Japan and several other Asian markets. Okamoto continues marketing in Japan and regulatory activities in a number of other Asian markets.

Financial Summary

Half-year revenues were \$8.0M, including revenue from commercial partners of \$7.2M (H1 FY23: \$1.1M) and interest income of \$0.8M (H1 FY23: \$0.5M). Revenue included a nonrecurring \$6.6M from the commercial settlement of the VivaGel® BV licence and supply agreement with

¹ Polymerase chain reaction.



Mundipharma in August 2023. Excluding the Mundipharma settlement, the half-year adjusted revenue was \$1.5M, an 8% decrease on H1 FY23, with lower product sales in the current period.

The half-year loss after tax was \$1.0M (H1 FY23: \$8.3M) and includes research and product development expenses of \$5.3M (H1 FY23: \$5.6M) net of the Australian Government's R&D tax incentive. Research expenditures were primarily associated with Starpharma's internal DEP[®] drug delivery programs, including DEP[®] docetaxel, DEP[®] cabazitaxel, DEP[®] irinotecan, DEP[®] ADCs and DEP[®] radiotheranostics, and the Viraleze[™] post-market study.

During the period, Starpharma received a \$7.2M R&D tax incentive and repaid the \$4.0M low-interest R&D loan with the Treasury Corporation of Victoria. Starpharma's balance sheet remains strong, with a closing cash position of \$32.1M at 31 December 2023.

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) is a world leader in dendrimer technology for medical applications. As an innovative Australian biopharmaceutical company, Starpharma is focused on developing and commercialising novel therapeutic products that address significant global healthcare needs. Starpharma boasts a strong portfolio of products, partnerships, and intellectual property.

Starpharma's innovative technology is based on proprietary polymers called dendrimers, which are precise, synthetically manufactured, nanoscale molecules. The unique properties of dendrimers – including their size, structure, high degree of branching, polyvalency, and water solubility – are advantageous in medical and pharmaceutical applications.

Starpharma uses its dendrimer technology to develop novel therapeutics and to improve the performance of existing pharmaceuticals. Starpharma's portfolio includes multiple clinical-stage oncology products, which utilise its Dendrimer Enhanced Product ('DEP[®]') drug delivery technology, and marketed products, including VIRALEZE[™] and VivaGel[®] BV, which utilise SPL7013, a proprietary dendrimer with antimicrobial properties.

Starpharma's DEP[®] drug delivery platform is being used to enhance the effectiveness of existing and novel therapies and to reduce drug-related toxicities through controlled and specified drug delivery.

In addition to Starpharma's internal DEP[®] programs, Starpharma has multiple DEP[®] partnerships with international biopharmaceutical companies, including AstraZeneca (oncology), MSD (Antibody-Drug Conjugates), Chase Sun (anti-infectives), and other world-leading pharmaceutical companies. Due to the broad applicability and optionality of Starpharma's DEP[®] platform, partnered DEP[®] programs have the potential to generate significant future milestones and royalties.

Starpharma's topical nasal spray, Viraleze[™], is registered in more than 35 countries, including Europe, the UK, and Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel[®] BV, for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 50 countries, including in the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on [LinkedIn](#).

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Disclosure

This ASX Announcement was authorised for release by the Chair, Mr Rob Thomas.

Forward-Looking Statements

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates, nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated, or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document, nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.



Starpharma Holdings Limited

ABN 20 078 532 180

Interim Report

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

This information should be read in conjunction with the 30 June 2023 Annual Report and any public announcements made by Starpharma Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

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Directors' Report

The directors are pleased to present this report on the consolidated entity (referred to hereafter as the "Group", "Company", or "Starpharma") consisting of Starpharma Holdings Limited (the "Parent Entity") and the entities it controlled at the end of, or during, the half-year ended 31 December 2023.

Directors

The following persons were directors of Starpharma Holdings Limited during the whole of the half-year and up to the date of this report unless otherwise stated:

R B Thomas, AO (Chairman)

L Cheng

D J McIntyre

J R Davies

R Basser

J K Fairley (retired as Chief Executive Officer and Managing Director on 8 January 2024)

C Maley (appointed as Chief Executive Officer and Managing Director on 8 January 2024)

Principal Activities

The principal activities of the Group consist of research, development and commercialisation of dendrimer products for pharmaceutical and healthcare applications. Activities within the Group are directed towards the development of precisely defined nano-scale materials, including the development of SPL7013 (astodimer sodium) as a vaginal gel, VivaGel® BV, for the management of bacterial vaginosis; Viraleze™ antiviral nasal spray; and as an antiviral condom coating. Starpharma is also applying its proprietary dendrimers to drug delivery to create improved pharmaceuticals and has developed the valuable DEP® (Dendrimer Enhanced Product) delivery platform.

Strategy, Future Developments and Prospects

The Company aims to generate value through the clinical development and commercialisation of its proprietary products, as well as partnerships with pharmaceutical and biotechnology companies based on its patented dendrimer technology in pharmaceutical and healthcare applications. The Company's key focus is to advance its DEP® programs and to fully leverage partnerships in target markets for VivaGel® and Viraleze™. Starpharma intends to achieve this by continuing to utilise a combination of internally funded and partnered projects across its dendrimer portfolio. The Company commercialises its development pipeline with corporate partners via licensing, and sales and distribution agreements at various stages in a product's development lifecycle; depending on the product, patent opportunity, a partner's commercial strategy and relative strength of product and market expertise, comparison of current and future potential returns.

Starpharma has extensive expertise, a strong intellectual property portfolio, a diverse product portfolio, and a strong cash position. Going forward, Starpharma's strategy is to extract the highest value from its patented DEP® technology, as well as its marketed products VivaGel® BV and Viraleze™. Efforts to achieve this will be increasingly focused on key markets and supported by a strengthened commercial capability.

Dividends

No dividends have been paid or declared by the Company during the current reporting period. No dividends were paid for the previous corresponding period.

Review of Operations

DEP® Drug Delivery Platform

Starpharma's DEP® platform is being used to enhance the therapeutic utility of drugs through improved solubility, efficacy and pharmacokinetic control, and reductions in certain drug-related toxicities. Starpharma's innovative and proprietary DEP® platform has shown advantages across a wide range of drug classes. It has the potential to provide benefits to small molecule drugs, peptides and proteins and in the development of DEP® Antibody-Drug Conjugates (ADCs) and radiotheranostics. The dendrimer technology could provide benefit to companies looking to extend patents of key drugs in their portfolio or looking to enhance the outcome of a drug currently in development to improve efficacy and / or reduce toxicity.

Key activities until the date of this report include:

The final results from the Phase 2 clinical trial programs of DEP® cabazitaxel and DEP® docetaxel were reported. Recruitment for the Phase 2 clinical trial of DEP® irinotecan was completed, and interim results were reported.

The DEP® cabazitaxel Phase 2 clinical trial met its objectives, with endpoints demonstrating positive anti-tumour efficacy in advanced, metastatic castrate-resistant prostate cancer, platinum-resistant ovarian cancer, and gastro-oesophageal cancers. The trial also confirmed the safety and tolerability of DEP® cabazitaxel.

The key results from the Phase 2 trial of DEP® cabazitaxel in patients with advanced gastro-oesophageal cancers were presented at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium in January 2024.

The DEP® docetaxel Phase 2 clinical program met its objectives, with endpoints demonstrating encouraging anti-tumour activity in multiple advanced, metastatic cancers, including pancreatic cancer, gastro-oesophageal cancer, non-small cell lung cancer, and cholangiocarcinoma. The safety and tolerability of DEP® docetaxel were also confirmed. These results were demonstrated in the monotherapy and combination arms, where DEP® docetaxel was administered either as a monotherapy or combination therapy with other anti-cancer agents, nintedanib or gemcitabine.

The interim clinical data on DEP® irinotecan showed durable anti-tumour responses in advanced colorectal cancer and platinum-resistant/refractory ovarian cancer and good tolerability across the study. Enrolment has been completed for both the monotherapy and combination arms. Several patients with advanced cancers, including ovarian and colorectal cancers, are continuing therapy and are experiencing prolonged responses to treatment and significant clinical benefits.

These interim data on DEP® irinotecan were presented at the International Conference on Molecular Targets and Cancer Therapeutics, co-hosted by the American Association of Cancer Research (AACR), National Cancer Institute (NCI), and the European Organisation for Research and Treatment of Cancer (EORTC) in the US (AACR-NCI-EORTC) in October 2023. Additional nonclinical data on DEP® irinotecan in combination with immune-oncology agents were also presented at this conference.

The DEP® radiotheranostics program made progress, with Starpharma's HER2-targeted radiodiagnostic candidate, DEP® HER2-zirconium, demonstrating a favourable biodistribution profile with excellent imaging contrast between tumour and normal tissues, as well as rapid uptake and high levels of tumour accumulation in a HER2-positive (HER2+) breast cancer model. These data were also presented at the AACR-NCI-EORTC Conference in October 2023.

The application, versatility, and benefits of the DEP® platform for targeted delivery of radiotheranostics, including an overview of Starpharma's two DEP® HER2-targeted radiotheranostic products, DEP® HER2-zirconium and DEP® HER2-lutetium, were also presented at the Targeted Radiopharmaceuticals Summit in Berlin in December 2023.

On 31 July 2023, following communication from AstraZeneca on 28 July 2023 and the subsequent release of their H1 and Q2 2023 results announcement that day, Starpharma reported that AstraZeneca had made the decision to discontinue the development of AZD0466 after an internal review prompted by a small number of asymptomatic adverse events that were unrelated to Starpharma's dendrimer drug delivery technology.

Starpharma's in-house preclinical DEP® Antibody-Drug Conjugates (ADCs) programs continued progressing alongside our partnered programs, including MSD and Genentech. The Company's partner programs involve a number of therapeutic areas, including oncology and ADCs.

A key focus for Starpharma is advancing its DEP® platform and assets towards commercialisation through partnerships and licensing. The Company is actively supporting its existing partners and, in parallel, is seeking and targeting new partnerships to leverage its dendrimer technology.

Viraleze™ and VivaGel® BV

Starpharma's topical nasal spray, Viraleze™, is registered in more than 35 countries, including Europe, the UK, and Asia. (Viraleze™ is not approved for use or supply in Australia). VivaGel® BV, for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 50 countries, including the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.

Key activities until the date of this report include:

The results of the post-market clinical study of Viraleze™ nasal spray in participants with COVID-19 were reported in January 2024. The results showed that Viraleze™ reduced SARS-CoV-2 viral load and increased the rate of virus clearance from the nose, and in parallel, improved key symptoms of COVID-19, including loss of smell. This benefit was statistically significant in all age cohorts 45+ years but was not significant when patients below 40 years of age were included. As seen in a previously announced trial in healthy volunteers, Viraleze™ was well-tolerated.

The results from the Viraleze™ clinical study provide significant clinical evidence of the performance of Viraleze™ in humans that will support regulatory processes for the transition to the new European Medical Device Regulations (MDR), which will come into full effect in 2029. The data will also support ongoing marketing and commercial activities for the product.

Starpharma continues to market Viraleze™ online through Amazon and dedicated product webstores. Starpharma also has commercial partners in several international markets, where the product is distributed online and in retail outlets, including pharmacies.

Viraleze™ is not approved for use or supply in Australia, where the review by the Therapeutic Goods Administration (TGA) for the SPL7013 nasal spray as a medical device is ongoing.

In February 2024, Starpharma completed the formal dispute resolution process with the US Food and Drug Administration (FDA) in relation to VivaGel® BV. The FDA maintained its position that they require additional clinical efficacy data to be generated for the regulatory approval of VivaGel® BV for bacterial vaginosis (BV) in the US. Starpharma is not planning to pursue additional clinical studies for VivaGel® BV on its own at this time. Starpharma remains committed to leveraging the VivaGel® BV development program and will work to maximise the commercial potential for VivaGel® BV in the more than 45 markets where it is already approved. The decision by the FDA does not alter the approval status in the countries where VivaGel® BV is already registered.

In January 2024, Starpharma partnered with ITROM Pharmaceutical Group for the sales and distribution of VivaGel® BV across 13 countries in the Middle East and North Africa region. ITROM has a strong presence throughout the region's public and private health sectors, maintaining strong relationships with key opinion leaders, specialist physicians, hospital chains and retail outlets.

This new partnership with ITROM followed the reversion of VivaGel® BV rights to Starpharma under a settlement agreement with Mundipharma in August 2023. Under the settlement, Starpharma received a one-off A\$6.6 million cash payment from Mundipharma in August 2023 and the VivaGel® BV commercial rights reverted to Starpharma.

Starpharma's partner Aspen continues to market VivaGel® BV in Australia and New Zealand; Fleurstat BVgel is the top-selling BV treatment by sales in Australia.

The Company continues to pursue additional commercial opportunities for both the Viraleze™ and VivaGel® BV products.

Starpharma and Okamoto signed a contract extension for the VivaGel® Condom product. This agreement covers Japan and several other Asian markets. Okamoto continues marketing in Japan and regulatory activities in a number of other Asian markets.

Other Activities

Cheryl Maley commenced as Starpharma's Chief Executive Officer and Managing Director on 8 January 2024. Upon Cheryl's commencement, Dr Jackie Fairley retired from the position. Dr Fairley will be available in an advisory capacity until June 2024.

Review of Financials

Income statement	31 December 2023 \$'000	31 December 2022 \$'000
Revenue	8,025	1,607
Cost of goods sold	(201)	(542)
Other income	-	104
Research and product development expense (net of R&D tax incentive)	(5,263)	(5,599)
Commercial and regulatory operating expense	(1,516)	(1,829)
Corporate, administration and finance expense	(2,079)	(2,018)
Loss for the period	(1,034)	(8,277)

Income statement

For the half-year ended 31 December 2023, the consolidated loss after income tax was \$1,034,000 (31 December 2022: \$8,277,000). The half-year loss included nonrecurring revenue of \$6,553,000 relating to the commercial settlement and termination of the VivaGel® BV license and supply agreement with Mundipharma in August 2023. The consolidated loss adjusted for the Mundipharma settlement was \$7,587,000, an 8% decrease on the prior corresponding period loss.

Revenue includes product sales, royalty and license, and research revenue from commercial partners of \$7,197,000 (31 December 2022: \$1,086,000), and interest income on cash invested in term deposits of \$828,000 (31 December 2022: \$521,000). Revenue included a nonrecurring \$6,553,000 from the Mundipharma commercial settlement. Excluding the Mundipharma settlement, half-year adjusted revenue was \$1,472,000, an 8% decrease on prior corresponding period revenues, with lower product sales in the current period.

Research and product development expenses include the costs of Starpharma's internal DEP® drug delivery programs, including DEP® docetaxel, DEP® cabazitaxel, DEP® irinotecan, DEP® ADCs and DEP® radiotheranostics as well as the post-market clinical study of Viraleze™. A contra research and product development expense of \$3,091,000 (31 December 2022: \$4,306,000) has been recorded for eligible research and development activities under the Australian Government's R&D Tax Incentive program.

Commercial and regulatory operating expense includes expenditure related to commercialisation of both VivaGel® / Viraleze™ and DEP® portfolios, including business development, marketing, regulatory, supply chain and quality assurance activities.

Corporate, administration and finance expense includes corporate costs, gains/losses on foreign currency held, and interest expense on borrowings.

Balance sheet

At 31 December 2023 the Group's cash position was \$32,131,000 (June 2023: \$35,180,000). Trade and other receivables of \$4,689,000 (June 2023: \$9,169,000) primarily comprises of \$3,091,000 (30 June 2023: \$7,244,000) of eligible expenditure reimbursable under the Australian Government's R&D tax incentive scheme. Trade and other payables of \$4,986,000 (June 2023: \$7,667,000) have decreased primarily due to lower accruals associated with expenditure on research programs.

Statement of cash flows

Net operating cash inflows for the half-year were \$2,098,000 (31 December 2022: \$5,079,000 outflow) and include the receipt of a \$7,244,000 R&D tax incentive and the \$6,553,000 Mundipharma commercial settlement. Net cash outflows from financing activities of \$5,143,000 (31 December 2022: \$340,000) include the \$4,000,000 repayment of the Invest Victoria R&D cash flow loan with Treasury Corporation of Victoria (TCV) in October 2023.

Earnings per share

	31 December 2023 Cents	31 December 2022 Cents
Basic / diluted loss per share	(0.25)	(2.03)

Matters subsequent to the end of the financial half-year

On 19 February 2024, Starpharma announced the completion of the formal dispute process with the US Food and Drug Administration (FDA) in relation to VivaGel® BV. The FDA maintained its position that they require additional clinical efficacy data to be generated for the regulatory approval of VivaGel® BV for bacterial vaginosis (BV) in the US. Starpharma is not planning to pursue additional clinical studies for VivaGel® BV on its own at this time. Starpharma remains committed to leveraging the VivaGel® BV development program and will work to maximise the commercial potential for VivaGel® BV in the more than 45 markets where it is already approved. The decision by the FDA does not alter the approval status in the countries where VivaGel® BV is already registered. As a result of the recent FDA decision, and in the absence of additional clinical data and a US FDA approval, proceeds under the US licensed agreement with ITF Pharma (now "EDW Pharma") will not occur.

No other matters or circumstances have arisen since 31 December 2023 that have significantly affected, or may significantly affect:

- (a) the consolidated entity's operations in future financial years, or
- (b) the results of the operations in future financial years, or
- (c) the consolidated entity's state of affairs in future financial years.

Rounding of amounts

The Company is of a kind referred to in ASIC Corporations (Rounding Financial/Directors' Reports) Instrument 2016/191, issued by the Australian Securities and Investments Commission, relating to the "rounding off" of amounts in the directors' report and financial report. Amounts in the directors' report and interim financial report have been rounded off to the nearest thousand dollars in accordance with that Instrument.

Auditor's independence declaration

A copy of the auditor's independence declaration, as required under section 307C of the *Corporations Act 2001* is set out on page 6.

This report is made in accordance with a resolution of the Directors.



Rob Thomas AO
Chairman
Melbourne, 28 February 2024

Auditor's Independence Declaration



Auditor's Independence Declaration

As lead auditor for the review of Starpharma Holdings Limited for the half-year ended 31 December 2023, I declare that to the best of my knowledge and belief, there have been:

- (a) no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- (b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Starpharma Holdings Limited and the entities it controlled during the period.

A handwritten signature in black ink that reads 'Brad Peake'.

Brad Peake
Partner
PricewaterhouseCoopers

Melbourne
28 February 2024

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Interim Financial Report

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

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This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2023 and any public announcements made by Starpharma Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

Consolidated Statement of Comprehensive Income

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

	Notes	31 December 2023 \$'000	31 December 2022 \$'000
Revenue	4	8,025	1,607
Cost of goods sold		(201)	(542)
Other income	4	-	104
Research and product development expense (net of R&D tax incentive)		(5,263)	(5,599)
Commercial and regulatory operating expense		(1,516)	(1,829)
Corporate, administration and finance expense		(2,079)	(2,018)
Loss before income tax		(1,034)	(8,277)
Income tax expense		-	-
Loss from continuing operations attributable to equity holders of the company		(1,034)	(8,277)
Other comprehensive income (loss)		-	-
Total comprehensive income (loss) for the period		(1,034)	(8,277)
Loss per share for loss from continuing operations attributable to the ordinary equity holders of the company		Cents	Cents
Basic loss per share	11	(0.25)	(2.03)
Diluted loss per share	11	(0.25)	(2.03)

The above consolidated statement of comprehensive income should be read in conjunction with the accompanying notes.

Consolidated Balance Sheet

AS AT 31 DECEMBER 2023

	Notes	31 December 2023 \$'000	30 June 2023 \$'000
Current assets			
Cash and cash equivalents		32,131	35,180
Trade and other receivables	6	4,689	9,169
Inventories		2,707	2,773
Total current assets		39,527	47,122
Non-current assets			
Property, plant and equipment		1,426	1,584
Right-of-use assets		2,979	3,380
Total non-current assets		4,405	4,964
Total assets		43,932	52,086
Current liabilities			
Trade and other payables		4,986	7,667
Borrowings	7	-	4,778
Lease liabilities		770	744
Provision for employee benefits		1,294	1,281
Deferred income		4	3
Total current liabilities		7,054	14,473
Non-current liabilities			
Lease liabilities		2,359	2,750
Provision for employee benefits		68	48
Total non-current liabilities		2,427	2,798
Total liabilities		9,481	17,271
Net assets		34,451	34,815
Equity			
Contributed capital	8	240,715	240,715
Reserves		28,968	28,299
Accumulated losses		(235,232)	(234,199)
Total equity		34,451	34,815

The above consolidated balance sheet should be read in conjunction with the accompanying notes.

Consolidated Statement of Changes in Equity

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

	Notes	Contributed equity \$'000	Reserves \$'000	Accumulated losses \$'000	Total equity \$'000
Balance at 1 July 2023		240,715	28,299	(234,199)	34,815
Loss for the period		-	-	(1,034)	(1,034)
Other comprehensive income (loss)		-	-	-	-
Total comprehensive income (loss) for the half-year		-	-	(1,034)	(1,034)
Transactions with owners, recorded directly in equity					
Employee performance rights plan		-	670	-	670
Total transactions with owners		-	670	-	670
Balance at 31 December 2023		240,715	28,968	(235,232)	34,451

	Notes	Contributed equity \$'000	Reserves \$'000	Accumulated losses \$'000	Total equity \$'000
Balance at 1 July 2022		240,669	26,285	(218,561)	48,393
Loss for the period		-	-	(8,277)	(8,277)
Other comprehensive income (loss)		-	-	-	-
Total comprehensive income (loss) for the half-year		-	-	(8,277)	(8,277)
Transactions with owners, recorded directly in equity					
Employee performance rights plan		-	905	-	905
Total transactions with owners		-	905	-	905
Balance at 31 December 2022		240,669	27,190	(226,839)	41,020

Consolidated Statement of Cash Flows

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

	Notes	31 December 2023 \$'000	31 December 2022 \$'000
Cash flow from operating activities			
Receipts from trade and other debtors (inclusive of GST)		7,001	1,574
Grant income and R&D tax incentives (inclusive of GST)		7,244	7,146
Payments to suppliers and employees (inclusive of GST)		(12,875)	(14,124)
Interest received		889	448
Interest paid		(161)	(123)
Net cash inflows/(outflows) from operating activities		2,098	(5,079)
Cash flow from investing activities			
Payments for property, plant and equipment		(9)	(464)
Proceeds from sale of available-for-sale financial assets		-	1
Net cash outflows from investing activities		(9)	(463)
Cash flow from financing activities			
Repayment of borrowings	7	(4,778)	-
Lease repayments		(365)	(340)
Net cash outflows from financing activities		(5,143)	(340)
Net increase (decrease) in cash and cash equivalents held		(3,054)	(5,882)
Cash and cash equivalents at the beginning of the half-year		35,180	49,918
Effects of exchange rate changes on cash and cash equivalents		5	2
Cash and cash equivalents at the end of the half-year		32,131	44,038

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

Notes to the Consolidated Financial Statements

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

1. Summary of Significant Accounting Policies

(a) Basis of preparation

This consolidated interim financial report for the half-year reporting period ended 31 December 2023 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2023 and any public announcements made by Starpharma Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

The accounting policies adopted are consistent with those of the previous financial year and the corresponding interim reporting period.

The Australian Accounting Standards and Interpretations that have recently been issued or amended but are not yet mandatory have not been adopted early by the Group for the period ended 31 December 2023.

The financial statements have been prepared on a going concern basis.

2. Critical Accounting Estimates and Judgements

The preparation of financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies.

Certain research and product development activities are eligible under an Australian Government tax incentive for eligible expenditure. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive program. For the half-year to 31 December 2023, the Group has recorded a contra research and development expense of \$3,091,000 (December 2022: \$4,306,000).

3. Segment Information

The Group has determined that on the basis of internal reporting and monitoring to the Chief Executive Officer, who is the chief operating decision maker, the Group operates in one business segment, being the discovery, development and commercialisation of dendrimers for pharmaceutical, life science and other applications.

4. Revenue and Other Income

	31 December 2023 \$'000	31 December 2022 \$'000
Revenue and other income from continuing operations		
Revenue from contracts with customers	7,197	1,086
Interest revenue	828	521
Total revenue from continuing operations	8,025	1,607
Other income	-	104
Total revenue and other income from continuing operations	8,025	1,711

Total revenue from contracts with customers was \$7,197,000 (December 2022: \$1,086,000) and included a nonrecurring \$6,553,000 from the commercial settlement and termination of the VivaGel® BV license and supply agreement with Mundipharma in August 2023. Revenue from contracts with customers also includes product sales, royalty, and research revenue from commercial partners.

Notes to the Consolidated Financial Statements

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

5. Expenses

	31 December 2023 \$'000	31 December 2022 \$'000
Loss from continuing operations before income tax expense includes the following items:		
R&D tax incentive (contra expense) ¹	(3,091)	(4,306)
Employee benefits expenses (including share-based payments)	4,529	5,020
Depreciation of property, plant and equipment	168	212
Depreciation of right-of-use assets	401	401

¹Included within the research and product development expense line item in the consolidated statement of comprehensive income.

6. Current Assets – Trade and Other Receivables

Trade and other receivables of \$4,689,000 (June 2023: \$9,169,000) primarily comprises of \$3,091,000 (30 June 2023: \$7,244,000) of eligible expenditure reimbursable under the Australian Government's R&D tax incentive scheme.

7. Current Liabilities – Borrowings

Borrowings are \$Nil (30 June 2023: \$4,778,000). The \$4,000,000 Invest Victoria R&D cash flow loan with Treasury Corporation of Victoria (TCV) was repaid in October 2023, and the final insurance premium loan instalment was repaid in December 2023.

8. Contributed Equity

(a) Share capital

	December 2023 Shares	June 2023 Shares	December 2023 \$'000	June 2023 \$'000
Share capital				
Ordinary shares – fully paid	411,797,758	410,493,077	240,715	240,715

(b) Ordinary shares

As at 31 December 2023 there were 411,797,758 issued ordinary shares. Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the Company in proportion to the number of and amounts paid on the shares held. Ordinary shares have no par value and the company does not have authorised capital.

(c) Employee Share Plan (\$1,000 Plan)

Shares issued under the Starpharma Holdings Limited Employee Share Plan (\$1,000 Plan) to eligible staff are granted for no consideration and are escrowed for 3 years while participants are employed by the Company. An allocation of 242,862 shares was issued to eligible staff on 31 January 2024, subsequent to the reporting date.

(d) Employee Performance Rights Plan

At 31 December 2023, there are 23,059,952 (30 June 2023: 17,548,885) performance rights on issue, of which 9,674,502 have vested and are exercisable at the reporting date and 13,385,450 unvested. There were 8,335,227 performance rights issued during the financial half-year, 1,304,681 performance rights converted into shares on the exercise of vested performance rights and 1,449,279 rights lapsing during the period.

Notes to the Consolidated Financial Statements

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

9. Contingencies

Upon receipt of cash proceeds under the VivaGel® BV product licence to ITF Pharma (now "EDW Pharma") in the US, Starpharma is required to pay a small proportion of its receipts to an investment bank which advised on the competitive licence process, up to a maximum of US\$1.35 million over the life of the licence. Following the completion of the US FDA dispute resolution process in February 2024 (see Note 10), Starpharma does not currently expect to receive license proceeds from ITF. The Group has no contingent liabilities in favour of the investment bank as at the date of this report.

There have been no other changes in contingent liabilities or contingent assets since the last annual reporting date, 30 June 2023.

10. Events occurring after the balance sheet date

On 19 February 2024, Starpharma announced the completion of the formal dispute process with the US Food and Drug Administration (FDA) in relation to VivaGel® BV. The FDA maintained its position that they require additional clinical efficacy data to be generated for the regulatory approval of VivaGel® BV for bacterial vaginosis (BV) in the US. Starpharma is not planning to pursue additional clinical studies for VivaGel® BV on its own at this time. Starpharma remains committed to leveraging the VivaGel® BV development program and will work to maximise the commercial potential for VivaGel® BV in the more than 45 markets where it is already approved. The decision by the FDA does not alter the approval status in the countries where VivaGel® BV is already registered. As a result of the recent FDA decision, and in the absence of additional clinical data and a US FDA approval, proceeds under the US license agreement with ITF Pharma (now "EDW Pharma") will not occur.

There are no other significant events occurring since 31 December 2023 that have significantly affected or may significantly affect the operations of the Group, the results of those operations, or the state of the Group.

11. Earnings per share

	31 December 2023	31 December 2022
Basic earnings/(loss) per share / Diluted earnings/(loss) per share		
Total earnings/(loss) per share attributable to the ordinary equity holders of the Company (cents)	(0.25)	(2.03)
Reconciliations of earnings/(loss) used in calculating earnings per share		
Profit/(loss) attributable to the ordinary equity holders of the Company used in calculating basic earnings/(loss) per share (\$'000):	(1,034)	(8,277)
Weighted average number of ordinary shares used as the denominator in calculating basic earnings/(loss) per share	410,864,776	408,588,694

The performance rights on issue at reporting date are not included in the determination of basic earnings per share. The rights are also not included in the determination of diluted earnings per share. They are not considered dilutive as their conversion would not increase loss per share from continuing operations.

Directors' Declaration

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

In the directors' opinion:

- (a) the financial statements and notes set out on pages 7 to 14 are in accordance with the *Corporations Act 2001*, including:
 - (i) complying with *Accounting Standards*, the *Corporations Regulations 2001* and other mandatory professional reporting requirements; and
 - (ii) giving a true and fair view of the consolidated entity's financial position as at 31 December 2023 and of its performance for the half-year ended on that date; and
- (b) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the directors.



Robert B Thomas AO
Chairman

Melbourne,
28 February 2024

Independent Auditor's Review Report

TO THE MEMBERS OF STARPHARMA HOLDINGS LIMITED



Independent auditor's review report to the members of Starpharma Holdings Limited

Report on the half-year financial report

Conclusion

We have reviewed the half-year financial report of Starpharma Holdings Limited (the Company) and the entities it controlled during the half-year (together the Group), which comprises the consolidated balance sheet as at 31 December 2023, the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, material accounting policy information and explanatory notes and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Starpharma Holdings Limited does not comply with the *Corporations Act 2001* including:

1. giving a true and fair view of the Group's financial position as at 31 December 2023 and of its performance for the half-year ended on that date
2. complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity* (ASRE 2410). Our responsibilities are further described in the *Auditor's responsibilities for the review of the half-year financial report* section of our report.

We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional & Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to the audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Responsibilities of the directors for the half-year financial report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement whether due to fraud or error.

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Auditor's responsibilities for the review of the half-year financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2023 and of its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

PricewaterhouseCoopers

PricewaterhouseCoopers

Brad Peake

Brad Peake
Partner

Melbourne
28 February 2024