Starpharma Holdings Limited

ABN 20 078 532 180

Appendix 4D
Half-year ended 31 December 2022

Lodged with the ASX under Listing Rule 4.2A
Previous corresponding period (pcp): Half-year ended 31 December 2021

Results for announcement to the market

				$'000
Revenue from continuing operations *(Appendix 4D item 2.1)*	Down	16%	to	**$1,607**
Loss from continuing operations after tax attributable to members *(Appendix 4D item 2.2)*	Down *(reduced loss)*	2%	to	**$8,277**
Loss for the period attributable to members *(Appendix 4D item 2.3)*	Down *(reduced loss)*	2%	to	**$8,277**

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 for the half-year is lower by 16% on the prior corresponding period with lower VIRALEZE™ product sales in the current period. The prior reporting period included sales on the commercial launch of VIRALEZE™ in Vietnam in December 2021. Revenue includes product sales, royalty, and research revenue from commercial partners of $1,086,000 (December 2021: $1,819,000), and interest income on cash invested in term deposits of $521,000 (December 2021: $94,000).

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

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

The consolidated loss after tax for the half-year to 31 December 2022 was $8,277,000 (December 2021: $8,449,000). The net loss is lower than the prior corresponding period, predominately due to a reduction in research and product development expenses (net of R&D tax incentive) 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. A contra research and product development expense of $4,306,000 (December 2021: $3,668,000) 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, as well as gains/losses on foreign currency held.

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 2022 is $0.10 (December 2021: $0.14).

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 2022 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 2022 half-year financial statements.

This information should be read in conjunction with the 30 June 2022 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*.

starpharma

ASX Announcement

Starpharma Interim Report and Half-Year Financial Results

Melbourne, Australia; 28 February 2023: Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) today releases its interim report and half-year financial results for the period ended 31 December 2022 (H1 FY23).

Key Financials

- Strong cash position with $44.0M as at 31 December 2022
- Loss of $8.3M for the half-year (H1 FY22: $8.4M)
- Revenue of $1.6M, down $0.3M on the prior corresponding period (H1 FY22: $1.9M)
- Receipt of a $7.1M Research and Development (R&D) tax incentive in December 2022

Operational Highlights

- Positive preliminary AZD0466 clinical data presented by Starpharma's partner, AstraZeneca, showed that it was well tolerated in leukemia patients, with no dose-limiting toxicities reported, in an ongoing Phase 1/2 trial
- Expansion of DEP® Antibody Drug Conjugates (ADCs) program with MSD, alongside the progression of other partnered DEP® programs, including with AstraZeneca, Genentech and Chase Sun
- Internal clinical-stage DEP® assets, DEP® cabazitaxel, DEP® docetaxel and DEP® irinotecan, advanced, with multiple arms approaching completion of recruitment
- Preclinical pipeline, which includes DEP® ADCs and DEP® radiotheranostics, continued to progress
- Ongoing commercialisation of VIRALEZE™ including product launch in Hong Kong and Macau, as well as registration in Indonesia

Dr Jackie Fairley, Starpharma CEO said: "We are pleased with the progress made during the half-year. Starpharma signed a second DEP® research agreement with MSD in the area of ADCs; and AstraZeneca reported positive preliminary AZD0466 clinical data from its ongoing Phase 1/2 trial in patients with leukemia. These results are significant in the context of the AZD0466 clinical trial and reinforce the potential of Starpharma's DEP® platform to deliver benefits to patients.

"Starpharma's internally developed DEP® oncology products – DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan – also advanced, with patient recruitment for the monotherapy arms of the DEP® docetaxel and DEP® cabazitaxel Phase 2 trials now in the final stages. In addition, Starpharma's preclinical pipeline, which includes DEP® ADCs and DEP® radiotheranostics continued to progress. Our internal DEP® assets continue to attract interest from potential licensing and collaboration partners.

"Starpharma also continues to expand the availability of VIRALEZE™ nasal spray, which is now registered in more than 30 countries; and was launched in Hong Kong and Macau during the half-year. VivaGel® BV is now registered in more than 45 countries, with new product launches planned in Asia and the Middle East in 2023."

Summary of Activities

DEP® Drug Delivery Platform

During the period, Starpharma expanded its DEP® Antibody Drug Conjugates (ADCs) program with MSD (Merck Sharp & Dohme LLC), signing a second research agreement focussed on the design and synthesis of DEP® ADCs.

In December 2022, Starpharma's partner, AstraZeneca, presented positive preliminary AZD0466 clinical data from the ongoing Phase 1/2 trial in patients with advanced relapsed/refractory leukemia. The clinical data reported showed that AZD0466 was well tolerated, with no dose-limiting toxicities (DLTs) reported and no discontinuations due to treatment-related adverse events. These results were presented by AstraZeneca at the American Society of Hematology Annual Meeting in December 2022. Patient enrolment continues for this Phase 1/2 trial at 18 sites across Europe, the United States, Asia, and Australia, with additional sites planned.

AstraZeneca's second Phase 1/2 clinical trial of AZD0466 in patients with non-Hodgkin lymphoma continued to enrol patients, with the expansion of trial sites across the United States, Asia, and Italy. Additional sites are planned in other parts of Europe, North America and Australia.

Starpharma's partnered DEP® programs with AstraZeneca, MSD, Genentech, and Chase Sun continued to progress. These partnerships span a number of therapeutic areas, including oncology and anti-infectives, and include DEP® ADCs.

Starpharma's internal clinical DEP® programs for DEP® cabazitaxel, DEP® docetaxel and DEP® irinotecan were advanced, with recruitment for the monotherapy arms of these studies in the final stages.

The DEP® cabazitaxel Phase 2 trial has enrolled 76 patients, with patient recruitment in the final stages and data analysis and biostatistics activities underway. During this period, promising additional interim clinical data were reported from the cohort of late-stage prostate cancer patients in Starpharma's Phase 2 DEP® cabazitaxel trial[1]. This cohort comprised 25 heavily pre-treated patients with metastatic castration-resistant prostate cancer across trial sites in the UK and Australia. The interim results reported showed a number of key advantages compared to published data for conventional cabazitaxel including longer progression-free survival (PFS) and improved rates of prostate-specific antigen[2] (PSA) reductions of 50% or more from baseline, as well as a lower incidence of key side effects. These benefits were observed despite this DEP® cabazitaxel patient cohort being significantly more heavily pre-treated compared with the populations reported in the published data for standard cabazitaxel clinical trials[3]. These interim results for the prostate cancer patient cohort were presented at the European Society of Medical Oncology (ESMO) Congress in September 2022.

The DEP® docetaxel clinical program continued to progress, with 76 patients enrolled across the monotherapy and combination arms. Recruitment for the monotherapy arm is in the final stages, with the final patient in screening. Encouraging efficacy signals have been observed, including in heavily pre-treated patients with lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers.

The DEP® irinotecan Phase 2 clinical trial continued to progress, with 89 patients enrolled across the monotherapy and combination arms. Final recruitment for the monotherapy arm is focused on platinum resistant ovarian cancer, where particularly encouraging responses have been observed.

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[1] Jones RH, et al. Efficacy and safety of dendrimer-enhanced (DEP) cabazitaxel (CTX-SPL9111) in men with metastatic castration-resistant prostate cancer (mCRPC) in a phase I/II trial. *Annals of Oncology*, 2022;33(Suppl 7):S1186-S1187. https://doi.org/10.1016/j.annonc.2022.07.1889

[2] Progression-free survival (PFS) is the length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not progress. For this study, PFS was defined as the time from start of treatment to the first of PSA or radiologic progression.

[3] Eisenberger M, et al. *J Clin Oncol*, 2017;35(28):3198-206

Encouraging efficacy signals with DEP® irinotecan have also been observed in heavily pre-treated patients with multiple other tumour types, including colorectal, breast, pancreatic, lung, and oesophageal cancers.

During this half-year, Starpharma also commenced patient recruitment for the combination arm utilising DEP® irinotecan plus fluorouracil (5-FU) and leucovorin. The combination of standard irinotecan with 5-FU and leucovorin is a commonly used treatment regimen in patients with colorectal cancer, known as "FOLFIRI". Patient enrolment continues for this combination arm, as well as for the DEP® docetaxel plus gemcitabine combination arm.

Commercial discussions with potential licensing partners continue for Starpharma's internal DEP® assets: DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan.

In addition to advancing its clinical stage programs, the Company continued to progress a number of preclinical programs, including in the areas of DEP® radiotheranostics and DEP® ADCs.

Marketed Products

During the period, VIRALEZE™ was launched in Hong Kong and Macau through a network of retail stores, online and other channels, including Mannings and A.S. Watson Group's PARKnSHOP. The launch followed the signing of a sales and distribution agreement with Hengan. Under this agreement, Starpharma supplies VIRALEZE™, with Hengan exclusively responsible for sales, final packing, distribution, and marketing in Hong Kong and Macau.

Marketing authorisation for VIRALEZE™ was recently achieved in Indonesia and discussions continue with potential distribution partners for this and other markets. In parallel, VIRALEZE™ sales and marketing activities continued elsewhere where Starpharma has distribution arrangements in place.

VIRALEZE™ is now registered in more than 30 countries[4] across various regions. In Australia, the review by the Therapeutic Goods Administration (TGA) for the SPL7013 nasal spray as a medical device is ongoing. Starpharma continues to focus on registration and commercialisation of the product in new markets, with a focus on commercially attractive markets with rapid regulatory pathways.

During the period, Starpharma commenced patient recruitment in the UK for a post-market clinical study of VIRALEZE™ in patients recently diagnosed with COVID-19. This study is intended to support ongoing regulatory, marketing, and commercial activities in multiple markets.

In vivo studies conducted at Scripps Research showed protection against infection with the SARS-CoV-2 Omicron variant in a viral challenge model. VIRALEZE™ administered nasally reduced viral load by >99.9% in the lungs and trachea of animals challenged with SARS-CoV-2 (vs. saline control). In addition, data from these studies presented at the international Respi DART meeting in December 2022 showed that VIRALEZE™ outperformed a number of marketed comparator nasal sprays in reducing SARS-CoV-2 Omicron viral load and infectious virus in the nasal cavity, lungs and trachea of animals challenged with virus following treatment with the products. These *in vivo* results against Omicron are consistent with previous *in vitro* findings showing VIRALEZE™ has the ability to trap and block multiple SARS-CoV-2 variants, including the Omicron and Delta variants.

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 45 countries.

Starpharma continues to support marketing and regulatory activities for its VivaGel® BV partners, Mundipharma and Aspen. Registration was achieved in Kuwait during the period and new product launches are planned in countries in the Middle East and Asia.

[4] VIRALEZE™ is not approved for use or supply in Australia.

Fleurstat BVgel marketing activities continued in Australia and New Zealand by Aspen, including digital marketing campaigns, promotional items in women's health and lifestyle print media, as well as shopping centre advertising.

Starpharma's VivaGel® Condom partner Okamoto continues marketing in Japan as well as regulatory activities in a number of other Asian markets.

Starpharma continues to review its existing product distribution arrangements to seek to maximise revenue opportunities in key markets.

Other

Dr Russell Basser was appointed as a non-executive Director from 20 February 2023. Dr Basser is a medical oncologist and former corporate executive who brings over 30 years of international medical and biopharmaceutical experience to Starpharma's Board.

Financial Summary

At 31 December 2022, Starpharma's cash position was $44.0M. The loss for the period was $8.3M (H1 FY22: $8.4M). Research and product development expense reflects the Company's investment in internal DEP® drug delivery programs, including DEP® cabazitaxel, DEP® docetaxel, DEP® irinotecan, DEP® ADCs and DEP® radiotheranostics. Revenue of $1.6M for the half-year was lower by $0.3M on the prior corresponding period (H1 FY22: $1.9M), with lower VIRALEZE™ product sales in H1 FY23 compared with H1 FY22, which had included the commercial launch of VIRALEZE™ in Vietnam. In December 2022, Starpharma received a $7.1M R&D tax incentive refund.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a biopharmaceutical company, focussed on the development of pharmaceutical and medical products for unmet patient needs, including in the areas of oncology and infectious diseases.

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 antiviral nasal spray, VIRALEZE™, is now registered in more than 30 countries*, including in Europe, in the UK, and in Southeast Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel® BV, for treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 45 countries, including in the UK, in Europe, in Southeast Asia, South Africa, Australia and New Zealand.

* Note: VIRALEZE™ is not approved for use or supply in Australia.

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Disclosure
This ASX Announcement was authorised for release by the Board of Directors.

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 – 31 December 2022

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Contents Page

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 2022.

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
Z Peach (resigned 29 November 2022)
J K Fairley (Chief Executive Officer)
J R Davies
D J McIntyre
R L Basser (appointed 20 February 2023)

Principal activities

The principal activities of the Group consist of research, development and commercialisation of dendrimer products for pharmaceutical, life-science and other applications. Activities within the Group are directed towards the development of precisely defined nano-scale materials, including the development of SPL7013 (astodrimer 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.

Business strategy, future developments and prospects

The Company aims to create value for shareholders through the clinical development and commercial exploitation 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 and broaden its product pipeline, including internal and partnered DEP® programs and to advance commercial opportunities 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, and the risks involved in advancing the product to the next value inflection point or milestone.

Starpharma's strategy remains consistent with previous years. Starpharma has extensive expertise, a strong intellectual property portfolio, a deep product portfolio, a culture and ability to innovate and develop its technology platform to commercial opportunities, proven risk management practices, and a strong cash position. The Company will continue using its cash resources and revenues to invest in selected research and development activities to achieve its objectives.

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. The novel DEP® platform has shown advantages across a wide range of drug classes and has the potential to be utilised in small molecule drugs, peptides and proteins, and in the development of unique DEP® based Antibody Drug Conjugates (ADCs) and radiotheranostics.

Key activities until the date of this report include:

- Starpharma expanded its DEP® ADC program with MSD (Merck Sharp & Dohme LLC), signing a second research agreement focussed on the design and synthesis of DEP® ADCs.
- Additional interim results were reported from the cohort of late-stage prostate cancer patients in Starpharma's Phase 2 DEP® cabazitaxel clinical trial. This cohort comprised 25 heavily pre-treated patients with metastatic castration-resistant prostate cancer across trial sites in the UK and Australia. The interim results showed a number of key advantages compared to published data for conventional cabazitaxel, including longer progression-free survival and a lower incidence of key side effects. These benefits were observed despite this DEP® cabazitaxel patient cohort being significantly more heavily pre-treated compared with the populations reported in the published data for standard cabazitaxel clinical trials. These interim results were presented at the European Society of Medical Oncology (ESMO) Congress in September 2022. Patient recruitment for this trial is in the final stages.
- Starpharma's partner, AstraZeneca, presented preliminary AZD0466 clinical trial results from the ongoing Phase 1/2 trial in patients with advanced relapsed/refractory leukemia. The clinical data reported showed that AZD0466 was well tolerated, with no dose-limiting toxicities (DLTs) reported and no discontinuations due to treatment-related adverse events. These results were presented by AstraZeneca at the American Society of Hematology Annual Meeting in December 2022. Patient enrolment continues for this Phase 1/2 trial at sites across Europe, the United States, Asia and Australia.
- AstraZeneca's second Phase 1/2 clinical trial of AZD0466 in patients with non-Hodgkin lymphoma continued to enrol patients, with the expansion of trial sites across the United States, Asia and Italy.

- Starpharma's DEP® docetaxel clinical program continued to progress, with recruitment for the monotherapy arm of the study in the final stages. Patient recruitment continues for the DEP® docetaxel plus gemcitabine combination arm.
- The DEP® irinotecan Phase 2 clinical trial continued to progress, with patient recruitment for the monotherapy arm in the final stages. In parallel, Starpharma commenced patient recruitment for a combination arm involving DEP® irinotecan plus fluorouracil (5-FU) and leucovorin.
- Commercial discussions with potential licensing partners continue for Starpharma's internal DEP® assets: DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan.
- Starpharma's partnered DEP® programs with AstraZeneca, MSD, Genentech and Chase Sun continued to progress. These partnerships span a number of therapeutic areas, including oncology and anti-infectives, and include DEP® ADCs.
- In addition to advancing Starpharma's clinical stage programs, Starpharma continued to progress a number of preclinical programs, including in the areas of DEP® radiotheranostics and DEP® ADCs.

VIRALEZE™

Starpharma's topical antiviral nasal spray, VIRALEZE™, is now registered in more than 30 countries (VIRALEZE™ is not approved for use or supply in Australia). The antiviral agent in VIRALEZE™, referred to as SPL7013, has been shown in laboratory studies to trap and block multiple respiratory viruses including influenza, respiratory syncytial virus (RSV) and multiple variants of coronavirus SARS-CoV-2.

Key activities until the date of this report include:

- A study conducted at Scripps Research showed protection against infection with the SARS-CoV-2 Omicron variant in a viral challenge model. VIRALEZE™ administered nasally reduced viral load by >99.9% in the lungs and trachea of animals challenged with SARS-CoV-2 (vs. saline control). These *in vivo* study results are consistent with previous *in vitro* findings showing VIRALEZE™ has the ability to trap and block multiple SARS-CoV-2 variants, including the Omicron, Delta, Alpha, Beta and Gamma variants.
- Launch of VIRALEZE™ in Hong Kong and Macau through a network of retail stores, online and other channels following the signing of a sales and distribution agreement with Hengan Pharmacare Company Limited. Under the agreement, Starpharma supplies VIRALEZE™, with Hengan exclusively responsible for sales, final packing, distribution, and marketing in Hong Kong and Macau.
- Marketing authorisation for VIRALEZE™ was achieved in Indonesia and discussions continue with potential distribution partners for this and other markets.
- VIRALEZE™ sales and marketing activities continued elsewhere where Starpharma has distribution arrangements in place.
- In Australia, the review by the Therapeutic Goods Administration (TGA) for the SPL7013 nasal spray as a medical device is ongoing.
- Starpharma commenced patient recruitment in the UK for a post-market clinical study of VIRALEZE™ in patients with COVID-19. This study is intended to support ongoing marketing and commercial activities in multiple markets, as well as to generate additional clinical safety and efficacy data relevant to future applicable European medical device regulations.

VivaGel® BV

Starpharma's novel, non-antibiotic vaginal gel, VivaGel® BV, for treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 45 countries.

Key activities until the date of this report include:

- Starpharma continues to support marketing and regulatory activities for its VivaGel® BV partners, Mundipharma and Aspen. Registration was achieved in Kuwait during the period.
- Fleurstat BVgel marketing activities continued in Australia and New Zealand by Aspen, including digital marketing campaigns, promotional items in women's health & lifestyle print media, as well as shopping centre advertising.
- In the US, a formal dispute resolution process is ongoing with the FDA for VivaGel® BV. As part of this process, Starpharma has had extensive external advice, met with FDA multiple times and made a number of submissions of data and analyses to FDA. Starpharma continues to work with its advisors as part of this ongoing dispute resolution process and we are planning a further submission in 2023.
- Starpharma's VivaGel® Condom partner Okamoto continues marketing in Japan as well as regulatory activities in a number of other Asian markets.

Other Activities

- The appointment of Dr Russell Basser as non-executive Director from 20 February 2023. Dr Basser is a medical oncologist and former corporate executive with over 30 years of international medical and biopharmaceutical experience.
- Ms Tracy Weimar was appointed as interim Company Secretary on 1 February 2023 as part of the transitional arrangements for Mr Nigel Baade's departure in March 2023.
- Receipt of a $7.1M research and development (R&D) tax incentive refund under the Australian Federal Government's R&D Tax Incentive scheme in December 2022.

Review of Financials

	Half-year ended 31 December	
Income statement	**2022 $'000**	2021 $'000
Revenue	**1,607**	1,913
Cost of goods sold	**(542)**	(916)
Other income	**104**	131
Research and product development expense (net of R&D tax incentive)	**(5,599)**	(6,251)
Commercial and regulatory operating expense	**(1,829)**	(1,613)
Corporate, administration and finance expense	**(2,018)**	(1,713)
Loss for the period	**(8,277)**	(8,449)

Income statement
For the half-year ended 31 December 2022 the consolidated loss after income tax was $8,277,000 (December 2021: $8,449,000).

Revenue for the half-year is lower by 16% on the prior corresponding period with lower VIRALEZE™ product sales in the current period. The prior reporting period included sales on the commercial launch of VIRALEZE™ in Vietnam in December 2021. Revenue includes product sales, royalty, and research revenue from commercial partners of $1,086,000 (December 2021: $1,819,000), and interest income on cash invested in term deposits of $521,000 (December 2021: $94,000).

Other income of $104,000 (December 2021: $131,000) primarily relates to proceeds received from an insurance claim. For the prior corresponding reporting period, other income included Medical Research Future Fund (MRFF) grant funding for the development of VIRALEZE™.

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. A contra research and product development expense of $4,306,000 (December 2021: $3,668,000) 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, as well as gains/losses on foreign currency held. The increase over the prior corresponding reporting period primarily reflects a foreign currency movement on foreign currencies held of $164,000 between the periods, with a higher gain in the prior corresponding period.

Balance sheet
At 31 December 2022 the Group's cash position was $44,038,000 (June 2022: $49,918,000). Trade and other receivables of $5,438,000 (June 2022: $7,916,000) primarily comprises of $3,918,000 (30 June 2022: $6,747,000) of eligible expenditure reimbursable under the Australian Government's R&D tax incentive scheme. Trade and other payables of $6,861,000 (June 2022: $7,731,000) have decreased primarily due to lower accruals associated with expenditure on research programs. Borrowings of $4,000,000 (30 June 2022: $4,000,000) represents the Invest Victoria R&D cash flow loan which provides low interest loans to support R&D expenditure. The Group's net cash position adjusted for borrowings is $40,038,000 as at 31 December 2022 (June 2022: $45,918,000).

Statement of cash flows
Net operating cash outflows for the half-year were $5,079,000 (December 2021: $11,243,000). In the prior corresponding reporting period, the R&D tax incentive was received after the 31 December 2021 reporting date. Net cash outflows from investing activities of $463,000 (December 2021: $193,000) reflects investment in new scientific equipment for Starpharma's laboratories.

Earnings per share

	Half-year ended 31 December	
	2022 Cents	2021 Cents
Basic / diluted loss per share	**(2.03)**	(2.08)

Matters subsequent to the end of the financial half-year

No matters or circumstances have arisen since 31 December 2022 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 2023

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 2022, 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.

Brad Peake
Partner
PricewaterhouseCoopers

Melbourne
28 February 2023

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Interim Financial Report

Contents

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 2022 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

	Notes	Half-year ended 31 December 2022 $'000	2021 $'000
Revenue	4	**1,607**	1,913
Cost of goods sold		**(542)**	(916)
Other income	4	**104**	131
Research and product development expense (net of R&D tax incentive)		**(5,599)**	(6,251)
Commercial and regulatory operating expense		**(1,829)**	(1,613)
Corporate, administration and finance expense		**(2,018)**	(1,713)
Loss before income tax		**(8,277)**	(8,449)
Income tax expense		**-**	-
Loss from continuing operations attributable to equity holders of the company		**(8,277)**	(8,449)
Other comprehensive income (loss)		**-**	-
Total comprehensive income (loss) for the period		**(8,277)**	(8,449)
Loss per share for loss from continuing operations attributable to the ordinary equity holders of the company		**Cents**	Cents
Basic loss per share	11	**(2.03)**	(2.08)
Diluted loss per share	11	**(2.03)**	(2.08)

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

Consolidated balance sheet

	Notes	31 December 2022 $'000	30 June 2022 $'000
Current assets			
Cash and cash equivalents		**44,038**	49,918
Trade and other receivables	6	**5,438**	7,916
Inventories		**2,817**	2,824
Total current assets		**52,293**	60,658
Non-current assets			
Property, plant and equipment		**1,572**	1,336
Right-of-use assets		**3,781**	4,181
Total non-current assets		**5,353**	5,517
Total assets		**57,646**	66,175
Current liabilities			
Trade and other payables		**6,861**	7,731
Borrowings	7	**4,000**	-
Lease liabilities		**719**	695
Provision for employee benefits		**1,385**	1,339
Deferred income		**462**	466
Total current liabilities		**13,427**	10,231
Non-current liabilities			
Borrowings	7	**-**	4,000
Lease liabilities		**3,130**	3,494
Provision for employee benefits		**69**	57
Total non-current liabilities		**3,199**	7,551
Total liabilities		**16,626**	17,782
Net assets		**41,020**	48,393
Equity			
Contributed capital	8	**240,669**	240,669
Reserves		**27,190**	26,285
Accumulated losses		**(226,839)**	(218,561)
Total equity		**41,020**	48,393

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

Consolidated statement of changes in equity

		Half-year ended 31 December 2022			
	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

		Half-year ended 31 December 2021			
	Notes	Contributed equity $'000	Reserves $'000	Accumulated losses $'000	Total equity $'000
Balance at 1 July 2021		240,630	24,077	(202,407)	62,300
Loss for the period		-	-	(8,449)	(8,449)
Other comprehensive income (loss)		-	-	-	-
Total comprehensive income (loss) for the half-year		-	-	(8,449)	(8,449)
Transactions with owners, recorded directly in equity					
Employee performance rights plan		-	1,229	-	1,229
Total transactions with owners		-	1,229	-	1,229
Balance at 31 December 2021		240,630	25,306	(210,856)	55,080

Consolidated statement of cash flows

	Notes	Half-year ended 31 December 2022 $'000	2021 $'000
Cash flow from operating activities			
Receipts from trade and other debtors (inclusive of GST)		**1,574**	1,729
Grant income and R&D tax incentives (inclusive of GST)		**7,146**	315
Payments to suppliers and employees (inclusive of GST)		**(14,124)**	(13,357)
Interest received		**448**	94
Interest paid		**(123)**	(24)
Net cash outflows from operating activities		**(5,079)**	(11,243)
Cash flow from investing activities			
Payments for property, plant and equipment		**(464)**	(193)
Proceeds from sale of available-for-sale financial assets		**1**	-
Net cash outflows from investing activities		**(463)**	(193)
Cash flow from financing activities			
Proceeds from borrowings	7	**-**	2,400
Lease repayments		**(340)**	(370)
Net cash (outflows)/inflows from financing activities		**(340)**	2,030
Net increase (decrease) in cash and cash equivalents held		**(5,882)**	(9,406)
Cash and cash equivalents at the beginning of the half-year		**49,918**	60,500
Effects of exchange rate changes on cash and cash equivalents		**2**	160
Cash and cash equivalents at the end of the half-year		**44,038**	51,254

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

Notes to the consolidated financial statements

31 December 2022

Contents

1. Summary of significant accounting policies

(a) Basis of preparation

This consolidated interim financial report for the half-year reporting period ended 31 December 2022 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 2022 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 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 2022.

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 2022, the Group has recorded a contra research and development expense of $4,306,000 (December 2021: $3,668,000).

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

	Half-year ended 31 December	
Revenue and other income from continuing operations	**2022 $'000**	2021 $'000
Revenue from contracts with customers	**1,086**	1,819
Interest revenue	**521**	94
Total revenue from continuing operations	**1,607**	1,913
Other income	**104**	131
Total revenue and other income from continuing operations	**1,711**	2,044

Revenue includes product sales, royalty, and research revenue from commercial partners of $1,086,000 (December 2021: $1,819,000) and interest income on cash deposits of $521,000 (December 2021: $94,000). Total revenue for the half-year is lower by 16% on the prior corresponding period with lower VIRALEZE™ product sales in the current period. The prior reporting period included sales on the commercial launch of VIRALEZE™ in Vietnam in December 2021.

Other income of $104,000 (December 2021: $131,000) relates to proceeds received from a successful insurance claim associated with TGA infringement notices for alleged advertising of VIRALEZE™ in the prior year. For the prior corresponding reporting period, other income included Medical Research Future Fund (MRFF) grant funding for the development of VIRALEZE™.

5. Expenses

	Half-year ended 31 December	
	2022 $'000	2021 $'000
Loss from continuing operations before income tax expense includes the following items:		
R&D tax incentive (contra expense)[1]	**(4,306)**	(3,668)
Employee benefits expenses (including share-based payments)	**5,020**	5,454
Depreciation of property, plant and equipment	**212**	157
Depreciation of right-of-use assets	**401**	361

[1] Included 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 $5,438,000 (June 2022: $7,916,000) primarily comprises of $3,918,000 (30 June 2022: $6,747,000) of eligible expenditure reimbursable under the Australian Government's R&D tax incentive scheme.

7. Current and non-current liabilities – Borrowings

Current borrowings of $4,000,000 (30 June 2022: non-current $4,000,000) relate to an Invest Victoria R&D cash flow loan with Treasury Corporation of Victoria (TCV). The Invest Victoria R&D Cash Flow Loan initiative supports innovative Victorian entities to invest in research and development activities. The facility matures in October 2023 and is secured against future refundable R&D tax incentives. The interest rate is a TCV variable rate determined with reference to the Reserve Bank of Australia's target cash rate and TCV's client lending fees. The interest rate was 3.265% per annum at the reporting date.

8. Contributed equity

(a) Share capital

	December 2022 Shares	June 2022 Shares	**December 2022 $'000**	June 2022 $'000
Share capital				
Ordinary shares – fully paid	**408,852,447**	408,443,407	**240,669**	240,669

(b) Ordinary shares

As at 31 December 2022 there were 408,852,447 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 67,620 shares was issued to eligible staff on 1 February 2023, subsequent to the reporting date.

(d) Employee Performance Rights Plan

At 31 December 2022, there are 19,951,708 (30 June 2022: 15,784,044) performance rights on issue, of which 10,468,353 have vested and are exercisable at the reporting date and 9,483,355 unvested. There were 5,189,084 performance rights issued during the financial half-year, 409,040 performance rights converted into shares on the exercise of vested performance rights and 612,380 rights lapsing during the period.

9. Contingencies

Starpharma engaged a number of service providers to develop and assist with the implementation of a full direct to market commercialisation plan for VIRALEZE™ antiviral nasal spray. In order to preserve capital, Starpharma negotiated to defer a majority of the fee to a service provider, subject to future VIRALEZE™ sales performance and licensing proceeds. The maximum amount payable under the arrangement at 30 June 2022 was A$1.2M. The obligation under the arrangement has now ceased, with no further amount payable.

There have been no other changes in contingent liabilities or contingent assets since the last annual reporting date, 30 June 2022.

10. Events occurring after the balance sheet date

There are no significant events occurring since 31 December 2022 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

	Half-year ended 31 December	
	2022	2021
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)	**(2.03)**	(2.08)
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):	**(8,277)**	(8,449)
Weighted average number of ordinary shares used as the denominator in calculating basic earnings/(loss) per share	**408,588,694**	406,318,249

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

In the directors' opinion:
(a) the financial statements and notes set out on pages 7 to 15 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 2022 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.

Rob Thomas *AO*
Chairman
Melbourne, 28 February 2023

Independent Auditor's Review Report to the Members

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 2022, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, significant accounting policies 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 2022 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 2022 and of its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

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

PricewaterhouseCoopers

Brad Peake
Partner

Melbourne
28 February 2023