starpharma

ASX Announcement

Starpharma Interim Report and Half-Year Financial Results

Melbourne, Australia; 21 February 2022: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its interim report and financial results for the half-year ended 31 December 2021.

Key Financials

- Cash balance at 31 December 2021 $51.3M, excluding $7.7M received in January 2022 for the FY21 R&D tax incentive refund
- Revenue of $1.9M, up 200% on the prior corresponding period (pcp), including significant sales of VIRALEZE™ in Vietnam following the product's launch in December 2021
- Net operating cash outflows of $11.2M, excluding $7.7M of R&D tax incentive refund
- Reported loss for half-year of $8.4M, 19% lower than pcp of $10.4M

VIRALEZE™

- Successfully launched VIRALEZE™ in Vietnam following registration of the product and signing of a sales and distribution agreement in Vietnam. VIRALEZE™ is now available through a number of the largest pharmacy chains in Vietnam both in store and online. Collectively, these pharmacy chains have ~1300 pharmacies throughout Vietnam.
- VIRALEZE™ registration was achieved in Saudi Arabia. This registration will be used to facilitate further registrations across the Middle East.
- Signed a sales and distribution agreement with Etqan & Nazahah (E&N), headquartered in Saudi Arabia, for VIRALEZE™. The agreement covers nine countries, including the entire Gulf Cooperation Council region (Saudi Arabia, United Arab Emirates, Qatar, Kuwait, Omar, and Bahrain).
- VIRALEZE™ was launched in Italy through LloydsFarmacia following signing of a sales and distribution agreement for VIRALEZE™ with ADMENTA Italia Group in the period. ADMENTA is a leader in pharmaceutical retail and wholesale distribution in Italy and the Italian holding company of McKesson Europe.
- In addition to Saudi Arabia, new registrations were also achieved for VIRALEZE™ in Vietnam, and New Zealand, bringing the number of countries where VIRALEZE™ is registered to more than 30, including in Europe. Regulatory processes are ongoing in a number of markets, including Australia and other countries in the Middle East. In the UK, dialogue continues between Starpharma and the UK regulator, MHRA.
- Impressive data established that SPL7013, the antiviral agent in VIRALEZE™, has potent virucidal activity (>99.99%) against the globally significant Delta variant of SARS-CoV-2. Antiviral testing at The Scripps Research Institute has now confirmed that SPL7013 has >99% virucidal activity against four of the WHO-designated SARS-CoV-2 variants of concern (Alpha, Beta, Gamma, Delta) in laboratory studies, as well as the closely related Kappa variant.
- Testing of SPL7013 against the Omicron variant is well advanced at The Scripps Research Institute.
- VIRALEZE™ demonstrated a high level of protection against SARS-CoV-2 in a WHO-recommended humanised mouse challenge model of coronavirus infection. VIRALEZE™ reduced viral load by >99.9% in the lungs and trachea of animals

pcp: prior corresponding period

challenged with SARS-CoV-2 (vs. saline control) when administered nasally. These results were published in the international peer-reviewed journal *Viruses*.

- VIRALEZE™ was shown to be safe and extremely well tolerated in a repeat-dose human clinical safety study. Results of the study also confirmed that SPL7013, in VIRALEZE™, is not absorbed into the bloodstream following nasal application, which is consistent with extensive previous nonclinical and clinical data.
- Extensive antiviral data for SPL7013 was published in the prestigious international scientific journal, *Antiviral Research*. In addition, SPL7013 was featured in the October 2021 issue of *Nature Biotechnology*.

DEP® Drug Delivery Platform

- Starpharma signed an exploratory DEP® Research Agreement with Genentech, a member of the Roche Group, building on our partnered DEP® programs with global companies, including AstraZeneca, Merck & Co., Inc, and Chase Sun, which continue to progress. Work for this exploratory program commenced during the half-year.
- Starpharma announced extremely positive interim results for the prostate cancer patient cohort of its DEP® cabazitaxel phase 2 clinical trial. Following treatment with DEP® cabazitaxel, 100% of patients assessed for efficacy demonstrated one or more encouraging efficacy signals (tumour shrinkage, PSA reduction, and/or lack of secondary bone disease progression). Recruitment of a small number of additional ovarian and gastro-oesophageal cancer patients continues following promising efficacy signals in both these tumours as well as prostate.
- The US Patent and Trademark Office granted a new 'composition of matter' patent for DEP® cabazitaxel, with a patent term to 2039 and the potential for a further 5-year extension.
- AstraZeneca continued to recruit patients with advanced haematological malignancies and open new sites in its global phase 1/2 clinical trial for DEP® AZD0466, which is currently recruiting in the USA, South Korea, and Australia.
- AstraZeneca recently announced a new multi-centre phase 1/2 trial of AZD0466, which is expected to commence shortly. This new trial is investigating AZD0466 in patients with advanced non-Hodgkin's lymphoma, which is one of the top 10 most commonly occurring cancers.
- AstraZeneca and MD Anderson Cancer Center researchers reported exciting new data for AZD0466 at the American Society of Hematology (ASH) Annual Meeting in December 2021. Work conducted at MD Anderson showed that AZD0466 in combination with acalabrutinib overcame therapeutic resistance in aggressive venetoclax-resistant mantle cell lymphoma (MCL) models. MCL is an aggressive subtype of non-Hodgkin's lymphoma.
- The DEP® irinotecan phase 2 trial progressed well with encouraging efficacy signals observed across a range of tumours, including colorectal, breast, platinum-resistant ovarian, pancreatic, lung, and oesophageal.
- Preparations continue for the addition of a phase 1/2 combination arm of DEP® irinotecan + 5-FU + Leucovorin ('FOLFIRI'). FOLFIRI is a commonly used combination treatment regimen for colorectal cancer. This combination arm will run in parallel with the ongoing monotherapy arm for DEP® irinotecan, with recruitment of patients expected to commence shortly.
- The DEP® docetaxel clinical program (monotherapy and combination arms) progressed with efficacy signals observed, including prolonged stable disease and significant tumour shrinkage in heavily pre-treated patients with lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers.

- Preparations for DEP® gemcitabine's commencement of a phase 1/2 clinical trial, including manufacture of clinical product, are well advanced.
- Starpharma continued to progress additional DEP® candidates towards the clinic, including DEP® Antibody Drug Conjugates (ADCs) and DEP® radiopharmaceutical candidates for both therapeutic and diagnostic applications.
- Work continued on Starpharma's multiple partnered DEP® programs, including the DEP® ADCs program with Merck & Co., Inc., and DEP® anti-infective program with Chase Sun. In addition, Starpharma is negotiating further partnered DEP® programs with other leading pharmaceutical companies and is also conducting discussions in relation to a number of internal candidates.

VivaGel®

- VivaGel® products are currently registered in more than 45 countries and available for sale in Europe, Japan, South East Asia, South Africa, Australia and New Zealand.
- Starpharma continues to support marketing and regulatory activities for its VivaGel® BV partners, Mundipharma and Aspen.
- Fleurstat BVgel marketing activities continued in Australia, including digital marketing campaigns, promotional items in women's health and lifestyle print media, and shopping centre advertising.
- Okamoto is preparing to launch a new VivaGel® condom brand in Japan and continues regulatory activities for the VivaGel® condom in a number of other Asian markets.

Revenue of $1.9 million for the half-year is up 200% on the prior corresponding period for product sales, royalty, and research revenue from commercial partners. The increase in revenue was contributed to by sales of VIRALEZE™ antiviral nasal spray, following launch in new international markets, including Vietnam. Starpharma concluded the half-year in a very strong financial position with a cash balance of $51.3 million. The 31 December 2021 cash balance excludes the receipt in January of $7.7M of R&D tax incentive refund.

The loss for the period of $8.4M, reduced by 19%. This improvement was driven by increased product sales of VIRALEZE™ and lower expenses. R&D expenditure reflects the continued investment in the company's internal DEP® drug delivery programs, including its three clinical-stage DEP® products - DEP® docetaxel, DEP® cabazitaxel, and DEP® irinotecan – as well as the further development of additional DEP® candidates towards the clinic, such as DEP® gemcitabine and the broader DEP® pipeline.

Dr Jackie Fairley, Starpharma CEO, commented: "Starpharma has achieved a number of valuable milestones throughout the half-year across our DEP® portfolio. We were delighted to sign a new DEP® Research Agreement with a leading global pharmaceutical company. This new partnership builds on our existing relationships with AstraZeneca, Merck & Co., Inc., and Chase Sun. It has also been exciting to see AstraZeneca expand the potential indications for AZD0466 through a new clinical trial in patients with advanced non-Hodgkin's lymphoma, which is expected to commence shortly.

"In parallel with our partnered DEP® programs, Starpharma also progressed its three internal clinical programs for DEP® cabazitaxel, DEP® docetaxel, and DEP® irinotecan. We reported positive interim findings from the prostate cancer cohort of the DEP® cabazitaxel phase 2 trial, showing that all patients assessed for efficacy experienced one or more efficacy signals following treatment with DEP® cabazitaxel. We have continued to observe encouraging efficacy signals in all programs.

"Our broad-spectrum antiviral nasal spray, VIRALEZE™, was launched in Vietnam and Italy, following the signing of a sales and distribution agreement with partners in those regions. VIRALEZE™ is now registered in more than 30 countries, including in Europe, India, Vietnam, New Zealand, and Saudi Arabia and also available online in certain other markets. Most recently, we expanded the distribution arrangements for VIRALEZE™, adding nine new countries through sales and distribution with E&N. Commercialisation in the Middle East will commence with Saudi Arabia where the product is already registered and launch preparations are well advanced," concluded Dr Fairley.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for respiratory viruses, DEP® drug delivery and VivaGel®. Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered for sale in the Europe, Vietnam, India, Saudi Arabia, and New Zealand, and available outside Australia in certain markets online. VIRALEZE™ is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel® condom and VivaGel® BV. VivaGel® BV has been licensed in >160 countries, is registered in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, South Africa, Australia and New Zealand.

As a leading company in dendrimer-based drug delivery, Starpharma's proprietary drug delivery platform technology, DEP®, is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP® versions of existing drugs, particularly in the area of anti-cancer therapies. DEP® partnerships include oncology programs with AstraZeneca, with Merck in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives and other world leading pharmaceutical companies. Starpharma's partnered DEP® programs have the potential to generate significant future milestones and royalties.

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Disclosure
This ASX Announcement was authorised for release by the Chairman, 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 – 31 December 2021

Lodged with the ASX under Listing Rule 4.2A

This information should be read in conjunction with the 30 June 2021 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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Results for Announcement to the Market

Starpharma Holdings Limited ABN 20 078 532 180

Half-year ended 31 December 2021

Previous corresponding period: Half-year ended 31 December 2020

Revenue *(Appendix 4D item 2.1)*	Up	200%	to	$1,913,000
Loss after tax attributable to members *(Appendix 4D item 2.2)*	Down (reduced loss)	19%	to	$8,449,000
Net Loss for the period attributable to members *(Appendix 4D item 2.3)*	Down (reduced loss)	19%	to	$8,449,000

Dividends/distributions *(Appendix 4D items 2.4 and, 2.5)*	Amount per security	Franked amount per security
Final dividend	Nil	Nil
Interim dividend	Nil	Nil

Record date for determining entitlements to the dividend: Not Applicable

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

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

Revenue for the half-year is up 200% on the prior corresponding period, with Viraleze™ product sales included in the current reporting period following its commercial launch in March 2021. Revenue includes product sales, royalty, and research revenue from commercial partners of $1,819,000 (December 2020: $486,000); and interest income on cash deposits of $94,000 (December 2020: $152,000).

Explanation of net loss *(Appendix 4D item 2.6)*

The consolidated loss after tax for the half-year to 31 December 2021 was $8,449,000 (December 2020: $10,430,000). The net loss is lower than the prior corresponding period predominately due to the higher product sales, including sales of Viraleze™ recorded in the current period and an unfavourable foreign exchange loss in the prior corresponding period.

Research and product development expenses include the costs of the internal DEP® drug delivery programs, including DEP® docetaxel, DEP® cabazitaxel, DEP® irinotecan, and DEP® gemcitabine. A contra research and product development expense of $3,668,000 (December 2020: $3,415,000) has been recorded for eligible research and development activities under the Australian Government's R&D Tax Incentive program.

Commercial and regulatory operating expenses were $1,613,000 (December 2020: $1,406,000) and include expenditure related to the commercialisation of Viraleze™, VivaGel® and DEP® portfolios, including business development, legal, regulatory, supply chain and quality assurance activities.

Corporate, administration and finance expenses were $1,713,000 (December 2020: $2,539,000) and include corporate costs, as well as gains/losses on foreign currency held. The decrease over the prior reporting period reflects a foreign currency loss of $928,000 recorded in the prior corresponding period.

Net tangible assets (NTA) *(Appendix 4D item 3)*

	Half-year ended 31 December	
	2021	2020
Net tangible asset backing per ordinary share	**$0.14**	$0.17

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

Additional Appendix 4D disclosure requirements can be found in the enclosed Directors' Report and the 31 December 2021 half-year financial statements.

This report is based on the consolidated 2021 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 2021 half-year financial statements.

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 2021.

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)	J K Fairley (Chief Executive Officer)	P R Turvey (resigned 29 July 2021)
Z Peach	D J McIntyre	L Cheng (appointed 1 August 2021)

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 VivaGel® for the management and prevention of bacterial vaginosis, as an antiviral condom coating, and VIRALEZE™ - an antiviral nasal spray. Starpharma is also applying its proprietary dendrimers to drug delivery to create improved pharmaceuticals and has developed the valuable DEP® delivery platform.

Business strategy, future developments and prospects

The Company aims to create value for shareholders through the clinical development and commercial exploitation of proprietary products 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. For some products a direct-to-consumer model is also adopted.

Starpharma's strategy remains consistent with the 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

Key highlights and significant events until the date of this report included:

VIRALEZE™

- Successfully launched VIRALEZE™ in Vietnam following registration of the product and signing of a sales and distribution agreement.
- Signed a sales and distribution agreement with Etqan & Nazahah (E&N), headquartered in Saudi Arabia, for VIRALEZE™. The agreement covers nine countries, including the entire Gulf Cooperation Council region (Saudi Arabia, United Arab Emirates, Qatar, Kuwait, Omar, and Bahrain).
- VIRALEZE™ registration was achieved in Saudi Arabia. This registration will be used to facilitate further registrations across the Middle East.
- VIRALEZE™ was launched through LloydsFarmacia in Italy following signing of a sales and distribution agreement for VIRALEZE™ with ADMENTA Italia Group in the period. ADMENTA is a leader in pharmaceutical retail and wholesale distribution in Italy and the Italian holding company of McKesson Europe.
- New registrations were achieved for VIRALEZE™ in Saudi Arabia, Vietnam, and New Zealand, bringing the number of countries where VIRALEZE™ is registered to more than 30, including in Europe and India. Regulatory processes are ongoing in a number of markets, including Australia and the Middle East. In the UK, dialogue continues between Starpharma and the UK regulator, MHRA.
- Impressive data established that SPL7013, the antiviral agent in VIRALEZE™, has potent virucidal activity (>99.99%) against the globally significant Delta variant of SARS-CoV-2. Antiviral testing at The Scripps Research Institute has now confirmed that SPL7013 has >99% virucidal activity against four of the WHO-designated SARS-CoV-2 variants of concern (Alpha, Beta, Gamma, Delta) in laboratory studies, as well as the closely related Kappa variant. Testing of SPL7013 against the Omicron variant is underway at The Scripps Research Institute.
- VIRALEZE™ also demonstrated a high level of protection against SARS-CoV-2 in a WHO-recommended humanised mouse challenge model of coronavirus infection. 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 results were published in the international peer-reviewed journal Viruses.
- VIRALEZE™ was shown to be safe and extremely well tolerated in a repeat-dose human clinical safety study. Results of the study also confirmed that SPL7013, in VIRALEZE™, is not absorbed into the bloodstream following nasal application, which is consistent with extensive previous nonclinical and clinical data.

- Extensive antiviral data for SPL7013 was published in the prestigious international scientific journal, Antiviral Research. In addition, SPL7013 was featured in the October 2021 issue of Nature Biotechnology.

DEP® Drug Delivery Platform

- Starpharma signed an exploratory DEP® Research Agreement with Genentech, a member of the Roche Group, building on our existing partnered DEP® programs with global companies, including AstraZeneca, Merck & Co., Inc, and Chase Sun, which continue to progress. Work for this exploratory program commenced during the half-year.
- Starpharma reported extremely positive interim results for the prostate cancer patient cohort of its DEP® cabazitaxel phase 2 clinical trial. Following treatment with DEP® cabazitaxel, 100% of patients assessed for efficacy demonstrated one or more encouraging efficacy signals (tumour shrinkage, PSA reduction, and/or lack of secondary bone disease progression). Recruitment of a small number of additional ovarian and gastro-oesophageal cancer patients continues following promising efficacy signals in both these tumours as well as prostate.
- The US Patent and Trademark Office granted a new 'composition of matter' patent for DEP® cabazitaxel. It specifically covers a DEP® dendrimer conjugated to multiple cabazitaxel drug molecules via a particular releasable linker, with a patent term to 2039 and the potential for a further 5-year extension.
- AstraZeneca continued to recruit patients with advanced haematological malignancies and open new sites in its global phase 1/2 clinical trial for DEP® AZD0466, which is currently recruiting in the USA, South Korea, and Australia.
- AstraZeneca recently announced a new multi-centre phase 1/2 trial of AZD0466, which is expected to commence shortly. This new trial is investigating AZD0466 in patients with advanced non-Hodgkin's lymphoma, which is one of the top 10 most commonly occurring cancers.
- AstraZeneca and MD Anderson Cancer Center researchers presented exciting new data for AZD0466 in two scientific poster presentations at the American Society of Hematology (ASH) Annual Meeting in December 2021. Work conducted at MD Anderson showed that AZD0466 in combination with acalabrutinib overcame therapeutic resistance in aggressive venetoclax-resistant mantle cell lymphoma (MCL) models. MCL is an aggressive subtype of non-Hodgkin's lymphoma.
- The DEP® irinotecan phase 2 trial progressed well with encouraging efficacy signals observed across a range of tumours, including colorectal, breast, platinum-resistant ovarian, pancreatic, lung, and oesophageal.
- Preparations continue for the addition of a phase 1/2 combination arm of DEP® irinotecan + 5-FU + Leucovorin ('FOLFIRI'). FOLFIRI is a commonly used combination treatment regimen for colorectal cancer. This combination arm will run in parallel with the ongoing monotherapy arm for DEP® irinotecan, with recruitment of patients expected to commence shortly.
- The DEP® docetaxel clinical program (monotherapy and combination arms) progressed with efficacy signals observed, including prolonged stable disease and significant tumour shrinkage in heavily pre-treated patients with lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers.
- Preparations for DEP® gemcitabine's commencement of a phase 1/2 clinical trial, including manufacture of clinical product, are well advanced. The company continues to progress additional DEP® candidates towards the clinic, including DEP® Antibody Drug Conjugates (ADCs) and DEP® radiopharmaceutical candidates for both therapeutic and diagnostic applications.
- Work continued on Starpharma's multiple partnered DEP® programs, including the DEP® ADCs program with Merck & Co., Inc., and DEP® anti-infective program with Chase Sun. In addition, Starpharma is negotiating further partnered DEP® programs with other leading pharmaceutical companies.
- Starpharma's laboratory and internal operations continued to operate with minimal disruption, under a COVID-safe plan.

VivaGel®

- VivaGel® products are currently registered in more than 45 countries and available for sale in Europe, Japan, South East Asia, South Africa, Australia and New Zealand.
- Starpharma continues to support marketing and regulatory activities for its VivaGel® BV partners, Mundipharma and Aspen.
- Fleurstat BVgel marketing activities continued in Australia, including digital marketing campaigns, promotional items in women's health and lifestyle print media, and shopping centre advertising.
- Okamoto is preparing to launch a new VivaGel® condom brand in Japan and continues regulatory activities for the VivaGel® condom in a number of other Asian markets.

VIRALEZE™

VIRALEZE™ is a broad-spectrum antiviral nasal spray. The antiviral agent in VIRALEZE™, referred to as SPL7013, has been shown to have potent antiviral and virucidal activity in multiple respiratory viruses (including influenza and RSV) and multiple variants of SARS-CoV-2, including inactivation of >99.9% of the highly infectious Delta variant, in laboratory studies. VIRALEZE™ is applied in the nose to provide a physical barrier - between viruses and the nasal mucous membrane - that traps and irreversibly inactivates virus. Importantly, the mechanism of action of VIRALEZE™ means that mutations of the spike protein that make SARS-CoV-2 more infectious, as occurred for the Delta strain, appear to make the virus more susceptible to trapping and blocking when exposed to SPL7013. VIRALEZE™ is registered in more than 30 countries, including Europe, Vietnam, India, New Zealand, and Saudi Arabia, and available in certain markets online. VIRALEZE™ is partnered with LloydsPharmacy in the UK, ADMENTA Italia Group in Italy, HealthCo/TBL in Vietnam, and E&N in countries in the Middle East. VIRALEZE™ is not approved for sale or supply in Australia.

VivaGel®

Starpharma's VivaGel® BV is a novel, breakthrough therapy for bacterial vaginosis (BV), the most common vaginal infection in the world. VivaGel® BV is available for sale under Mundipharma's Betadine brand and Fleurstat BVgel (Australia & New Zealand) and has been licensed in more than 160 countries around the world. In the US, the FDA process is ongoing, and COVID-19 has had an impact on timing.

Starpharma's VivaGel® condom is the world's first and only anti-viral condom. The condom lubricant contains VivaGel® and has been launched in Japan, Australia, Canada, and Europe.

DEP® Drug Delivery Platform

Internal DEP® programs

Starpharma's proprietary dendrimer-based DEP® platform has broad commercial applicability in drug delivery and has the potential to enhance the therapeutic utility of drugs through improved solubility, efficacy and pharmacokinetic control, reductions in certain toxicities (e.g. bone marrow toxicity) and create a unique intellectual property position. The novel DEP® platform has shown reproducible advantages across a wide range of drug classes and has the potential to be utilised with both small molecule drugs, peptides and proteins, and in the development of unique DEP® based antibody drug conjugates (ADCs), radiotherapies and radiodiagnostics.

Starpharma has three phase 2 clinical stage DEP® assets (DEP® cabazitaxel, DEP® irinotecan, and DEP® docetaxel), multiple preclinical DEP® programs, and has applied its DEP® technology in partnership with pharmaceutical companies for many different applications (passive and targeted ADC and radiotheranostics) and diseases (oncology and non-oncology applications).

Partnered DEP® programs

In addition to its internal DEP® programs, Starpharma has numerous partnered DEP® programs underway, particularly in the area of anti-cancer therapies. Starpharma's DEP® partnerships include programs with AstraZeneca, Merck & Co., Inc., Chase Sun, and others.

Starpharma's partnership with AstraZeneca includes a multiproduct license for the development and commercialisation of AstraZeneca oncology compounds, including AZD0466, with potential to add more products. AZD0466 is a highly optimised nanomedicine formulation of AstraZeneca's Bcl2/xL inhibitor, which utilises DEP® to improve the preclinical efficacy and therapeutic index. AZD0466 is currently the subject of two multi-centre phase 1/2 trials, with all development costs funded by AstraZeneca.

Review of Financials

	Half-year ended 31 December	
Income statement	**2021 $'000**	2020 $'000
Revenue	**1,913**	638
Cost of goods sold	**(916)**	(286)
Other income	**131**	660
Research and product development expense (net of R&D tax incentive)	**(6,251)**	(7,497)
Commercial and regulatory operating expense	**(1,613)**	(1,406)
Corporate, administration and finance expense	**(1,713)**	(2,539)
Loss for the period	**(8,449)**	(10,430)

Income statement
For the half-year ended 31 December 2021 the consolidated loss after income tax was $8,449,000 (December 2020: $10,430,000).

Revenue for the half-year is up 200% on the prior corresponding period with Viraleze™ product sales included in the current reporting period following its commercial launch in March 2021. Revenue includes product sales, royalty, and research revenue from commercial partners of $1,819,000 (December 2020: $486,000), and interest income on cash invested in term deposits of $94,000 (December 2020: $152,000).

Other income of $131,000 (December 2020: $660,000) primarily relates to grant funding of $123,000 (December 2020: $221,000) awarded to Starpharma by the Medical Research Future Fund (MRFF) to expedite development and commercialisation of the Viraleze™ antiviral nasal spray. For the prior corresponding reporting period, other income included JobKeeper payments.

Research and product development expenses include the costs of Starpharma's internal DEP® drug delivery programs, including DEP® docetaxel, DEP® cabazitaxel, DEP® irinotecan, and DEP® gemcitabine. A contra research and product development expense of $3,668,000 (December 2020: $3,415,000) 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 the expenditure related to the commercialisation of both VivaGel® / VIRALEZE™ and DEP® portfolios, including business development, legal, regulatory, supply chain and quality assurance activities.

Corporate, administration and finance expense include corporate costs, as well as gains/losses on foreign currency held. The decrease over the prior corresponding reporting period primarily reflects a foreign currency loss of $928,000 on foreign currencies held in the prior corresponding period.

Balance sheet
At 31 December 2021 the Group's cash position was $51,254,000 (June 2021: $60,500,000). Trade and other receivables of $11,950,000 (June 2021: $8,534,000) primarily comprises of $10,902,000 (30 June 2021: $7,233,000) of eligible expenditure reimbursable under the Australian Government's R&D tax incentive scheme, of which $7,748,000 has been received in January 2022 after the reporting date. Trade and other payables of $6,262,000 (June 2021: $7,954,000) have decreased primarily due to lower accruals associated with expenditure on the DEP® and VIRALEZE™ programs. Borrowings of $2,400,000 (30 June 2021: $nil) represents the first draw-down on a $4,000,000 Invest Victoria low-interest R&D cash flow loan to support R&D expenditure. The Group's net cash position adjusted for borrowings is $48,854,000 as at 31 December 2021.

Statement of cash flows
Net operating cash outflows for the half-year were $11,243,000 (December 2020: $5,373,000), with the receipt of the FY21 R&D tax incentive refund occurring in January 2022. In the prior corresponding reporting period, the R&D tax incentive was received before the 31 December 2020 reporting date. Cash flows from financing activities include the draw-down of $2,400,000 from the Invest Victoria R&D cash flow loan, with the prior corresponding reporting period including the net proceeds of $46,963,000 from an equity raising completed in September/October 2020.

Earnings per share

	Half-year ended 31 December	
	2021 Cents	2020 Cents
Basic / diluted loss per share	**(2.08)**	(2.69)

Matters subsequent to the end of the financial half-year

No matters or circumstances have arisen since 31 December 2021 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 7.

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

Rob Thomas *AO*
Chairman
Melbourne, 21 February 2022

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 2021, 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
21 February 2022

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Interim Financial Report

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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 2021 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

		Half-year ended 31 December	
		2021	2020
	Notes	**$'000**	$'000
Revenue	4	**1,913**	638
Cost of goods sold		**(916)**	(286)
Other income	4	**131**	660
Research and product development expense (net of R&D tax incentive)		**(6,251)**	(7,497)
Commercial and regulatory operating expense		**(1,613)**	(1,406)
Corporate, administration and finance expense		**(1,713)**	(2,539)
Loss before income tax		**(8,449)**	(10,430)
Income tax expense		**-**	-
Loss from continuing operations attributable to the ordinary equity holders of the Company		**(8,449)**	(10,430)
Other comprehensive income (loss)		**-**	-
Total comprehensive income (loss) for the period		**(8,449)**	(10,430)
Loss per share for loss from continuing operations attributable to the ordinary equity holders of the Company		**Cents**	Cents
Basic loss per share	11	**(2.08)**	(2.69)
Diluted loss per share	11	**(2.08)**	(2.69)

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

Consolidated balance sheet

	Notes	31 December 2021 $'000	30 June 2021 $'000
Current assets			
Cash and cash equivalents		**51,254**	60,500
Trade and other receivables	6	**11,950**	8,534
Inventories		**1,897**	1,721
Total current assets		**65,101**	70,755
Non-current assets			
Property, plant and equipment		**964**	1,373
Right-of-use assets		**1,259**	1,110
Total non-current assets		**2,223**	2,483
Total assets		**67,324**	73,238
Current liabilities			
Trade and other payables		**6,262**	7,954
Lease liabilities		**794**	692
Provision for employee benefits		**1,403**	1,371
Deferred income		**831**	412
Total current liabilities		**9,290**	10,429
Non-current liabilities			
Lease liabilities		**513**	475
Borrowings	7	**2,400**	-
Provision for employee benefits		**41**	34
Total non-current liabilities		**2,954**	509
Total liabilities		**12,244**	10,938
Net assets		**55,080**	62,300
Equity			
Contributed capital	8	**240,630**	240,630
Reserves		**25,306**	24,077
Accumulated losses		**(210,856)**	(202,407)
Total equity		**55,080**	62,300

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

Consolidated statements of changes in equity

		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					
Contributions of equity, net of transaction costs	8	-	-	-	-
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

		Half-year ended 31 December 2020			
	Notes	Contributed equity $'000	Reserves $'000	Accumulated losses $'000	Total equity $'000
Balance at 1 July 2020		193,661	20,340	(182,675)	31,326
Loss for the period		-	-	(10,430)	(10,430)
Other comprehensive income (loss)		-	-	-	-
Total comprehensive income (loss) for the half-year		-	-	(10,430)	(10,430)
Transactions with owners, recorded directly in equity					
Contributions of equity, net of transaction costs	8	46,963	-	-	46,963
Employee performance rights plan		-	1,896	-	1,896
Total transactions with owners		46,963	1,896	-	48,859
Balance at 31 December 2020		240,624	22,236	(193,105)	69,755

Consolidated statement of cash flows

	Notes	Half-year ended 31 December 2021 $'000	2020 $'000
Cash flow from operating activities			
Receipts from trade and other debtors (inclusive of GST)		**1,729**	253
Grant income and R&D tax incentives (inclusive of GST)		**315**	6,318
Payments to suppliers and employees (inclusive of GST)		**(13,357)**	(12,073)
Interest received		**94**	160
Interest paid		**(24)**	(31)
Net cash outflows from operating activities		**(11,243)**	(5,373)
Cash flow from investing activities			
Payments for property, plant and equipment		**(193)**	(108)
Net cash outflows from investing activities		**(193)**	(108)
Cash flow from financing activities			
Proceeds from borrowings	7	**2,400**	**-**
Proceeds from issue of shares		**-**	48,862
Share issue transaction costs		**-**	(1,899)
Lease repayments		**(370)**	(298)
Net cash inflows from financing activities		**2,030**	46,665
Net increase (decrease) in cash and cash equivalents held		**(9,406)**	41,184
Cash and cash equivalents at the beginning of the half-year		**60,500**	30,054
Effects of exchange rate changes on cash and cash equivalents		**160**	(964)
Cash and cash equivalents at the end of the half-year		**51,254**	70,274

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

Notes to the consolidated financial statements

31 December 2021

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1. Summary of significant accounting policies

(a) Basis of preparation

This consolidated interim financial report for the half-year reporting period ended 31 December 2021 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 2021 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 financial statements have been prepared on a going concern basis.

2. Critical accounting estimates and judgments

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 2021, the Group has recorded a contra research and development expense of $3,668,000 (December 2020: $3,415,000).

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	**2021 $'000**	2020 $'000
Revenue from contracts with customers	**1,819**	486
Interest revenue	**94**	152
Total revenue from continuing operations	**1,913**	638
Other income	**131**	660
Total revenue and other income from continuing operations	**2,044**	1,298

Revenue for the half-year is up 200% on the prior corresponding period with Viraleze™ product sales included in the current reporting period following its commercial launch in March 2021. Revenue includes product sales, royalty, and research revenue from commercial partners of $1,819,000 (December 2020: $486,000); and interest income on cash deposits of $94,000 (December 2020: $152,000).

Other income of $131,000 (December 2020: $660,000) primarily relates grant funding of $123,000 (December 2020: $221,000) awarded to Starpharma by the Medical Research Future Fund (MRFF) to expedite development and commercialisation of the Viraleze™ antiviral nasal spray. For the prior corresponding period, other income included JobKeeper payments.

5. Expenses

	Half-year ended 31 December	
	2021 $'000	2020 $'000
Loss from continuing operations before income tax expense includes the following items:		
R&D tax incentive (contra expense)[1]	**(3,668)**	(3,415)
Employee benefits expenses (including share-based payments)	**5,454**	5,516
Depreciation of property, plant and equipment	**157**	142
Depreciation of right-of-use assets	**361**	308

[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 $11,950,000 (June 2021: $8,534,000) primarily comprises of $10,902,000 (30 June 2021: $7,233,000) of eligible expenditure reimbursable under the Australian Government's R&D tax incentive scheme, of which $7,748,000 has been received after the reporting date.

7. Non-Current Assets – Borrowings

Borrowings of $2,400,000 (30 June 2021: $nil) relate to the first draw-down from a $4,000,000 Invest Victoria low-interest 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 0.265% per annum at the reporting date.

8. Contributed equity

(a) Share capital

	December 2021 Shares	June 2021 Shares	**December 2021 $'000**	June 2021 $'000
Share capital				
Ordinary shares – fully paid	**406,680,155**	406,078,026	**240,630**	240,630

(b) Ordinary shares

As at 31 December 2021 there were 406,680,155 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 a limited amount of 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 37,128 shares was issued to eligible staff on 1 February 2022, subsequent to the reporting date.

(d) Employee Performance Rights Plan

At 31 December 2021, there are 18,159,789 (30 June 2021: 17,472,497) performance rights on issue, of which 10,749,765 have vested and are exercisable at the reporting date and 7,410,024 unvested. There were 2,360,027 performance rights issued during the financial half-year, 602,129 performance rights converted into shares on the exercise of vested performance rights and 1,070,606 rights lapsing during the period.

9. Contingencies

There have been no changes in contingent liabilities or contingent assets since the last annual reporting date, 30 June 2021.

10. Events occurring after the balance sheet date

There are no significant events occurring since 31 December 2021 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	
	2021	2020
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)	**(2.08)**	(2.69)

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):	**(8,449)**	(10,430)
Weighted average number of ordinary shares used as the denominator in calculating basic earnings/(loss) per share	**406,318,249**	387,798,476

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 8 to 16 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 2021 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, 21 February 2022

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 2021, 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, 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 2021 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.

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 2021 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*.

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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
Partner

Melbourne
21 February 2022