ASX Announcement

Quarterly Activities Report & Appendix 4C

- *The positive results from the Phase 2 clinical trial of DEP® cabazitaxel in patients with advanced gastro-oesophageal cancers were presented at the American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium in San Francisco in January 2024.*
- *The Phase 2 clinical trial program of DEP® docetaxel yielded positive results and met its objectives, demonstrating encouraging anti-tumour activity in multiple metastatic cancers, including pancreatic, lung, and gastro-oesophageal.*
- *The application of Starpharma's DEP® platform for precision cancer radiotheranostics, which are designed to assist in improving the diagnosis, staging, monitoring, and treatment of HER2+ cancers, was presented at the Targeted Radiopharmaceuticals Summit Europe in Berlin in December 2023.*
- *The results from the Viraleze™ post-market study in participants with COVID-19 demonstrated antiviral efficacy, with effects more pronounced in older patient groups. Viraleze™ achieved a statistically significant reduction in SARS-CoV-2 viral load in the cohort of participants aged 45 and over. Viraleze™ also improved key symptoms of COVID-19, including loss of smell (anosmia).*
- *A new sales and distribution agreement for VivaGel® BV was signed with ITROM Pharmaceutical Group, covering 13 countries across the Middle East and North Africa (MENA).*
- *Cash balance at the end of the quarter was $32.1 million, with total net cash outflows of $3.5 million, including the receipt of a $7.2 million R&D tax incentive refund and the one-off repayment of the $4.0 million low-interest R&D cashflow loan with Invest Victoria.*

Melbourne, Australia; 31 January 2024: Starpharma (ASX: SPL, OTCQX: SPHRY) today releases its Quarterly Activities Report and Appendix 4C for the period ended 31 December 2023 (Q2 FY24). Starpharma's closing cash balance as at 31 December 2023 was $32.1 million.

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

"Since starting as CEO of Starpharma in January, I, along with the Management Team, have been reviewing Starpharma's business, the current opportunities and the key challenges, and what is abundantly clear to us is that there remain significant opportunities to enhance the value and application of Starpharma's dendrimer technology and to optimise the current value of Viraleze and VivaGel BV.

"The recently announced DEP clinical study results support Starpharma's previous clinical studies and highlight the potential for this technology to add significant benefit to existing treatments, as well as the potential for new treatments that are currently in development.

"Key priorities for the DEP program are advancing partnering activity and our internal development program, which will allow us to maximise the potential of the technology across different therapeutic areas, to bring significant safety and efficacy benefits to patients, improve commercialisation opportunities for partners and improve shareholder value. Following Starpharma's attendance at J.P. Morgan in January and other recent business development activities, our efforts will increasingly focus on these opportunities in the coming months.

"The recent results from the post-market study of Viraleze reinforced Starpharma's existing dataset on the product. Importantly, the clinical data will support the new European Medical Device Regulations, which will come into full effect in 2029. We will also leverage the data from the study, particularly the 45+ cohort, to support ongoing regulatory, marketing, and distribution efforts.

"The recently executed ITROM sales and distribution agreement for VivaGel BV in the MENA region and other concurrent business development activity highlights our ongoing commitment to make VivaGel BV more accessible to women in regions with a high need.

"There is no doubt that the past few years have been challenging with regard to shareholder value. This can be attributed to a number of factors, some specific to Starpharma and some relating to the sector and macro environment. As we move forward, the learnings from the past few years will be invaluable to focus our efforts on what drives value for patients, partners, and shareholders.

"The Company ended the quarter with a strong cash position, and we remain committed to ensuring the allocation of resources matches our strategic priorities."

DEP® Programs

During the quarter, Starpharma announced positive final results from the Phase 2 clinical program of DEP® docetaxel. The Phase 2 trial objectives were met, with endpoints demonstrating encouraging anti-tumour activity of DEP® docetaxel when administered as a monotherapy or in combination with other anti-cancer agents, nintedanib or gemcitabine in multiple, advanced, metastatic cancers, including pancreatic, gastro-oesophageal, non-small cell lung cancer (NSCLC) and cholangiocarcinoma.

The safety and tolerability of DEP® docetaxel were also confirmed, with DEP® docetaxel demonstrating an improved tolerability profile versus conventional docetaxel in terms of key adverse events, including myelosuppression (severe neutropenia), oedema (fluid retention), alopecia (hair loss) and allergic reactions (anaphylaxis/hypersensitivity).

The clinical trial also demonstrated the ability of DEP® docetaxel to effectively target tumours, with treated patient biopsies showing that tumour tissues achieved tissue levels of docetaxel up to 60 times higher than levels in blood. This tumour-targeting effect was demonstrated across multiple cancer types. The findings confirm the ability of DEP® to increase the delivery of drug to tumours, as also shown in multiple preclinical models.

In January 2024, Starpharma's positive results from the Phase 2 clinical trial of DEP® cabazitaxel in patients with advanced gastro-oesophageal cancers were presented at the American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium in San Francisco. ASCO is the world's leading professional organisation for physicians and oncology professionals, and this specialist GI Cancers Symposium is the only global meeting of its kind focusing on the latest innovative science and clinical developments in GI cancer treatment, research and care. Starpharma's presentation highlighted the key results from the Phase 2 trial of DEP® cabazitaxel in patients with advanced gastro-oesophageal cancers, announced on 18 October 2023, and additional efficacy data for DEP® cabazitaxel in two subgroups of the gastro-oesophageal cohort with different types of GI cancers: adenocarcinoma and squamous cell carcinoma (SCC).

The clinical trial of DEP® irinotecan is also ongoing, as several patients with advanced cancers, including ovarian and colorectal cancers, are continuing therapy and are experiencing prolonged responses to treatment and significant clinical benefits.

In December 2023, Starpharma delivered a presentation on the application of its DEP® platform for precision cancer radiotheranostics at the Targeted Radiopharmaceuticals Summit Europe in Berlin. This presentation covered the application, versatility and benefits of the DEP® platform for targeted delivery of radiotheranostics and Starpharma's two DEP® HER2-targeted radiotheranostic products, DEP® HER2-zirconium and DEP® HER2-lutetium, which are designed to assist in improving the diagnosis, staging, monitoring, and treatment of HER2+ cancers.

Starpharma's in-house preclinical DEP® Antibody-Drug Conjugates (ADCs) and DEP® radiotheranostics programs continue progressing alongside our partnered programs, including with MSD and Genentech.

As part of its business development program, Starpharma executives attended the J.P. Morgan Healthcare Conference in San Francisco in January 2024. Starpharma met with existing partners, healthcare investors, and other interested companies at the conference. In the oncology space, antibody-drug conjugates, radiopharmaceuticals and immunotherapies garnered much attention at the conference, while obesity and other metabolic diseases were also of interest.

Viraleze™ and VivaGel® BV

Starpharma recently announced the results of the post-market clinical study of Viraleze™ nasal spray in participants with COVID-19. The results showed that Viraleze™ reduced SARS-CoV-2 viral load and increased the rate of virus clearance from the nose, and in parallel, improved key symptoms of COVID-19, including loss of smell (anosmia), and was well-tolerated.

Viraleze™ achieved a statistically significant reduction in SARS-CoV-2 viral load, the primary endpoint of the study, in the cohort of participants aged 45 and over (N=118, p=0.017). Viraleze™ reduced viral load in the full study population including all patient age groups (N=197), although the difference vs placebo was not statistically significant.

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

In this clinical study, the benefits of Viraleze™ were more pronounced in older participants and have potential relevance to older individuals who are typically more susceptible to respiratory infection and disease. These findings are consistent with Starpharma's nonclinical in vivo and in vitro studies of Viraleze™ in SARS-CoV-2 and other cold/respiratory viruses, including influenza, and provide further support for Viraleze™ in helping to protect against respiratory infection and disease. Reduced viral load and increased viral clearance have the potential to protect against infection, improve symptoms, and reduce onward transmission.

In January 2024, Starpharma signed a sales and distribution agreement for its VivaGel® BV product with ITROM Pharmaceutical Group, covering 13 countries across the Middle East and North Africa (MENA). ITROM specialises in introducing new pharmaceutical products to the MENA region and has a proven track record of successfully launching and growing the market share of new pharmaceutical products in multiple therapeutic areas within its region. The prevalence of bacterial vaginosis among a female population of 238 million in the MENA region is 25%, indicating a high need for new effective therapeutic approaches and a significant opportunity for VivaGel® BV. This new partnership with ITROM follows the recent reversion of VivaGel® BV rights to Starpharma under a settlement agreement with Mundipharma, announced in August 2023. Starpharma has now commenced the transferral processes for the existing VivaGel® BV registrations.

As foreshadowed at Starpharma's Annual General Meeting in November 2023, Starpharma lodged a further VivaGel® BV submission to the US Food and Drug Administration (FDA) during Q2 FY24. Starpharma has since also met with the FDA to discuss this submission. Starpharma will provide an update on this submission upon receiving an outcome from the FDA.

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

Starpharma continues to market Viraleze™ through Amazon UK and a dedicated product website. Starpharma also has commercial partners in several international markets, where the product is distributed online and in retail outlets, including pharmacies. The Company continues to pursue additional commercial opportunities for the product.

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

Financial Summary

Starpharma's cash balance as at 31 December 2023 was $32.1 million, with net cash outflows of $3.5 million for the quarter. Total receipts of $7.4 million in the quarter included $7.2 million received under the Australian Government's R&D Tax Incentive scheme and receipts from customers of $0.2 million. Customer receipts include sales from Viraleze™ and VivaGel® BV.

Cash outflows for the quarter included research and development costs of $3.4 million related to the concurrent completion of multiple DEP® clinical programs and the post-market clinical study of Viraleze™ nasal spray. R&D expenditure also included development costs for Starpharma's targeted DEP® radiotheranostics and DEP® antibody-drug conjugates programs. Administration and corporate costs of $0.7 million include insurance costs. Product manufacturing and operating costs for the quarter were $0.5 million. Staffing costs were $2.6 million and included non-executive and executive directors' fees of $417,000. Cash outflows from financing activities included the one-off repayment of the $4.0 million low-interest R&D Loan with Invest Victoria in October 2023.

About Starpharma

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

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

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

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

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

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

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on LinkedIn.

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

The Quarterly Activities Report & Appendix 4C is not subject to formal external audit or review. Management has procedures in place with relevant staff to allow the CEO and CFO to make appropriate certifications prior to approval.

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Disclosure
This ASX Announcement was authorised for release by non-executive director Dr Jeff Davies.

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.

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Starpharma Holdings Limited

ABN	Quarter ended ("current quarter")
20 078 532 180	**31-Dec-23**

Consolidated statement of cash flows		**Current quarter** $A'000	**Year to date (6 months)** $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	169	7,001
1.2	Payments for		
(a)	research and development	(3,373)	(6,786)
(b)	product manufacturing and operating costs	(507)	(976)
(c)	advertising and marketing	(3)	(19)
(d)	leased assets	-	-
(e)	staff costs	(2,585)	(4,585)
(f)	administration and corporate costs	(661)	(1,287)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	517	889
1.5	Interest and other costs of finance paid	(71)	(161)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	7,244	7,244
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**730**	**1,320**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
(a)	entities	-	-
(b)	businesses	-	-
(c)	property, plant and equipment	-	(9)
(d)	investments	-	-
(e)	intellectual property	-	-
(f)	other non-current assets	-	-
2.2	Proceeds from disposal of:		
(a)	entities	-	-
(b)	businesses	-	-
(c)	property, plant and equipment	-	-
(d)	investments	-	-
(e)	intellectual property	-	-
(f)	other non-current assets		
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**(9)**
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(4,000)	(4,000)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (principal repayments on lease liability in compliance with AASB16)	(184)	(365)
3.10	**Net cash from / (used in) financing activities**	**(4,184)**	**(4,365)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	35,587	35,180
4.2	Net cash from / (used in) operating activities (item 1.9 above)	730	1,320
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(9)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(4,184)	(4,365)
4.5	Effect of movement in exchange rates on cash held	(2)	5
4.60	**Cash and cash equivalents at end of period**	**32,131**	**32,131**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	528	645
5.2	Call deposits	31,603	34,942
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**32,131**	**35,587**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	417
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

Item 6.1 consists of the following:
(a) remuneration paid to the Chief Executive Officer;
(b) director's fees paid to non-executive directors.

7.	Financing facilities *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	Total facility amount at quarter end $A'000	Amount drawn at quarter end $A'000
7.1	Loan facilities	800	369
7.2	Credit standby arrangements	150	25
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**950**	**394**

7.5	**Unused financing facilities available at quarter end**	**556**

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Item 7.1 consists of:
- $0.8M National Australia Bank master asset finance facility for leased laboratory equipment, secured against equipment and a term deposit, interest rate 2.8%.

8.	Estimated cash available for future operating activities	$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	730
8.2	Cash and cash equivalents at quarter end (item 4.6)	32,131
8.3	Unused finance facilities available at quarter end (item 7.5)	556
8.4	Total available funding (item 8.2 + item 8.3)	32,687
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**N/A**

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 31 January 2024

Authorised by: Dr Jeff Davies, Non-Executive Director
(Name of body or officer authorising release – see note 4)

Notes

1 This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2 If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3 Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4 If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5 If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.