ASX Announcement

Quarterly Activities Report & Appendix 4C

Highlights

- *Progress against the company's strategic priorities, including advancing licensing and collaboration opportunities.*
- *Positive feedback from the FDA on the clinical pathway options to registration for DEP® SN38 in Platinum-Resistant Ovarian Cancer in the US, including potential for Fast Track designation and accelerated approval for DEP® SN38.*
- *Advanced DEP® radiopharmaceuticals program and active engagement with potential global collaborators.*
- *VivaGel® BV is expected to launch in Saudi Arabia and the United Arab Emirates (UAE) during the next quarter (Q4 FY25).*
- *Following six months of focused efforts on digital marketing initiatives, including launching a new website, online sales of Viraleze™ are improving, with sales exceeding the prior corresponding period.*
- *Cash balance at 31 December 2024 was $20.3 million.*

Melbourne, Australia; 29 January 2025: Starpharma (ASX: SPL, US OTC: SPHRY), an innovative biotechnology company with two decades of experience in advancing dendrimer technology from the lab to the patient, today releases its Quarterly Activities Report and Appendix 4C for the quarter ended 31 December 2024 (Q2 FY25).

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

"Last quarter was extremely busy for all of us at Starpharma, and the progress we made served as a great reminder to me of the strength and versatility of our unique dendrimer technology, our robust intellectual property, and the multiple commercial opportunities available to a platform technology. From confirming the clinical pathway to commercialisation for DEP® SN38 in the treatment of platinum-resistant ovarian cancer to accelerating our research with early-stage assets and strategic partners, significant strides were made.

"We were particularly pleased by the DEP® SN38 feedback from the FDA, which confirmed the significant unmet medical need for patients with platinum-resistant ovarian cancer, and the potential for Fast Track designation and accelerated approval.

"Our research and development teams are highly focused on producing exceptional outcomes for our partners and internal programs. We have been collaborating closely with Petalion for approximately nine months now, focusing on the development of a single oncology asset, which has allowed us to work quickly and efficiently toward the desired results.

"With a strong emphasis on achieving our strategic objectives, Starpharma concluded 2024 with multiple opportunities to convert our unique dendrimer technology to commercial opportunity in 2025. We look forward to sharing updates with our shareholders this year."

Maximising DEP® Asset Value

Important clinical and regulatory progress for DEP® SN38 (DEP® irinotecan)

In December 2024, Starpharma met with the US Food and Drug Administration (FDA) to discuss the clinical pathway options for DEP® SN38 in Platinum-Resistant Ovarian Cancer (PROC), which the FDA recognises as a patient group with significant unmet medical need. During this meeting, Starpharma received positive feedback from the regulator on the proposed regulatory approval pathways aimed at obtaining registration for DEP® SN38.

The key outcomes from the meeting were:

- The FDA agreed with Starpharma's proposal that DEP® SN38 could be considered for FDA Fast Track designation, acknowledging that PROC is a serious condition with significant unmet medical need.
- The FDA also agreed that a "505(b)(2)" regulatory pathway is appropriate for DEP® SN38, as the product delivers the active moiety of the FDA-approved drug, irinotecan (Camptosar®). The 505(b)(2) pathway allows Starpharma to utilise existing FDA findings of safety and efficacy for an already approved drug, potentially streamlining the approval process by removing the need for some additional studies.
- The FDA indicated that DEP® SN38 may qualify for accelerated approval based on an interim analysis of early surrogate endpoints from the proposed Phase 2/3 clinical trial program. Final outcomes will depend on the results of these studies and the overall data package; however, this accelerated approval pathway could provide early access to DEP® SN38 for patients with platinum-resistant ovarian cancer.

This feedback from the FDA provides confidence for an Investigational New Drug (IND) application for DEP® SN38, a valuable asset for a commercial partner to advance. Additionally, this feedback is also relevant to the DEP® cabazitaxel program.

In parallel with this important clinical and regulatory progress for the DEP® assets, Starpharma's business development team has continued extensive engagement for both DEP® SN38 and DEP® cabazitaxel, which remain the company's top priority.

DEP® platform benefits showcased at multiple industry conferences

During the quarter, Starpharma delivered presentations at several industry conferences, highlighting the advantages of its DEP® platform technology. These events offer valuable opportunities for the company to connect with industry experts and potential collaborators both locally and internationally.

The conferences attended included the Australasian Gastro-Intestinal Trials Group (AGITG) Annual Scientific Meeting in Brisbane, AusBiotech in Melbourne, and the 6th Targeted Radiopharmaceuticals Summit Europe in Amsterdam, Netherlands. Several follow-up meetings have already been held following these events, expanding our network of potential partners and collaborators.

Accelerating Early Asset Development

DEP® radiopharmaceuticals program advances

Starpharma has made important progress in its DEP® radiopharmaceuticals program. During the quarter, several preclinical evaluations were completed, all of which contribute to creating a product that could offer a competitive edge in the HER2-positive (HER2+) cancer market. We are continuing to optimise our assets to achieve the desired characteristics for the products, including the optimal pharmacokinetic and biodistribution profile and the potential for accurate assessment of the HER2 status of tumours throughout the body. These characteristics and the targeted delivery of radioisotopes to tumours, combined with Starpharma's dendrimer technology, could enhance both the patient and clinician experience by providing new options for the effective management of patients with HER2+ cancers.

We are confident that if this program succeeds, Starpharma's HER2 radio products will offer distinct advantages for patients with HER2+ cancers. Given we already have two assets focused on the HER2 target, the decision has been made to redirect the focus of our current ADC program to explore other targets.

Additionally, we are actively engaging with potential collaborators in the radiopharmaceuticals sector to secure more partnerships and further demonstrate the advantages of our dendrimer platform in the development of radiodiagnostic and radiotherapeutic products.

Research collaborations update

Starpharma's research collaborations typically involve companies evaluating the use of Starpharma's dendrimer technology for the development of novel assets. During the quarter, Starpharma has made good progress with its ongoing DEP® partnerships while actively engaging potential future collaborators. The company has also increased its internal chemistry resourcing to meet the growing needs of our collaborators.

On 26 November 2024, Starpharma provided shareholders with an update on the AstraZeneca partnership, whereby both parties agreed to terminate our agreement after almost 18 months of inactivity. Starpharma took this action to provide clarity about the status of the partnership for investors and to allow Starpharma to pursue other opportunities.

Building Long-Term Sustainability

Ongoing initiatives to increase revenue from VivaGel® BV and Viraleze™

ITROM, Starpharma's distribution partner for VivaGel® BV in the Middle East and North Africa (MENA) region, is making significant progress with the product launch in Saudi Arabia and the UAE. Starpharma is preparing to supply the product to ITROM next month, with the product launch expected to follow soon after.

Starpharma is actively engaging with potential partners for licensing VivaGel® BV in Europe, including in the UK, as this region is a key market for the product. Starpharma has already obtained regulatory certification under the new EU Medical Device Regulations.

During the quarter, Starpharma launched a new website for Viraleze™, enhancing the brand positioning and customer experience journey. This initiative is part of several digital activities being undertaken to boost revenue from the product. Online sales of Viraleze™ are showing a positive trend, with sales up 30% compared to the previous corresponding period.

Earlier this month, Starpharma received certification for Viraleze™ under the new European Union (EU) Medical Device Regulations (MDR). Under the new EU MDR classifications, medical device manufacturers must demonstrate compliance with certain essential requirements and undergo a new conformity assessment process with a European-based Notified Body. Achieving EU MDR certification demonstrates that Viraleze™ and the research supporting the product meet the necessary safety and performance standards set by the EU regulatory authorities.

Q2 FY25 Financial Summary

Starpharma's cash balance as at 31 December 2024 was $20.3 million. Customer receipts in the quarter were $0.9 million related to sales of Viraleze™ and VivaGel® BV and R&D service fees. Net operating cash outflows for the quarter were $3.1 million, including research and development (R&D) costs of $1.2 million and staffing costs of $2.5 million, which included a one-off payment of $390,000, as highlighted in the FY24 Remuneration Report. Staffing costs included payments to non-executive and executive directors of $258,000. Other related party payments include $12,238 for consulting services to Centre for Biopharmaceutical Excellence Pty Ltd, of which Starpharma non-executive director Dr Jeff Davies is also a director and shareholder.

About Starpharma

Starpharma (ASX: SPL, US OTC: SPHRY) is an innovative biotechnology company with two decades of experience in advancing dendrimer technology from the lab to the patient. Our mission is to help patients with significant illnesses, such as cancer, achieve improved health outcomes and quality of life through the application of our unique dendrimer technology.

Dendrimers are precise, synthetically manufactured, nanoscale molecules. Their unique properties—including their size, structure, high degree of branching, polyvalency, and water solubility—are advantageous in medical and pharmaceutical applications.

Starpharma's portfolio of dendrimer-based products includes three clinical-stage DEP® (dendrimer enhanced product) assets, preclinical radiopharmaceutical assets, research collaborations, and three commercially marketed over-the-counter (OTC) products.

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

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 the Chair, Mr Rob Thomas.

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

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-24**

	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	866	1,516
1.2	Payments for		
	(a) research and development	(1,242)	(3,417)
	(b) product manufacturing and operating costs	(325)	(756)
	(c) advertising and marketing	(62)	(79)
	(d) leased assets	-	-
	(e) staff costs	(2,452)	(4,959)
	(f) administration and corporate costs	(161)	(317)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	264	561
1.5	Interest and other costs of finance paid	(35)	(72)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	5,527
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,147)**	**(1,996)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(31)
	(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**	**-**	**(31)**
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	(330)	(660)
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)	(197)	(390)
3.10	**Net cash from / (used in) financing activities**	**(527)**	**(1,050)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	23,955	23,360
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,147)	(1,996)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(31)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(527)	(1,050)
4.5	Effect of movement in exchange rates on cash held	(4)	(6)
4.60	**Cash and cash equivalents at end of period**	**20,277**	**20,277**

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	478	531
5.2	Call deposits	19,799	23,424
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)**	**20,277**	**23,955**

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	270
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 (a) remuneration paid to the Chief Executive Officer; (b) director's fees paid to non-executive directors; (c) $12,238 for consulting services to Centre for Biopharmaceutical Excellence Pty Ltd, which Starpharma non-executive director Dr Jeff Davies, is also a director and shareholder.

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	911	332
7.2	Credit standby arrangements	150	19
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**1,061**	**351**

7.5	**Unused financing facilities available at quarter end**	**710**

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)	(3,147)
8.2	Cash and cash equivalents at quarter end (item 4.6)	20,277
8.3	Unused finance facilities available at quarter end (item 7.5)	710
8.4	Total available funding (item 8.2 + item 8.3)	20,987
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**6.7**

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: 29 January 2025

Authorised by: Rob Thomas, Chairman
(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.