starpharma

ASX Announcement

Quarterly Activities Report & Appendix 4C

Highlights

- *Phase 2 clinical trial results of DEP® irinotecan (DEP® SN38) and DEP® cabazitaxel, Starpharma's priority candidates for licensing, were showcased in two oral podium presentations at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.*
- *Highly promising Phase 2 clinical results on DEP® SN38 in advanced colorectal cancer and platinum-resistant ovarian cancer were reported. DEP® SN38 showed clinically meaningful improvements in efficacy compared with published data on the standard-of-care regimens and a consistently improved tolerability profile.*
- *DEP® platform benefits in radiopharmaceuticals were highlighted in a scientific poster presentation at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting.*
- *Starpharma's strategic priorities – 1) maximise DEP® asset value, 2) accelerate early asset development, and 3) build long-term sustainability – were shared with the market following a comprehensive business review led by CEO Cheryl Maley.*
- *Closed the financial year with a cash position of $23.4 million as at 30 June 2024.*

Melbourne, Australia; 30 July 2024: Starpharma (ASX: SPL, OTCQX: SPHRY), dedicated to helping patients with significant illnesses, such as cancer, achieve improved health outcomes and quality of life through the application of our unique dendrimer technology, today releases its Quarterly Activities Report and Appendix 4C for the period ended 30 June 2024 (Q4 FY24).

Starpharma's closing cash balance as at 30 June 2024 was $23.4 million. The net cash outflow for Q4 was $3.2 million, down from Q3, as expected, in line with the completion of the DEP® clinical trials. Net cash outflows for FY24 were $11.8 million (FY23: $14.7 million). The Company is anticipating an inflow of ~$5 million under the Australian Government's R&D Tax Incentive scheme in H1FY25.

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

"Since sharing our strategic priorities with the market in May 2024, the entire team at Starpharma has been highly focused on achieving specific milestones relating to the three strategic imperatives: maximising DEP® asset value, accelerating early asset development, and building long-term sustainability.

"We were pleased to receive positive feedback from investors and other market participants on the details of our strategy. Our immediate focus includes securing a licensing deal for a priority DEP® asset, driving forward the DEP® HER2 radiopharmaceutical assets, advancing our partnerships, and boosting revenue from VivaGel® BV and Viraleze™. We have realigned our internal resources to rigorously pursue these strategic imperatives.

"Starpharma's DEP® presentations at the ASCO and SNMMI annual meetings in June marked an important step towards our goal of maximising DEP® asset value. These presentations showcased the value of the dendrimer technology in chemotherapy, radiopharmaceuticals and other novel applications, and attracted great interest from global companies. Additionally, we have achieved important progress in advancing our DEP® HER2 radiopharmaceutical assets. We have also launched a new Viraleze™ digital marketing campaign and initiated an online brand refresh aimed at enhancing the customer experience and driving revenue growth."

Maximising DEP® Asset Value

Presentations at the American Society of Clinical Oncology (ASCO) Annual Meeting and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

In June 2024, the clinical results of DEP® SN38 and DEP® cabazitaxel were presented as podium presentations at the highly prestigious ASCO Annual Meeting in Chicago, United States. The clinical investigators delivered compelling presentations, highlighting the benefits of dendrimers in advancing chemotherapy options for patients with advanced cancers.

While in the US for ASCO, Starpharma also attended the BIO 2024 Conference in Chicago and delivered a presentation on its radiopharmaceutical program at the SNMMI Annual Meeting in Toronto, Canada. Attending all three of these conferences proved highly valuable from a partnering perspective, as many meetings with companies interested in applying dendrimers to their pipeline products were generated.

Promising Phase 2 clinical results for DEP® SN38

During the quarter, Starpharma was pleased to report positive final results from its Phase 2 clinical trial of DEP® irinotecan (DEP® SN38). The trial met its objectives, with endpoints demonstrating positive anti-tumour efficacy in multiple cancers and confirming the product's favourable safety and tolerability profile. Key efficacy results included longer median progression-free survival (mPFS) compared to published data on irinotecan in advanced colorectal cancer and to standard-of-care (SoC) single-agent therapies in platinum-resistant/ refractory ovarian cancer.

DEP® SN38 was very well tolerated, with a notable lack of gastrointestinal adverse events and no instances of cholinergic syndrome, in contrast to irinotecan. Several patients who have had prolonged responses to therapy and are experiencing ongoing clinical benefit continue to receive access to DEP® SN38 treatment and will be monitored for safety and any changes to their disease.

Ongoing business development activities to maximise DEP® asset value

Following Starpharma's business update in May 2024, the Company has been acutely focused on achieving its goal of securing a DEP® licensing deal and has recruited an additional business development resource to support these efforts.

Accelerating Early Asset Development

DEP® radiopharmaceuticals program advancing towards a clinical study

In the May 2024 business update, Starpharma announced plans to advance its DEP® HER2 radiodiagnostic candidate towards a first-in-human clinical study in 2025. Additionally, the Company presented a scientific poster at the SNMMI Annual Meeting in Toronto, Canada, in June 2024, highlighting the promising utility of dendrimers in precision radiotheranostics for cancer imaging and therapeutic applications.

Presentations at conferences like this are important for demonstrating the advantageous application of dendrimers in radiopharmaceuticals and raising the profile of Starpharma's DEP® platform within the radio imaging and therapeutic community. They also present significant opportunities for business development.

Ongoing collaborations

Starpharma was delighted to host Dr Mehdi Shahidi, CEO of Petalion Therapeutics and Venture Partner at Medicxi, and Shyam Masrani, Principal at Medicxi and Board Chair of Petalion, at its office in Melbourne in June 2024. The visit allowed Starpharma's team to meet Mehdi and Shyam in person and discuss the Petalion project.

Starpharma's partnered research programs, including those with MSD and Genentech, continued during the quarter.

Starpharma's dendrimers to be applied to the research and development of an mRNA vaccine in collaboration with The University of Technology Sydney (UTS) and CSIRO, funded by the Medical Research Future Fund (MRFF)

Starpharma will collaborate with UTS and CSIRO on the research and development of an mRNA vaccine for antimicrobial-resistant (AMR) urinary tract infections (UTIs). The Australian Government's MRFF Global Health Initiative has awarded $1.8 million to this project, which will be led by Associate Professor Iain Duggin from UTS.

As part of the program, Starpharma's DEP® dendrimer technology will be investigated for its ability to improve the formulation and performance of the nanoparticle-based mRNA vaccine candidates being developed by UTS and CSIRO.

If successful, Starpharma's DEP® dendrimers could potentially be investigated for broader application to mRNA vaccines to improve their delivery by providing better encapsulation and greater protection, stability, cellular uptake, and endosomal escape of mRNA in order to achieve the best immunogenic response.

Building Long-Term Sustainability

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

During the quarter, Starpharma successfully achieved regulatory certification of VivaGel® BV under the new EU Medical Device Regulations (MDR), which recently introduced a range of more stringent requirements to demonstrate medical device safety and performance, including an increased need for clinical evidence. Certification under the EU MDR gives renewed certainty about the status of VivaGel® BV in Europe, and is an important factor for potential commercial partners in this region, as the new regulations introduce significant hurdles that other products that make claims for treatment of BV may not be able to overcome.

Starpharma continued working with ITROM Pharmaceutical Group to transfer the VivaGel® BV market authorisations from Mundipharma to ITROM. In parallel, ITROM achieved registration for VivaGel® BV in Saudi Arabia. ITROM is planning to launch VivaGel® BV in Saudi Arabia and the United Arab Emirates (UAE) markets first, following the marketing authorisation transfer for UAE from Mundipharma.

For Viraleze™, as part of Starpharma's focus on increasing revenue, the Company has implemented a targeted digital marketing campaign focused on the UK market and is initiating an online brand refresh to enhance the customer experience and optimise online sales.

In last quarter's update, Starpharma noted the Therapeutic Goods Administration's (TGA) interim decision to amend the Poisons Standard in relation to SPL7013 (astodrimer sodium). The TGA announced its final decision in May 2024, in support of Starpharma's application to amend the Standard. This outcome means that if a nasal spray containing astodrimer sodium were approved for sale in Australia, the product could be labelled appropriately for nasal spray applications and sold in pharmacies. This outcome is separate from, and does not influence, the application for marketing authorisation. Viraleze™ is not approved for use or supply in Australia, where the regulatory review by the TGA for the SPL7013 nasal spray marketing application as a medical device is ongoing.

Q4 FY24 Financial Summary

Starpharma's cash balance as at 30 June 2024 was $23.4 million. Total customer receipts of $1.0 million in the quarter included sales of Viraleze™ and VivaGel® BV and R&D service fees.

Net operating cash outflows for Q4 FY24 were $3.0 million, including research and development (R&D) costs of $1.8 million. As expected, the June quarter outflows decreased from Q3, which had R&D costs of $3.3 million. The Q3 costs included clinical trial close-out expenses associated with the completion of the DEP® cabazitaxel, DEP® docetaxel, and Viraleze™ clinical programs.

Administration and corporate costs for the quarter were $0.3 million. Staffing costs were $2.1 million, including accrued leave entitlements paid to former CEO Jackie Fairley upon the completion of her employment with the company in June 2024. Non-executive and executive directors' fees were $253,000.

Based on Starpharma's 4C, which is appended, the Company's cash balance of $23.4 million as at 30 June 2024 represents eight quarters of cash. Starpharma is focused on increasing revenue and managing resources to extend the Company's cash runway as it continues to prioritise the monetisation of its assets.

About Starpharma

Starpharma ASX: SPL, OTCQX: SPHRY) is dedicated to helping 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	**30-Jun-24**

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1,040	8,412
1.2	Payments for		
	(a) research and development	(1,837)	(11,933)
	(b) product manufacturing and operating costs	(75)	(1,497)
	(c) advertising and marketing	(4)	(29)
	(d) leased assets	-	-
	(e) staff costs	(2,120)	(8,555)
	(f) administration and corporate costs	(307)	(1,927)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	365	1,532
1.5	Interest and other costs of finance paid	(32)	(224)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	7,244
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,970)**	**(6,977)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(58)	(89)
	(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**	**(58)**	**(89)**
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	886	886
3.6	Repayment of borrowings	(888)	(4,888)
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)	(191)	(745)
3.10	**Net cash from / (used in) financing activities**	**(193)**	**(4,747)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	26,589	35,180
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,970)	(6,977)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(58)	(89)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(193)	(4,747)
4.5	Effect of movement in exchange rates on cash held	(8)	(7)
4.60	**Cash and cash equivalents at end of period**	**23,360**	**23,360**

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	531	1,170
5.2	Call deposits	22,829	25,419
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)**	**23,360**	**26,589**

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	253
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.

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	1,575	1,070
7.2	Credit standby arrangements	150	32
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**1,725**	**1,102**

7.5	**Unused financing facilities available at quarter end**	**623**

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)	(2,970)
8.2	Cash and cash equivalents at quarter end (item 4.6)	23,360
8.3	Unused finance facilities available at quarter end (item 7.5)	623
8.4	Total available funding (item 8.2 + item 8.3)	23,983
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**8.1**

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: 30 July 2024

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.