

Quarterly Activities Report & Appendix 4C

Highlights

- *Strategic partnership with Medicxi to develop a novel targeted cancer therapy using Starpharma's dendrimer technology through Petalio Therapeutics was signed and has begun.*
 - *Two abstracts on Starpharma's DEP[®] clinical programs were accepted for oral presentations at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.*
 - *Starpharma's Phase 2 clinical trial of DEP[®] irinotecan as monotherapy and in combination with 5-fluorouracil (5FU) and leucovorin (LV) is nearing database lock. Preparations for analysis of the full data are well underway, with the final data to be released ahead of and presented at the ASCO meeting in early June.*
 - *Closing cash position of \$26.6 million for Q3 FY24, with cash outflows expected to reduce next quarter in line with the completion of the DEP[®] clinical trials.*
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Melbourne, Australia; 30 April 2024: Starpharma (ASX: SPL, OTCQX: SPHRY), which is dedicated to enhancing the quality of life for patients with unmet medical needs, such as cancer, by creating innovative therapies using dendrimer technology, today releases its Quarterly Activities Report and Appendix 4C for the period ended 31 March 2024 (Q3 FY24). Starpharma's closing cash balance as at 31 March 2024 was \$26.6 million.

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

"During my first quarter at Starpharma, the management team and I have conducted a comprehensive review of the business that has shed light on areas of key opportunity and where we must improve and sharpen our focus. It is no secret that our industry is fiercely competitive, and our success hinges on our ability to adapt to evolving market dynamics while staying true to our core purpose of driving better patient outcomes through the application of Starpharma's unique dendrimer technology.

"Starpharma has created substantial value by clinically validating its dendrimer technology platform, DEP[®], through multiple clinical programs. Our ability to successfully treat more than 350 patients with the dendrimer drug delivery technology and demonstrate patient benefit have provided significant benefit to the organisation and have been instrumental in securing collaboration partners, including Genentech, Merck, and Medicxi.

"Our future success requires a renewed emphasis on forging strategic partnerships and collaborations that enhance our licensing opportunities and expand the application of DEP[®] in novel therapies. We aim to be discerning in our choice of collaborators, ensuring that each partnership aligns with our long-term vision and brings tangible value to our shareholders.

"We recently announced our collaboration with Medicxi, kickstarting a highly innovative partnership focused on developing a novel targeted cancer therapy using Starpharma's dendrimer technology. The creation of a new company, Petalio Therapeutics, will allow Petalio to focus on this asset with the goal of accelerating its development. We are very enthusiastic about the potential of this partnership and have already commenced the first phase of work.



“We are pleased to have had two abstracts accepted for oral presentations at the renowned ASCO Annual Meeting in Chicago. The acceptance process for abstracts is highly competitive, and it is even more challenging to get selected for an oral presentation. This opportunity to present our DEP[®] technology in a global forum is a significant achievement for Starpharma and highlights the clinical interest in the positive outcomes of the DEP[®] clinical trials. In addition to presenting the DEP[®] clinical trial results at ASCO during the next quarter, we look forward to presenting data from our radiotheranostics program at the Society of Nuclear Medicine and Molecular Imaging Annual Meeting.

“Our business development activities for the DEP[®] clinical assets are now more focused, with a clearer prioritisation of each asset, potential therapeutic indication, and partner opportunities. We also remain committed to advancing our novel therapy development programs, such as radiopharmaceuticals, with commercial assessments undertaken within the last quarter.

“We are focused on managing costs efficiently to extend our cash runway, and we expect our cash outflows to reduce during Q4 FY24. While our commitment to innovation is unwavering, we recognise the importance of maintaining fiscal discipline to safeguard our financial health and preserve shareholder value. This may necessitate difficult decisions and trade-offs, but any action we take is guided by a steadfast commitment to long-term sustainability and growth.”

New Strategic Partnership With Medicxi To Co-Found Petalion Therapeutics

On 8 April 2024, Starpharma announced a new strategic partnership with Medicxi, a leading life sciences investment firm, to co-found a new UK-based company called Petalion Therapeutics. Petalion will initially focus on developing a novel targeted dendrimer-drug conjugate therapy in oncology, utilising Starpharma’s proprietary DEP[®] dendrimer platform technology.

Medicxi will fund Petalion with an initial investment of up to USD \$25 million (~AUD \$38 million) to finance the development of the novel oncology drug candidate. Starpharma will license certain intellectual property (Starpharma Background IP) to Petalion as required for the research, development, manufacture and commercialisation of this potential new therapeutic and, in exchange, will receive an equity holding of 22.5% in Petalion. Starpharma’s Background IP remains protected and remains the property of Starpharma.

Starpharma hosted an investor webinar on 9 April 2024 to discuss this announcement. A recording of the webinar is available on Starpharma’s website.

DEP[®] Irinotecan And DEP[®] Cabazitaxel Data Accepted For Oral Presentations At The Upcoming American Society Of Clinical Oncology (ASCO) Annual Meeting

Starpharma’s Phase 1/2 clinical data for DEP[®] cabazitaxel and DEP[®] irinotecan have both been accepted for oral presentations at the ASCO Annual Meeting, which will take place in Chicago, US, from 31 May to 4 June 2024.

ASCO is one of the world’s largest conferences for oncology professionals from industry and clinical practice. It provides a forum for presenting clinical trial results for new cancer treatments and updates on the latest advancements and emerging technologies in cancer treatment and care.

Tens of thousands of abstracts are submitted for the ASCO Annual Meeting each year, yet only a small percentage are accepted as posters or oral presentations. This year, only about 7% of the accepted abstracts were granted oral presentations. Acceptance of both the DEP[®] cabazitaxel and DEP[®] irinotecan clinical data for oral presentations is a positive outcome for Starpharma and highlights the interest in the unique features and benefits of the two clinical candidates and the potential of and clinical interest in the DEP[®] technology platform more broadly. The oral presentations will provide a significant opportunity for Starpharma to be featured on a global stage, highlighting the value of the DEP[®] technology.



DEP® Irinotecan Phase 2 Trial Data Analysis Preparations Underway

Starpharma's Phase 2 clinical trial of DEP® irinotecan as monotherapy and in combination with 5-fluorouracil (5FU) and leucovorin (LV) is nearing database lock. Preparations for analysis of the full data are well underway, with the data to be released ahead of and presented at the ASCO meeting in early June. The ASCO presentation will follow on from the interim DEP® irinotecan clinical data that were announced in September 2023 and presented at the International Conference on Molecular Targets and Cancer Therapeutics, co-hosted by the American Association of Cancer Research (AACR), the National Cancer Institute (NCI) and the European Organisation for Research and Treatment of Cancer (EORTC) in October 2023.

Several heavily pre-treated patients with advanced cancers, including platinum-resistant ovarian and colorectal cancers, and who, in some cases, have been receiving DEP® irinotecan treatment in the study for more than 12 months, continue to experience prolonged responses to treatment and significant clinical benefits. These patients will transition to a maintenance protocol that will allow these patients continued access to DEP® irinotecan therapy.

DEP® Radiotheranostic Data Accepted For Poster Presentation At The Society Of Nuclear Medicine And Molecular Imaging (SNMMI) Annual Meeting

Starpharma will present data from its internally developed DEP® HER2 radiotheranostic program at the upcoming SNMMI Annual Meeting, which will be held from 8 to 11 June in Toronto, Canada. The SNMMI Annual Meeting is a leading conference for nuclear medicine and molecular imaging, attracting physicians and radiologists, amongst other industry professionals, to discuss the latest research and development in the field.

Starpharma's R&D program for radiotheranostics has shown promising results, demonstrating that DEP® dendrimers have strong potential as a versatile and multifunctional platform for the customisation of precision radiotheranostics for cancer imaging and therapeutic applications. As Starpharma continues to strengthen its radiopharmaceuticals program, presentation opportunities like the SNMMI Annual Meeting will become increasingly important for highlighting the benefits of dendrimer technology in novel diagnostic and therapeutic areas, including radiopharmaceuticals.

The data, which has been accepted for scientific poster presentation at the SNMMI Annual Meeting, will build on Starpharma's previously reported results on its DEP® HER2 radiotheranostic program.

TGA Interim Decision To Amend The Current Poisons Standard In Relation To SPL7013 (Astodrim® Sodium)

On 3 April 2024, the Therapeutic Goods Administration (TGA) announced an interim decision on Starpharma's requested amendments to the Poisons Standard in relation to astodrim® sodium (SPL7013), Starpharma's proprietary dendrimer that is used in its vaginal gel, condom, and nasal spray products.

Starpharma does not usually comment on these regulatory processes; however, the Company believes it is important to clarify the meaning of the interim decision for shareholders, as we have received questions about this.

The TGA's recent interim decision about astodrim® sodium relates to the Poisons Standard, which specifies how any product containing astodrim® sodium must be labelled, advertised and the channels through which it can be sold, and is separate from the application to approve the SPL7013 nasal spray for sale.

The interim decision to amend the Poisons Standard published this month, and if implemented as a final decision on 1 June 2024, would mean that if a nasal spray containing astodrim® sodium were approved for sale in Australia, the product could be labelled appropriately for nasal spray applications and sold in pharmacies. Starpharma has provided the TGA with its response to the interim decision and will await the final decision.



The regulatory review by the TGA for the SPL7013 nasal spray marketing application as a medical device is ongoing.

Partner Updates During Q3 FY24

Starpharma continued working with ITROM Pharmaceutical Group to transfer the VivaGel® BV market authorisation from Mundipharma to ITROM. This will enable ITROM to launch VivaGel® BV in the Middle East market.

Starpharma's partnered research programs, including those with MSD and Genentech, continued to progress.

Financial Summary

Starpharma's cash balance as at 31 March 2024 was \$26.6 million. Total customer receipts of \$0.4 million in the quarter included sales of Viraleze™ and VivaGel® BV.

Starpharma has previously indicated that its operating costs are expected to begin reducing from previous levels in H2 FY24, and this is still the case. Net operating cash outflows for Q3 FY24 were \$5.3 million, including research and development (R&D) costs of \$3.3 million. This quarter's R&D costs included clinical trial close-out costs of \$1.6 million related to the completion of the DEP® cabazitaxel, DEP® docetaxel, and Viraleze™ clinical programs. With the majority of these clinical trial close-out costs now paid, Starpharma expects its R&D cash outflows to reduce next quarter.

Administration and corporate costs for the quarter were \$0.3 million. Product manufacturing and operating costs were \$0.4 million, including inventory costs. Staffing costs were \$1.9 million, including \$296,000 in non-executive and executive directors' fees.

Starpharma is focused on managing its resources to extend the Company's cash runway as it continues to prioritise the monetisation of its assets.

Shareholder Webinar

Starpharma is preparing to host a shareholder webinar in May and will announce details closer to the time.



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](https://www.linkedin.com/company/starpharma).

* 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
20 078 532 180

Quarter ended ("current quarter")
31-Mar-24

Consolidated statement of cash flows		Current quarter	Year to date (9 months)
		\$A'000	\$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	371	7,372
1.2	Payments for		
	(a) research and development	(3,310)	(10,096)
	(b) product manufacturing and operating costs	(446)	(1,422)
	(c) advertising and marketing	(6)	(25)
	(d) leased assets	-	-
	(e) staff costs	(1,850)	(6,435)
	(f) administration and corporate costs	(333)	(1,620)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	278	1,167
1.5	Interest and other costs of finance paid	(31)	(192)
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	(5,327)	(4,007)
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(22)	(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	(22)	(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	-	(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)	(189)	(554)
3.10	Net cash from / (used in) financing activities	(189)	(4,554)
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	32,131	35,180
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,327)	(4,007)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(22)	(31)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(189)	(4,554)
4.5	Effect of movement in exchange rates on cash held	(4)	1
4.60	Cash and cash equivalents at end of period	26,589	26,589

ASX Listing Rules Appendix 4C (17/07/20)

+ See chapter 19 of the ASX Listing Rules for defined terms.

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

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	1,170	528
5.2	Call deposits	25,419	31,603
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)	26,589	32,131

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current quarter \$A'000
296
-

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.

- 7.1 Loan facilities
7.2 Credit standby arrangements
7.3 Other (please specify)
7.4 Total financing facilities

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
800	332
150	27
-	-
950	359

7.5 Unused financing facilities available at quarter end

591

- 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)	(5,327)
8.2	Cash and cash equivalents at quarter end (item 4.6)	26,589
8.3	Unused finance facilities available at quarter end (item 7.5)	591
8.4	Total available funding (item 8.2 + item 8.3)	27,180
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.1

- 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 April 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.