ASX Announcement

Quarterly Activities Report & Appendix 4C

- New data for DEP® HER2-zirconium, a radiodiagnostic, showed imaging benefits in a HER2-positive (HER2+) breast cancer model, including rapid uptake, high levels of tumour accumulation, and rapid clearance.
- The monotherapy arm of the Phase 2 clinical trial of DEP® irinotecan completed patient enrolment.
- Clinical trial finalisation activities are well advanced for Starpharma's two recently completed Phase 2 clinical trials of DEP® cabazitaxel and DEP® docetaxel as monotherapy. Top-line results are expected to be announced in Q3 CY23.
- The post-market clinical study of VIRALEZE™ nasal spray in people with COVID-19 continued to recruit ahead of schedule, with recruitment now ~90% complete.
- Starpharma achieved regulatory approval for VIRALEZE™ antiviral nasal spray in Malaysia and is progressing discussions with potential regional distributors.
- In June 2023, Starpharma's CEO, Dr Jackie Fairley, announced her intention to retire in 2024 after 17 years. Dr Fairley, the Board and Senior Management team are working closely to ensure a seamless transition.
- Starpharma closed the financial year with a strong cash position of $35.2 million at 30 June 2023.

Melbourne, Australia; 31 July 2023: Starpharma (ASX: SPL, OTCQX: SPHRY) today releases its Quarterly Activities Report and Appendix 4C for the period ended 30 June 2023 (Q4 FY23). Starpharma's closing cash balance as at 30 June 2023 was $35.2 million. Net cash outflows for FY23 totalled $14.7 million, with a net cash outflow of $3.7 million for the June quarter.

"During the quarter, Starpharma made significant progress across multiple DEP® programs and marketed products. We completed recruitment in the monotherapy arm of the Phase 2 clinical trial of DEP® irinotecan, and the Starpharma team is currently working closely with our specialist clinical partners to finalise patient data sets and complete quality control processes, ahead of reporting top-line clinical data from our three Phase 2 clinical trials. Top-line data for DEP® cabazitaxel and DEP® docetaxel as monotherapy are expected in Q3 CY23.

"We look forward to the quarter ahead and a number of important milestones for DEP® and VIRALEZE™. Starpharma closed the year in a strong financial position, with $35.2 million cash in the bank, providing a solid foundation for the future," said **Dr Jackie Fairley**.

DEP® Programs

Starpharma recently announced[1] new data for **DEP® HER2-zirconium**, a HER2-targeted radiodiagnostic product, demonstrating imaging benefits in a HER2+ breast cancer model. These benefits include a favourable biodistribution profile, excellent imaging contrast between tumour and normal tissues, rapid uptake, high levels of tumour accumulation, and rapid clearance. Translated clinically, DEP® HER2-zirconium has the potential to detect cancers more accurately with greater sensitivity than traditional imaging methods.

DEP® HER2-zirconium is a radiodiagnostic product that belongs to the rapidly growing "radiotheranostic" category – which includes both radiodiagnostic and radiotherapeutic products. DEP® HER2-zirconium is designed to specifically diagnose, stage, and monitor HER2+ cancers with greater sensitivity, meaning that patients suffering from these cancers could be diagnosed earlier and monitored more accurately during cancer treatment.

[1] ASX Announcement dated 21 July 2023

As part of Starpharma's research and development in the radiotheranostics area, the Company announced a new partnership with The University of Queensland's Hub for Advanced Manufacture of Targeted Radiopharmaceuticals (AMTAR Hub), which has been awarded $4.8 million from the Australian Government's Australian Research Council. The partnership will allow Starpharma to leverage these specialist capabilities to expedite the development of Starpharma's targeted DEP® radiotheranostic products.

Starpharma completed patient enrolment in the monotherapy arm of the Phase 2 clinical trial of **DEP® irinotecan** during the quarter. With this development, Starpharma has completed enrolment for the monotherapy arms of all three of its Phase 2 clinical trials and is progressing with the final requisite data verification and review process. Starpharma expects to report top-line results for the Phase 2 trial of **DEP® cabazitaxel** and the Phase 2 monotherapy trial of **DEP® docetaxel** in Q3 CY23.

DEP® irinotecan is a highly optimised nanoparticle formulation of SN-38, the active metabolite of irinotecan, which is marketed by Pfizer as Camptosar®. Irinotecan is a common treatment regimen either alone or in combination with other agents for a number of cancers including colorectal cancer. The DEP® irinotecan Phase 2 trial involves both monotherapy and combination arms.

In the monotherapy arm, 88 patients across multiple sites in the UK and Australia have been enrolled. Encouraging results have been seen in patients with multiple cancer types, including colorectal cancer, platinum-resistant ovarian cancer, gastrointestinal cancer, and breast cancer, including durable responses for up to 72 weeks.

Additionally, DEP® irinotecan has demonstrated a significantly better tolerability profile compared to conventional irinotecan. Approximately 20-40% of patients treated with conventional irinotecan experience severe diarrhoea (seven or more bowel movements per day), frequently leading to hospitalisation[2]. However, during treatment with DEP® irinotecan, there have been no reports of severe diarrhoea.

Starpharma has also been progressing well with the combination arms of the DEP® docetaxel and DEP® irinotecan Phase 2 trials. The DEP® docetaxel and gemcitabine combination arm continues to recruit patients, focusing on pancreatic cancer. The DEP® irinotecan and 5-FU/leucovorin (equivalent to the commonly used 'FOLFIRI' regimen) combination arm, which is focused on colorectal cancer, is also progressing well with recruitment ongoing.

Alongside completing the relevant clinical activities for these trials, Starpharma is engaging with various potential partners for these products.

Starpharma notes a positive development, during the quarter, for Sanofi in the US. A key Jevtana® patent was upheld, preventing the sale of generic cabazitaxel formulations in the US until 2030. This is also a positive outcome for Starpharma's DEP® cabazitaxel, which has its own unique suite of patents that extend to at least 2039. This development would likely make DEP® cabazitaxel the only alternative to Jevtana® in the US market, enhancing the value of DEP® cabazitaxel. In contrast to generic products, DEP® cabazitaxel is water-soluble and does not require pre-treatment with corticosteroids or antihistamines.

During the period, Starpharma also progressed with its other preclinical programs in DEP® antibody-drug conjugates (ADCs) and DEP® radiotheranostics. These programs are also the subject of commercial discussions with potential collaboration and licensing partners.

Starpharma continues to make important progress with its DEP® programs with industry leaders MSD and Genentech, as well as Chase Sun. This quarter saw an expansion of our existing partnered DEP® programs. These programs involve the application of Starpharma's DEP® platform to a number of novel therapeutic modalities including antibody-drug conjugates. Starpharma is

[2] H. Bleiberg. & E. Cvitkovic. (1996) Characterisation and Clinical Management of CPT-11 (Irinotecan)-induced Adverse Events. European Journal of Cancer, Volume 32 Supplement 3.

also in discussions with a number of potential new DEP® partners for programs across several therapeutic areas.

On 27 June 2023, Starpharma announced that a voluntary partial clinical hold had been implemented by AstraZeneca on the trial of AZD0466 in patients with advanced haematological malignancies (NCT04865419). AstraZeneca confirmed that the asymptomatic reported events leading to the voluntary partial hold were assessed as not related to Starpharma's DEP® technology.

Marketed Products

Starpharma received regulatory approval for its **VIRALEZE™ antiviral nasal spray** product in Malaysia and is in discussions with potential distribution partners to provide access to the country's population of over 33 million. VIRALEZE™ continues to be marketed in various jurisdictions, including Hong Kong, Macau, Vietnam, Italy, the UK, and Europe. The Company has also expanded its e-commerce channels in the UK, making VIRALEZE™ available to consumers in the UK through a dedicated product website and Amazon UK, in addition to its arrangement with LloydsPharmacy. Starpharma is also actively working on bringing VIRALEZE™ to new markets, with active commercial discussions with potential partners in several countries. 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.

Starpharma's post-market clinical study of VIRALEZE™ in individuals with COVID-19 will support marketing activities. The study is recruiting ahead of schedule, with recruitment now ~90% complete.

Starpharma's **VivaGel® BV** product continues to be marketed by its partners, with registrations and product launches planned in additional markets, including the Middle East and Southeast Asia. During the quarter, iNova Pharmaceuticals (iNova) announced the acquisition of part of Mundipharma's consumer health product portfolio. In the United States, a formal dispute resolution process is ongoing with the FDA for VivaGel® BV. As previously reported, Starpharma plans to lodge a further submission to the FDA, which will include precedents of other FDA approvals.

Corporate

During the quarter, Starpharma's CEO, Dr Jackie Fairley, advised the Board of her intention to retire in 2024. An international search process is underway and Dr Fairley, the Board, and the senior executive team are working closely to facilitate a seamless transition.

Cash Flows for the Quarter

Starpharma's cash balance as at 30 June 2023 was $35.2 million, with net cash outflows of $3.7 million for Q4 FY23. Receipts from customers for FY23 were $3.1 million, with $0.9 million for Q4. Receipts from customers include VIRALEZE™ and VivaGel® BV product sales, royalties, and research revenues. Cash outflows for the quarter comprised research and development costs of $1.9 million related to Starpharma's internal DEP® clinical programs, which are at advanced stages, with monotherapy enrolment now complete for all three trials, as well as preclinical targeted DEP® programs. Product manufacturing and operating costs were $0.4 million. Staffing costs were $2.0 million and include non-executive and executive directors' fees of $263,000. Other related party payments include $6,636 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 Holdings Limited (ASX: SPL, OTCQX: SPHRY) is a biopharmaceutical company, focused on developing pharmaceutical and medical products for unmet patient needs, including oncology and infectious diseases.

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 antiviral nasal spray, VIRALEZE™, is now registered in more than 30 countries*, including Europe, the UK, and Southeast 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 45 countries, including in the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.

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

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Disclosure
This ASX Announcement was authorised for release by Chair, Mr Rob Thomas.

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.

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-23**

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	919	3,085
1.2	Payments for		
	(a) research and development	(1,916)	(10,152)
	(b) product manufacturing and operating costs	(357)	(4,097)
	(c) advertising and marketing	(48)	(208)
	(d) leased assets	-	-
	(e) staff costs	(2,004)	(8,500)
	(f) administration and corporate costs	(393)	(1,724)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	366	1,194
1.5	Interest and other costs of finance paid	(83)	(277)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	7,146
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,516)**	**(13,533)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(70)	(621)
	(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	9	11
	(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**	**(61)**	**(610)**
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	-	-
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)	(178)	(695)
3.10	**Net cash from / (used in) financing activities**	**(178)**	**(695)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	38,897	49,918
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,516)	(13,533)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(61)	(610)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(178)	(695)
4.5	Effect of movement in exchange rates on cash held	38	100
4.60	**Cash and cash equivalents at end of period**	**35,180**	**35,180**

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	1,661	3,074
5.2	Call deposits	33,519	35,823
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)**	**35,180**	**38,897**

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	269
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; and
(b) director's fees paid to non-executive directors.
(c) $6,636 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	5,578	5,219
7.2	Credit standby arrangements	150	14
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**5,728**	**5,233**

7.5	**Unused financing facilities available at quarter end**	**495**

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 existing National Australia Bank master asset finance facility for leased laboratory equipment, secured against equipment and a term deposit, interest rate 2.8%.
- $4.0M Invest Victoria R&D cash flow loan with Treasury Corporation of Victoria maturing Oct-2023, secured against future refundable R&D tax incentives, current interest rate 4.3%.
- $0.8M IQumulate insurance premium loan maturing Dec-2023, interest rate 3.0%.

Item 7.2 is a National Australia Bank corporate credit card facility (rate 12.65%).

8.	Estimated cash available for future operating activities	$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,516)
8.2	Cash and cash equivalents at quarter end (item 4.6)	35,180
8.3	Unused finance facilities available at quarter end (item 7.5)	495
8.4	Total available funding (item 8.2 + item 8.3)	35,675
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**10.1**

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: 31 July 2023

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.