ASX Announcement

Quarterly Activities Report & Appendix 4C

Highlights:

- Completed enrolment and treatment of patients for the Phase 2 clinical trial of DEP® cabazitaxel
- Completed enrolment and treatment of patients for the Phase 2 monotherapy trial of DEP® docetaxel
- AstraZeneca AZD0466 DEP® program reported encouraging results and progress at international oncology conference:
    - AZD0466 well tolerated in patients with advanced solid tumours, with efficacy signals (stable disease) in 33% of patients for up to 5.5 months
    - Dose escalation continues in the global Phase 1/2 trial of AZD0466 in advanced haematological malignancies; initial efficacy signals observed from AZD0466 in patients through reduction of bone marrow blasts and no dose-limiting toxicities reported to date
    - AZD0466 also shown to be active in preclinical small cell lung cancer (SCLC) models, including models resistant to the current standard-of-care treatments for SCLC
- Starpharma's HER2-targeted DEP® SN-38 antibody-drug conjugate (ADC) shown to outperform the approved ADC product, Enhertu®[1], with significant anti-tumour activity and improved survival in a HER2+ human ovarian cancer xenograft model
- Post-market clinical study of VIRALEZE™ nasal spray in people with COVID-19 is well advanced, with more than 70% of participants recruited to date
- Strong cash position of $38.9 million at 31 March 2023

Melbourne, Australia; 28 April 2023: Starpharma (ASX: SPL, OTCQX: SPHRY) today releases its Quarterly Activities Report and Appendix 4C for the period ended 31 March 2023 (Q3 FY23). Starpharma's net operating cash outflows for the quarter were $4.9 million, and the closing cash balance as at 31 March 2023 was $38.9 million.

Internal Clinical DEP® Programs

Starpharma has now completed enrolment and treatment of patients for both of its Phase 2 monotherapy clinical trials of DEP® cabazitaxel and DEP® docetaxel.

The Phase 2 clinical trial of **DEP® cabazitaxel** enrolled a total of 76 patients across sites in the United Kingdom (UK) and Australia, with the final patient having recently completed treatment. Encouraging efficacy signals, including significant tumour shrinkage and substantial tumour biomarker reductions, have been observed in multiple cancer types, including prostate, ovarian, gastro-oesophageal, cholangiocarcinoma, and head and neck cancer, following treatment with DEP® cabazitaxel. Starpharma and its specialist clinical research organisation are now focused on follow-up and finalising the patient data set and quality control processes. At this stage, Starpharma expects to report top-line results from the

[1] ENHERTU® is a registered trademark of Daiichi Sankyo Company Limited. Enhertu® comprises the humanised monoclonal antibody/HER2-directed antibody, trastuzumab, covalently linked to a topoisomerase I inhibitor payload, DXd (an exatecan derivative)

Phase 2 clinical trial of DEP® cabazitaxel during Q3 CY23, following the final requisite data verification and review.

The Phase 2 trial of **DEP® docetaxel** has also now completed both enrolment and treatment of patients in the monotherapy arm. A total of 80 patients have been enrolled across the monotherapy and combination arms of the DEP® docetaxel clinical trial to date.

The DEP® docetaxel clinical program includes two combination arms: the already completed DEP® docetaxel plus nintedanib arm in lung cancer and the ongoing DEP® docetaxel plus gemcitabine arm, which is focused on pancreatic cancer. In the Phase 2 monotherapy arm of the DEP® docetaxel trial, a total of 50 patients have been enrolled across multiple sites in the UK. Encouraging efficacy signals, including prolonged stable disease and significant tumour shrinkage, have been observed in heavily pre-treated patients (typically having failed multiple other treatments, including taxanes) with cancers including pancreatic, gastro-oesophageal and cholangiocarcinoma. Patients treated with DEP® docetaxel did not experience any hypersensitivity reactions, including anaphylaxis, and had a notable lack of bone marrow toxicity (e.g., neutropenia) and other common side effects such as hair-loss, mouth ulcers and oedema, as compared to conventional docetaxel. Both neutropenia and severe hypersensitivity/anaphylaxis are considered serious toxicities associated with conventional docetaxel treatment, and can be dose limiting and potentially fatal. Recruitment for the DEP® docetaxel and gemcitabine combination arm is ongoing, and Starpharma expects to report the results of the DEP® docetaxel monotherapy and available combination data during Q3 CY23.

Starpharma's Phase 2 clinical trial of **DEP® irinotecan** continued to progress during the quarter, with 94 patients now recruited across both the monotherapy and the 5-FU/leucovorin (equivalent to the commonly used 'FOLFIRI' regimen) combination arms. Starpharma is continuing to enrol patients in this trial, with recruitment for the monotherapy cohort in the final stages. Encouraging efficacy signals with DEP® irinotecan have been observed in multiple tumour types, including colorectal, breast, pancreatic, lung, and oesophageal, including in heavily pre-treated patients, some of whom have failed to respond to previous treatment with conventional irinotecan.

In parallel with completing enrolment and treatment of patients in these clinical trials, licensing activities are ongoing for all three products as part of Starpharma's DEP® commercialisation strategy.

Partnered DEP® Programs

AstraZeneca recently presented new clinical and preclinical data on **AZD0466** at the 2023 AACR Annual Meeting held in Orlando, Florida. Newly released clinical data from AstraZeneca's first-in-human trial (NCT04214093), which treated 9 patients with advanced solid tumours, showed that AZD0466 was well tolerated, with efficacy signals (stable disease) observed in 33% of patients for up to 5.5 months. AstraZeneca's AZD0466 poster at the AACR Annual Meeting also included updated clinical data from the ongoing global Phase 1/2 clinical trial of AZD0466 in patients with advanced haematological malignancies (NCT04865419). This trial has now treated 24 patients at doses up to 3600mg, with patient treatment ongoing and further dose escalations planned. Initial clinical activity has been observed through reduction of bone marrow blasts following AZD0466 treatment, with the mean treatment duration being 4.4 months to date.

In addition to these new clinical data, AstraZeneca also presented results from a preclinical study of AZD0466 in patient-derived small cell lung cancer (SCLC) models at the AACR Annual Meeting. SCLC is an aggressive form of lung cancer with limited treatment options and

a five-year survival rate of ~7%[2]. The positive results presented showed that AZD0466 was active in 50% of SCLC models, with regression in 33% of models. Notably, AZD0466 was active in models resistant to the standard-of-care treatment for SCLC patients (platinum/etoposide), and also outperformed the marketed BcL-2 inhibitor, venetoclax, in 60% of models.

Both clinical trials of AZD0466 in patients with advanced haematological malignancies (NCT04865419) or non-Hodgkin lymphoma (NCT05205161) continue to progress, with recruitment ongoing at sites in the USA, Europe, Asia, and Australia.

In parallel with the recent and upcoming developments of AZD0466, Starpharma's DEP® partnerships with MSD, Genentech and Chase Sun continue to progress well, with significant activity across our partnered programs during the quarter.

Internal Preclinical DEP® Programs

Alongside advancing Starpharma's internal clinical DEP® programs, the Company continued to progress its preclinical programs in the areas of DEP® antibody drug conjugates (ADCs) and DEP® radiotheranostics, which are also the subject of other commercial and collaborative discussions.

This week, Starpharma announced[3] results for a new DEP® ADC, **HER2-targeted DEP® SN-38 ADC**, which demonstrated significant anti-tumour activity ($p<0.0001$) and improved survival in a HER2+ human ovarian cancer model (SKOV-3), outperforming the marketed HER2 ADC, Enhertu®. ADCs represent an innovative area of cancer treatment, with the global ADC market expected to reach USD ~$22.9 billion in 2030[4]. Starpharma's DEP® platform delivers a number of advantages in ADCs, including its ability to achieve higher drug-to-antibody ratio (DAR), and therefore higher drug payload, than conventional ADCs; its greater flexibility in terms of linker strategies to precisely control drug release profiles; and its ability to widen the therapeutic index of toxic drug payloads.

Marketed Products

Marketing and commercialisation of Starpharma's nasal spray, VIRALEZE™, continues in Europe, UK, Italy, Vietnam, Hong Kong and Macau. In Hong Kong, Starpharma's distribution partner, Hengan, recently partnered VIRALEZE™ with the Hong Kong Premier League football club, Kitchee SC. In addition to distribution through LloydsPharmacy UK, Starpharma has recently expanded the VIRALEZE™ e-commerce channels in the UK. Product is expected to also be available through a dedicated VIRALEZE™ product UK webstore within the next week and through other online channels within the next month. VIRALEZE™ is not approved for use or supply in Australia, and these additional online channels in the UK are not accessible in Australia. In parallel, Starpharma continues to pursue registration and commercialisation of VIRALEZE™ in other countries, with the Company continuing to focus on commercially attractive markets with rapid regulatory pathways.

Starpharma's post-market clinical study of VIRALEZE™ nasal spray in people with COVID-19 is recruiting well, with more than 70% of participants enrolled to date. The study continues to enrol participants at Ashford and St Peter's Hospitals NHS Foundation Trust (ASPH) in the southwest London region and surrounding areas. As previously announced, the results from

[2] Gazdar A et al. Nat Rev Cancer 2017
[3] ASX Announcement titled, 'HER2-targeted DEP SN38 ADC outperforms in HER2 cancer model', dated 26 April 2023
[4] https://www.grandviewresearch.com/industry-analysis/antibody-drug-conjugates-market

this post-market clinical study in COVID-19-positive participants will support ongoing marketing, regulatory and commercial activities for VIRALEZE™.

In Australia, the review by the Therapeutic Goods Administration (TGA) for the SPL7013 nasal spray as a medical device is ongoing.

During the quarter, Starpharma supplied product to both of its **VivaGel® BV** partners, Mundipharma and Aspen, to support sales and marketing activities in their licensed regions. Further VivaGel® BV registrations and product launches are planned in the Middle East and Southeast Asia. Product has been supplied to these regions and launch activities are well advanced. Marketing campaigns by partners to build brand awareness and sales are ongoing, including for consumer and healthcare professional audiences.

In the United States, a formal dispute resolution process is ongoing with the FDA for VivaGel® BV. As part of this process, Starpharma has had extensive external advice, met with the FDA multiple times, and made a number of submissions of data and analyses to the FDA. The Company is preparing to lodge a further submission to the FDA this year. This submission will include precedents of other FDA approvals with the timing of lodgement now governed by the publication and incorporation of the relevant precedent information.

Commenting on the quarter, Starpharma CEO, Dr Jackie Fairley, said: "Starpharma's DEP® technology is showing continued momentum across our commercial partnerships and in-house programs. We are pleased to report completion of recruitment and treatment for both our Phase 2 monotherapy trials of DEP® docetaxel and DEP® cabazitaxel in parallel with partner presentations at international conferences and recent results for Starpharma's HER2-targeted DEP® antibody drug conjugate.

"It was exciting to see Starpharma's commercial partner, AstraZeneca, present new clinical data for our partnered DEP® product, AZD0466, in advanced solid tumours where they reported good tolerability across the cohort as well as stable disease in 33% of patients. In addition, patient recruitment and dose escalation continue in the two global Phase 1/2 trials of AZD0466 in haematological malignancies, with no dose-limiting toxicities reported to date and initial clinical activity observed in patients.

"Starpharma's post-market clinical study of VIRALEZE™ in people with COVID-19 is recruiting ahead of schedule in the UK, with more than 70% of participants enrolled to date. Marketing and commercialisation activities for VIRALEZE™ continue, including in Hong Kong, Vietnam, UK, and Europe, alongside regulatory activities in other countries."

Cash Flows for the Quarter

Starpharma's cash balance as at 31 March 2023 was $38.9 million, with net operating cash outflows of $4.9 million for the quarter. Receipts from customers were $0.6 million, including from VIRALEZE™ and VivaGel® BV product sales. Cash outflows of $2.4 million for research and development includes the costs for Starpharma's internal DEP® clinical programs, which are at advanced stages, having recently completed recruitment for both DEP® cabazitaxel and DEP® docetaxel monotherapy. Product manufacturing and operating costs were $1.2 million and include inventory and manufacturing costs related to the ongoing supply of VIRALEZE™ and VivaGel® BV. Staffing costs were $2.0 million and include non-executive and executive directors' fees of $252,000.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a biopharmaceutical company, focussed on the development of pharmaceutical and medical products for unmet patient needs, including in the areas of 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 in Europe, in the UK, and in Southeast Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel® BV, for treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 45 countries, including in the UK, in Europe, in 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 Non-Executive Director, Dr Jeff Davies.

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	**31-Mar-23**

Consolidated statement of cash flows		**Current quarter** $A'000	**Year to date (9 months)** $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	592	2,166
1.2	Payments for		
(a)	research and development	(2,391)	(8,236)
(b)	product manufacturing and operating costs	(1,225)	(3,740)
(c)	advertising and marketing	(49)	(160)
(d)	leased assets	-	-
(e)	staff costs	(2,010)	(6,496)
(f)	administration and corporate costs	(164)	(1,331)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	380	828
1.5	Interest and other costs of finance paid	(71)	(194)
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**	**(4,938)**	**(10,017)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
(a)	entities	-	-
(b)	businesses	-	-
(c)	property, plant and equipment	(87)	(551)
(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	1	2
(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**	**(86)**	**(549)**
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)	(177)	(517)
3.10	**Net cash from / (used in) financing activities**	**(177)**	**(517)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	44,038	49,918
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,938)	(10,017)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(86)	(549)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(177)	(517)
4.5	Effect of movement in exchange rates on cash held	60	62
4.60	**Cash and cash equivalents at end of period**	**38,897**	**38,897**

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	3,074	1,642
5.2	Call deposits	35,823	42,396
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)**	**38,897**	**44,038**

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	252
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.

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	4,800	4,477
7.2	Credit standby arrangements	150	16
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**4,950**	**4,493**

7.5	**Unused financing facilities available at quarter end**	**457**

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 3.8%.

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)	(4,938)
8.2	Cash and cash equivalents at quarter end (item 4.6)	38,897
8.3	Unused finance facilities available at quarter end (item 7.5)	457
8.4	Total available funding (item 8.2 + item 8.3)	39,354
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**8.0**

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: 28 April 2023

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.