ASX Announcement

Quarterly Activities Report & Appendix 4C

Highlights:

- **Preliminary clinical trial data showed AZD0466 to be well tolerated at multiple escalating doses in patients with advanced relapsed/refractory leukemia, as presented by AstraZeneca at the American Society of Hematology (ASH) 2022 Annual Meeting**
- **Internal Phase 2 DEP® trials are expected to complete recruitment soon, with the final patient in screening for DEP® docetaxel and a small number of patients to be recruited into the final monotherapy cohorts in the DEP® cabazitaxel and DEP® irinotecan trials**
- **Continued commercialisation and registrations of VIRALEZE™ across Asia, including the launch of VIRALEZE™ in Hong Kong and Macau by Hengan, and the registration of VIRALEZE™ in Indonesia**
- **Commencement of recruitment in the UK for the post-market clinical study of VIRALEZE™ nasal spray in patients with COVID-19**
- **Strong cash position with a closing cash balance of $44.0 million as at 31 December 2022, including receipt of a $7.1 million R&D tax incentive refund**

Melbourne, Australia; 30 January 2023: **Starpharma Holdings Limited** (ASX: SPL, OTCQX: SPHRY) today releases its Quarterly Activities Report and Appendix 4C for the period ended 31 December 2022 (Q2 FY23).

Starpharma's cash balance as at 31 December 2022 was $44.0 million, with a positive net operating cash flow of $2.2 million for the quarter. Total receipts of $8.1 million in the quarter include $7.1 million received from the Australian Government under its R&D tax incentive scheme[1] and receipts from customers of $1.0 million. Customer receipts, including from sales of VIRALEZE™ and VivaGel® BV, were up 59% from the previous quarter (Q1 FY23: $0.6 million).

Partnered DEP® Programs

During Q2 FY23, Starpharma announced preliminary **AZD0466**[2] safety and tolerability results from AstraZeneca's ongoing Phase 1/2 clinical trial in patients with advanced relapsed/refractory leukemia (NCT04865419). The preliminary safety and tolerability results from 18 patients showed that AZD0466 was very well tolerated at multiple escalating dose levels (between 75 mg and 2400 mg), with no dose-limiting toxicities (DLTs) reported and no discontinuations due to treatment-related adverse events. The data showing increased patient numbers and significantly higher doses, with no DLTs, are significant in the context of the clinical trial. These preliminary results were presented by AstraZeneca at the American Society of Hematology (ASH) Annual Meeting in December 2022. This Phase 1/2 clinical trial continues with further dose escalations planned. AstraZeneca is currently enrolling patients at

[1] See company announcement dated 23 December 2022.

[2] AZD0466 is a highly optimised dendrimer nanoparticle formulation of AstraZeneca's dual Bcl-2/xL inhibitor, which utilises Starpharma's DEP® technology and is being developed by AstraZeneca under their multi-product DEP® license with Starpharma.

17 sites across the United States, Europe, Asia and Australia, with more than 30 sites expected to participate in the study.

AZD0466 is also the subject of a second Phase 1/2 clinical trial in patients with advanced non-Hodgkin lymphoma (NCT05205161). AstraZeneca is enrolling patients into this trial at six sites across the United States, Korea and Italy, with 18 additional sites planned.

Starpharma's other partnered DEP® programs with MSD, Genentech, and Chase Sun continued to progress well during the quarter. These partnered programs include DEP® antibody drug conjugates (ADCs) and other DEP® products across both oncology and anti-infectives. These and other DEP® programs continue to be the subject of active discussions with Starpharma's partners, including at the J.P. Morgan Healthcare Conference in January 2023. Meetings held at the JPM Conference included both new and existing partners.

Internal DEP® Programs

Starpharma's internal clinical DEP® programs continue to advance, and are approaching completion of recruitment.

The **DEP® docetaxel** clinical program continued to progress during the quarter, with 76 patients enrolled across the monotherapy and combination arms. The monotherapy arm is expected to complete recruitment within the next month, with the final patient now in screening. The DEP® docetaxel and gemcitabine combination arm continues to recruit. Encouraging efficacy signals have been observed, including in heavily pre-treated patients with lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers.

The **DEP® cabazitaxel** Phase 2 trial has enrolled 76 patients to date, with the final patients with specific tumour types currently being screened and scheduled for treatment. Recruitment is expected to complete within the next 1-2 months. Data analyses and biostatistics activities are already underway. Starpharma has previously reported promising interim results from the prostate cancer cohort[3] of this trial. Other encouraging observations include significant tumour shrinkage and substantial tumour biomarker reductions in heavily pre-treated patients with advanced ovarian, gastro-oesophageal, cholangiocarcinoma, and head and neck cancers.

The **DEP® irinotecan** Phase 2 trial continued to progress during the quarter, with 89 patients now recruited across both the monotherapy and combination arms. Final recruitment for the monotherapy arm is focused on platinum resistant ovarian cancer, where particularly encouraging responses have been observed, and is expected to complete within 2 months. Encouraging efficacy signals with DEP® irinotecan have also been observed in heavily pre-treated patients with multiple other tumour types, including colorectal, breast, pancreatic, lung, and oesophageal cancers.

Starpharma continue commercial discussions with potential licensing partners for these internal DEP® assets, as well as other commercial and collaborative discussions for other DEP® programs and opportunities. Starpharma's internal preclinical DEP® programs, including DEP® radiotheranostics and DEP® ADCs, continue to progress in parallel.

[3] See company announcement dated 12 September 2022.

Marketed Products

Soon after signing a sales and distribution agreement with Hengan[4], **VIRALEZE™** nasal spray was launched in Hong Kong and Macau both online and in major pharmacy and retail outlets, Mannings; and PARKnSHOP, which is part of the A.S. Watson Group. The VIRALEZE™ rollout continues to be supported with marketing activities by Hengan, including advertising on television, newspapers and online platforms; billboards; and in-store promotion.

VIRALEZE™ sales and marketing activities also continue elsewhere, including in the UK, Italy, and Vietnam where Starpharma has distribution arrangements in place. In December 2022, Starpharma achieved VIRALEZE™ registration in Indonesia[5], a country with a population of more than 280 million. Starpharma continues to pursue registration and commercialisation activities for VIRALEZE™ in multiple other countries, with a focus on commercially attractive markets with rapid regulatory pathways. In Australia, the review by the Therapeutic Goods Administration (TGA) for the SPL7013 nasal spray as a medical device is ongoing.

New data generated by Scripps Research in the US on the efficacy of VIRALEZE™ against SARS-CoV-2 Omicron infection in an animal challenge model were presented at international virology conference, Respi DART[6], held in Mexico in December 2022[7]. In the study presented, VIRALEZE™ essentially eliminated SARS-CoV-2 Omicron virus (≥99.99% reduction in viral load compared with saline-treated animals) in the lung and trachea of virus-challenged animals, even when VIRALEZE™ was administered only after animals were exposed to virus. VIRALEZE™-treated animals also exhibited significantly reduced proinflammatory cytokines compared with saline-treated animals; and achieved normal body weight gain compared to significant weight loss observed in saline-treated animals. Collectively, the results from this experiment indicate that VIRALEZE™ provides protection against SARS-CoV-2 infection and disease in animals challenged with the virus[8].

In December 2022, Starpharma commenced recruitment in the UK for a post-market clinical study of VIRALEZE™. The study is enrolling patients with COVID-19 at Ashford and St Peter's Hospitals NHS Foundation Trust (ASPH) in the UK. The post-market study will support ongoing marketing and commercial activities and will build on the positive in-market experience with the product.

Starpharma continues to work with its **VivaGel® BV** partners, Mundipharma and Aspen. Further VivaGel® BV registrations and product launches are planned in the Middle East and Philippines. Marketing campaigns by partners to build brand awareness and sales are ongoing, including for consumer and healthcare professional audiences.

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[4] See company announcement dated 21 October 2022.

[5] See company announcement dated 14 December 2022.

[6] Respi DART brings together key opinion leaders and experts from around the world to discuss innovative strategies to tackle respiratory virus disease, including the SARS-CoV-2 pandemic.

[7] See AGM Presentation dated 29 November 2022 (pp. 35 – 36)

[8] Gallay PA, et al. Utility of 1% astodrimer sodium nasal spray for pandemic preparedness demonstrated by broad-spectrum antiviral effects and protection against SARS-CoV-2 Omicron, and Influenza A and B virus infection. *Global Antiviral Journal (Online)* 2022; Abstract RP4, HIV & Respi DART 2022 Abstract Booklet.

Commenting on the Quarter's highlights, Starpharma CEO, Dr Jackie Fairley, said:

"Starpharma continues to progress and drive value through its multiple internal and external DEP® programs, including AZD0466, and its marketed product pipeline. We continue to maintain a strong cash position and were pleased to receive $7.1 million from the Federal Government's R&D tax incentive scheme this quarter. Starpharma has continued to progress its multiple DEP® partnerships with AstraZeneca, MSD, Genentech and Chase Sun. In parallel, Starpharma's internal Phase 2 DEP® trials are expected to complete recruitment soon, with only a handful of patients to be recruited into the monotherapy arms.

"It was exciting to attend the ASH Meeting in December to hear firsthand the presentation of updated preliminary clinical data in relation to AZD0466, and to engage with AstraZeneca. AZD0466 is a novel dendrimer nanoparticle, which was developed under Starpharma's multiproduct license with AstraZeneca. The preliminary results presented showed AZD0466 to be very well tolerated in patients with advanced relapsed/refractory leukemia, with no dose-limiting toxicities reported.

"Starpharma also continues to expand the sales and distribution of its antiviral nasal spray, VIRALEZE™, with the product launched in Hong Kong and Macau and the registration of VIRALEZE™ in Indonesia during the quarter. Our post-market clinical study of VIRALEZE™ also commenced in the UK. This will support ongoing marketing and commercialisation of VIRALEZE™."

"The Company looks forward to continuing this momentum and activity in calendar year 2023."

Cash Flows

Starpharma's closing cash balance as at 31 December 2022 was $44.0 million, with net operating cash inflows of $2.2 million for the quarter. Total receipts of $8.1 million in the quarter includes $7.1 million received under the Australian Government's R&D Tax Incentive scheme and receipts from customers of $1.0 million. Customer receipts include sales from VIRALEZE™ and VivaGel® BV. R&D cash outflows of $2.6 million include clinical trial costs for Starpharma's ongoing internal DEP® clinical programs. Product manufacturing and operating costs were $0.9 million and include inventory and manufacturing costs related to the ongoing supply of VIRALEZE™ and VivaGel® BV. Staffing costs were $2.6 million and include non-executive and executive directors' fees of $442,000. Other related party transactions include $7,000 for consulting services to Centre for Biopharmaceutical Excellence Pty Ltd, which Starpharma non-executive director Dr Jeff Davies is also a director and shareholder. Cash outflows from investing activities of $0.4 million reflects investment in new scientific equipment for Starpharma's laboratories.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for DEP® drug delivery, respiratory viruses and VivaGel®.

Starpharma's proprietary drug delivery platform technology, DEP®, is being used to improve pharmaceuticals to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP® versions of existing drugs, particularly in the area of anti-cancer therapies.

DEP® partnerships include oncology programs with AstraZeneca, with MSD in the area of Antibody Drug Conjugates (ADCs), with Chase Syn in the area of anti-infectives, and with other world leading pharmaceutical companies. Partnered DEP® programs have the potential to generate significant future milestones and royalties.

Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered in a number of countries, including in Europe and the UK. VIRALEZE™ is not approved for use or supply in Australia. SPL7013 is also utilised in the following products: VivaGel® condom and VivaGel® BV. VivaGel® products have been licensed in >160 countries and are registered in >45 countries, including the in UK, in Europe, Japan, in Southeast Asia, South Africa, Australia, and New Zealand.

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Disclosure
This ASX Announcement was authorised for release by the 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	**31-Dec-22**

Consolidated statement of cash flows		**Current quarter** $A'000	**Year to date (6 months)** $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	959	1,574
1.2	Payments for		
	(a) research and development	(2,547)	(5,845)
	(b) product manufacturing and operating costs	(870)	(2,515)
	(c) advertising and marketing	(44)	(111)
	(d) leased assets	-	-
	(e) staff costs	(2,620)	(4,486)
	(f) administration and corporate costs	(24)	(1,167)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	281	448
1.5	Interest and other costs of finance paid	(67)	(123)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	7,135	7,146
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**2,203**	**(5,079)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(363)	(464)
	(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	1
	(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**	**(362)**	**(463)**
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)	(171)	(340)
3.10	**Net cash from / (used in) financing activities**	**(171)**	**(340)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	42,343	49,918
4.2	Net cash from / (used in) operating activities (item 1.9 above)	2,203	(5,079)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(362)	(463)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(171)	(340)
4.5	Effect of movement in exchange rates on cash held	25	2
4.60	**Cash and cash equivalents at end of period**	**44,038**	**44,038**

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	1,642	2,180
5.2	Call deposits	42,396	40,163
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)**	**44,038**	**42,343**

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	448
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;
(b) director's fees paid to non-executive directors; and
(c) $6,600 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	4,800	4,513
7.2	Credit standby arrangements	150	17
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**4,950**	**4,530**

7.5	**Unused financing facilities available at quarter end**	**420**

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 3.3%.

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)	2,203
8.2	Cash and cash equivalents at quarter end (item 4.6)	44,038
8.3	Unused finance facilities available at quarter end (item 7.5)	420
8.4	Total available funding (item 8.2 + item 8.3)	44,458
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**N/A**

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 January 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.