ASX Announcement

Quarterly Activities Report & Appendix 4C

Highlights

- **Expanded DEP® Research Agreement with a large US biopharmaceutical company**
- **VIRALEZE™ relaunched in the UK through LloydsPharmacy**
- **VIRALEZE™ demonstrated highly protective effects against the Omicron variant of SARS-CoV-2 in a viral challenge model**
- **AstraZeneca expanded AZD0466 clinical program and initiates recruitment at multiple new trial sites in the US, Europe, Asia Pacific**
- **SPL7013 in VIRALEZE™ demonstrated virucidal activity against influenza A and B viruses**
- **Well-funded with a cash balance of $49.9 million**

Melbourne, Australia; 29 July 2022: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Quarterly Activities Report and Appendix 4C for the period ended 30 June 2022.

Starpharma's closing cash balance as at 30 June 2022 was $49.9 million. The net cash burn for the financial year was $10.6 million. Receipts from customers and grants for FY22 totaled $13.0 million, including receipts from customers of $4.8 million (FY21: $2.4 million).

Commenting on the quarter, Dr Jackie Fairley, Starpharma CEO, said:

"Starpharma continues to attract and deepen our partnerships with industry leading pharma companies, reaffirming the broad applicability of our DEP® technology which has the potential to be applied to a vast number of therapeutic products under multiple, independent commercial agreements. During the quarter, existing DEP® partner AstraZeneca, expanded the clinical program for their DEP® product, AZD0466. This expanded program includes an additional indication (non-Hodgkin's lymphoma) as well as a significant increase in the number of recruitment sites globally to accelerate patient enrolment in the planned expansion phase of the ongoing leukemia trial. In parallel, our three clinical stage DEP® products and our preclinical candidates have continued to make good progress.

"Marking an important milestone, VIRALEZE™ was relaunched this quarter in the UK through our commercial partner, LloydsPharmacy, with promotional activities underway. We were delighted to also report new results from our collaboration with The Scripps Research Institute, demonstrating the highly protective effects of VIRALEZE™ against the Omicron variant of SARS-CoV-2 in an in vivo viral challenge model. Importantly, these findings showed that VIRALEZE™ could provide significant benefit when used either before and after exposure to virus, or when used only after exposure to virus. VIRALEZE™ is now registered in over 30 countries and available in pharmacies, retail outlets and online."

Partnered DEP® Programs

Starpharma recently signed an expanded DEP® Research Agreement with Genentech. During the quarter, Starpharma has commenced work on this new program, which involves the design and synthesis of DEP® dendrimer conjugates incorporating a Genentech proprietary molecule.

Under Starpharma's DEP® licence with AstraZeneca, the international clinical program for AZD0466 continued to advance with multiple new sites opening and commencement of a new clinical trial in an additional indication – non-Hodgkin's lymphoma (NHL), one of the most commonly occurring cancers. The new NHL Phase 1/2 trial of AZD0466 is now recruiting at sites in the US and Korea. AstraZeneca plans to further expand recruitment for this trial, with more than 20 additional sites expected to open across the US, Canada, Europe, Australia, and Asia.

In the Phase 1/2 leukemia trial of AZD0466 in patients with advanced haematological malignancies additional sites were also opened. This trial is now recruiting at sites in the US, Australia, Italy, Germany, and Korea.

A further new DEP® agreement with a leading pharmaceutical company is well advanced. Active commercial discussions continue in other areas including DEP® radiopharmaceuticals.

Internal DEP® Programs

Starpharma's Phase 2 clinical trial of **DEP® cabazitaxel** continues to recruit well with 68 patients enrolled to date, including a number of advanced refractory ovarian cancer and gastro-oesophageal cancer patients. Patients in this trial continue to show encouraging efficacy signals, including prolonged stable disease, significant tumour shrinkage, and reductions in tumour markers.

DEP® cabazitaxel has been selected for a poster presentation at the upcoming *European Society of Medical Oncology (ESMO)* conference in early September. The poster will focus on a summary of the clinical data on DEP® cabazitaxel in prostate cancer. ESMO is considered one of the largest international oncology conferences and is attended by clinicians, researchers, and healthcare industry representatives from all over the world, representing an excellent platform for presenting these results.

The **DEP® irinotecan** Phase 2 clinical trial continues to progress well, with 82 patients now enrolled. Efficacy signals such as prolonged tumour shrinkage and reductions in tumour markers have been observed in multiple tumour types, including colorectal, breast, ovarian, pancreatic, lung, and oesophageal cancers. Starpharma is finalising preparations for the commencement of a combination arm for DEP® irinotecan in combination with 5-FU + Leucovorin ('FOLFIRI', a commonly used combination treatment regimen in colorectal cancer) to run in parallel with the ongoing monotherapy study. The combination arm is expected to commence shortly at sites in the UK and Australia.

The clinical program for **DEP® docetaxel** has enrolled 71 patients across the monotherapy and combination arms, with additional patients in screening. Encouraging efficacy signals such as prolonged stable disease and significant tumour shrinkage have been observed in heavily pre-treated patients with lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers.

Manufacture of **DEP® gemcitabine** product is now complete in readiness for Starpharma to commence a Phase 1/2 clinical trial, with planned clinical trial sites in the UK and Australia. Preparations for trial commencement are well advanced, with the clinical research

organisation (CRO) and site selection processes, regulatory and ethics preparations nearing completion.

In parallel with progressing these clinical candidates, Starpharma continues to undertake discussions with potential licensing partners. Starpharma continues to deepen its pipeline of DEP® assets by actively progressing a number of its own internal programs in areas including **DEP® radiotheranostics** and **DEP® antibody drug conjugates** (ADCs).

Marketed Products

During the quarter, VIRALEZE™ nasal spray was relaunched in the UK through LloydsPharmacy, with a number of promotional activities underway. LloydsPharmacy is one of the largest pharmacy groups in the UK with ~1400 stores, and its affiliated wholesale arm AAH, is also one of the largest pharmaceutical wholesalers in the UK, supplying over 14,000 independent pharmacies.

VIRALEZE™ recently demonstrated excellent protection against infection with the highly transmissible SARS-CoV-2 Omicron variant in a stringent *in vivo* viral challenge model. The findings are important because they indicate, even when VIRALEZE™ is only used after exposure to virus (e.g., if you forget to use the spray before exposure to a high-risk situation), it has potential to provide significant benefit.

The broad-spectrum activity of VIRALEZE™ was further highlighted with impressive results for SPL7013, in VIRALEZE™, against influenza A and B. SPL7013 achieved more than 90% reduction in viral infectivity of both influenza A and B viruses within one minute. These influenza viruses are responsible for seasonal epidemics of influenza, with influenza A being known to cause flu pandemics. SPL7013 also demonstrated irreversible virucidal properties against both types of influenza virus. In addition, testing at Scripps Research assessed the activity of two antiviral agents used in marketed nasal sprays - hydroxypropyl methyl cellulose (HPMC) and iota-carrageenan. In contrast to the potent and rapid effect of SPL7013, seen within one minute, HPMC and iota-carrageenan did not exhibit virucidal effect in this experiment, even after 30 minutes.

VIRALEZE™ is registered in more than 30 countries and is available in pharmacies, retail outlets and online in a number of countries. Starpharma continues to pursue registration and commercialisation for VIRALEZE™ in multiple other countries, with active commercial discussions underway. In Australia, the review by the TGA for the nasal spray application as a medical device is ongoing.

Regulatory approvals for VivaGel® BV were achieved in Bahrain and Qatar and pre-launch marketing activities have commenced. Starpharma's marketing partner, Mundipharma is also progressing further launches of VivaGel® BV in Asia as well as undertaking joint regulatory activities across a number of countries.

Other Business Development Activities

In an endorsement of interest in Starpharma's DEP® technology, the company was invited to present DEP® at the Novel Format Conjugates Summit, an industry conference focusing on next generation non-traditional ADCs, which took place in Boston in April. The conference participants included senior representatives from AstraZeneca, Merck, and Sanofi. An abridged version of Starpharma's presentation is available on our website.

During the quarter, Starpharma also participated in major industry conferences, including *American Society of Clinical Oncology* (ASCO) and *BIO International.* The company also met with a number of existing DEP® partners and potential new partners during these meetings.

Cash Flows

Starpharma's closing cash balance as at 30 June 2022 was $49.9 million. Receipts from customers and grants for FY22 totaled $13.0 million, including receipts from customers of $4.8 million (FY21: $2.4 million) and total grants of $8.2 million, including $7.7 million R&D tax incentive.

During the quarter, Starpharma continued to invest in research and development (R&D) for its three clinical stage DEP® programs as well as a number of preclinical programs, including in DEP® antibody drug conjugates and DEP® radiotheranostics. Net operating cash outflows for the quarter were $4.9 million, including R&D outflows of $2.2 million and product manufacturing and operating costs of $1.2 million for VIRALEZE™, VivaGel® BV and key raw material inventory. Staffing costs of $2.0 million include non-executive and executive directors' fees of $258,000. Other related party transactions required for disclosure were $3,479 for consulting services.

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 has developed VIRALEZE™, an antiviral nasal spray that is registered for sale in >30 countries, and available outside Australia in certain markets online. VIRALEZE™ is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel® condom and VivaGel® BV. VivaGel® products have been licensed in >160 countries, are registered in >45 countries and available for sale in the UK, Europe, Japan, Southeast Asia, South Africa, Australia and New Zealand.

As a leading company in dendrimer-based drug delivery, 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 Merck & Co., Inc., in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives and other world leading pharmaceutical companies. Starpharma's partnered DEP® programs have the potential to generate significant future milestones and royalties.

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Disclosure
This ASX Announcement was authorised for release by the Chairman, 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-22**

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	543	4,846
1.2	Payments for		
	(a) research and development	(2,202)	(10,540)
	(b) product manufacturing and operating costs	(1,202)	(4,484)
	(c) advertising and marketing	(64)	(64)
	(d) leased assets	-	-
	(e) staff costs	(1,977)	(8,900)
	(f) administration and corporate costs	(76)	(1,575)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	48	166
1.5	Interest and other costs of finance paid	(11)	(47)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	48	8,165
1.8	Other	-	(729)
1.9	**Net cash from / (used in) operating activities**	**(4,893)**	**(13,162)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(40)	(837)
	(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
	(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**	**(40)**	**(836)**
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	-	4,000
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)	(202)	(772)
3.10	**Net cash from / (used in) financing activities**	**(202)**	**3,228**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	54,830	60,500
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,893)	(13,162)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(40)	(836)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(202)	3,228
4.5	Effect of movement in exchange rates on cash held	223	188
4.60	**Cash and cash equivalents at end of period**	**49,918**	**49,918**

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	4,126	5,713
5.2	Call deposits	45,792	49,117
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)**	**49,918**	**54,830**

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	261
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) $3,479 for consulting services to Centre for Biopharmaceutical Excellence Pty Ltd, which Starpharma non-executive director 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	4,584
7.2	Credit standby arrangements	150	23
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**4,950**	**4,607**

7.5	**Unused financing facilities available at quarter end**	**343**

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 low-interest R&D cash flow loan with Treasury Corporation of Victoria maturing Oct-2023, secured against future refundable R&D tax incentives, current interest rate 1.5%. A$4.0M drawn per item 3.5 above.

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)	(4,893)
8.2	Cash and cash equivalents at quarter end (item 4.6)	49,918
8.3	Unused finance facilities available at quarter end (item 7.5)	343
8.4	Total available funding (item 8.2 + item 8.3)	50,261
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**10.3**

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: 29 July 2022

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.