starpharma

ASX Announcement

Quarterly Cashflow and Activities Report

Melbourne, Australia; 29 October 2021: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 30 September 2021.

Starpharma's cash balance as at 30 September 2021 was $53.4 million. Receipts for the quarter from customers and grants totalled $0.8 million, with receipts from customers including VIRALEZE™ and VivaGel® BV product sales as well as royalties for VivaGel® BV. The result includes significant investment in R&D, intellectual property and operating expenses as well as a number of one-off costs. Other cash outflows include VIRALEZE™ product manufacture to support international roll-out including in Italy and Vietnam, clinical trial costs for Starpharma's three phase 2 DEP® clinical programs, as well as further development of multiple preclinical DEP® candidates, such as DEP® gemcitabine, DEP® radiopharmaceuticals and DEP® ADCs. As in prior years, first quarter corporate and administration outflows are higher than other quarters due to one-off costs including annual ASX listing fees, annual insurance premiums and audit fees, totalling $1.2 million.

Key recent activities and events:

- Following signing of the recent supply arrangement, VIRALEZE™ antiviral nasal spray is expected to be launched in Vietnam in November, with the first delivery into Vietnam expected in early November. Vietnam, which has a population of approximately 97 million, is experiencing a significant Delta outbreak with only ~23 per cent of its population fully vaccinated. Registration of VIRALEZE™ in Vietnam is already well progressed and is expected shortly and a further ongoing distribution agreement for additional larger orders of VIRALEZE™ in Vietnam is currently being finalised for subsequent orders and ongoing supply. Starpharma is also in advanced discussions with potential commercial partners elsewhere in Europe, Asia, India, and other regions.
- VIRALEZE™ antiviral nasal spray is also expected to be launched in Italian pharmacies next month following a sales and distribution agreement with ADMENTA Italia Group, a leading pharmaceutical retail and wholesale distribution company in Italy. The arrangements are exclusive for retail pharmacies in Italy.
- VIRALEZE™ demonstrated a very high level of protection against SARS-CoV-2, in a rigorous challenge (animal) model reducing viral load by >99.9% (vs. saline control), and significantly reducing levels of pro-inflammatory cytokines.
- VIRALEZE™ featured in a several leading international journals. Results of the VIRALEZE™ animal study were published in a special issue of the international peer-reviewed journal, ***Viruses***, titled, *Medical Interventions for Treatment and Prevention of SARS-CoV-2 Infections*. VIRALEZE™ was also featured in the October issue of ***Nature Biotechnology***, titled, *Nanotechnology offers alternative ways to fight COVID-19 pandemic with antivirals*.
- Starpharma continues to work closely with the MHRA to address their requests and make the necessary changes in relation to promotional claims for VIRALEZE™ in packaging and promotional materials. Returned UK stock has been undergoing repacking for sale, incorporating a longer shelf-life as additional stability data are now available.
- A number of other regulatory submissions for VIRALEZE™ in further countries and regions have also been made, including in Vietnam where registration is expected

shortly. The review by the TGA of an application for registration in Australia is ongoing. Starpharma continues discussions with a number of State and Federal Government Department representatives, parliamentarians and COVID public health management bodies.

- AstraZeneca continues to recruit patients and open new trial sites in its global, phase 1/2 trial for DEP® AZD0466 in advanced haematological malignancies. The phase 1/2 trial design is aimed at seamless transition to phase 2, to facilitate rapid development and marketing approval.
- AstraZeneca will present AZD0466, their first DEP® oncology product, in a poster presentation at the 63rd American Society of Hematology (ASH) Annual Meeting in December 2021. The ASH Annual Meeting is the world's premier event in malignant and non-malignant hematology.
- AZD0466 studies were published in *Nature*, with AZD0466 shown to be as effective as standard-of-care chemotherapy (Cisplatin) at inhibiting tumour growth in a human mesothelioma model, when used alone, and even more effective when used in combination. AZD0466 also demonstrated significantly reduced thrombocytopenia compared to the non-dendrimer version of AZD0466 (AZD4320). Thrombocytopenia is a common dose limiting toxicity of this class of anti-cancer compounds (Bcl-xL).
- In addition to its programs with AstraZeneca, Starpharma is also progressing its partnered programs, including its Antibody Drug Conjugates (ADC) programs with Merck & Co Inc., DEP® anti-infective program with Chase Sun and other programs with undisclosed DEP® partners. Additionally, further partnered DEP® programs are at an advanced stage of negotiation with other leading pharmaceutical companies, including in the area of ADCs and radiopharmaceuticals.
- DEP® irinotecan clinical trial continues to progress well, with 60 patients now recruited, and multiple patients exhibiting encouraging efficacy signals, including impressive and prolonged tumour shrinkage and reductions in tumour marker levels for multiple tumour types, including colorectal, breast, ovarian, pancreatic, lung and oesophageal cancer.
- DEP® docetaxel clinical program - a total of 64 patients have been recruited across the DEP® docetaxel clinical program (monotherapy and combination arms). The program continues to progress well with encouraging efficacy signals observed including prolonged stable disease and significant tumour shrinkage in heavily pre-treated patients in tumours including lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers.
- DEP® cabazitaxel clinical trial continues to progress well, with 47 patients now recruited and multiple patients exhibiting efficacy signals in its major indication, prostate cancer, including: radiological responses, significant reductions in prostate-specific antigen (PSA) and lack of new bone metastases. In addition, efficacy signals of prolonged and significant tumour shrinkage and/or reductions in tumour markers have also been seen following treatment with DEP® cabazitaxel in heavily pre-treated patients with gastro-oesophageal, ovarian, cholangiocarcinoma, lung, thymic and head and neck cancers.
- DEP® cabazitaxel: US Patent and Trademark Office granted a new 'composition of matter' patent. It specifically covers a DEP® dendrimer conjugated to multiple cabazitaxel drug molecules via a particular releasable linker, with a patent term to 2039 and the potential for a further 5 year extension.
- Starpharma also continues to advance a number of further DEP® candidates toward the clinic, including DEP® gemcitabine, with key preclinical work progressing well to facilitate its entry into a phase 1/2 trial. The development of multiple other preclinical DEP®

candidates is continuing, including several in the area of radiopharmaceuticals and antibody drug conjugates (ADCs).

- Starpharma continues to undertake discussions with potential partners interested in licensing the company's internal clinical and preclinical DEP® products including Starpharma's internal DEP® radiopharmaceutical candidates and DEP® ADCs.
- Starpharma was invited to present its DEP® technology at leading industry conference, Partnership Opportunities in Drug Delivery conference on 28 October 2021.
- Starpharma continues to support a range of Mundipharma and Aspen marketing activities. In parallel, the teams continue to progress regulatory activities for VivaGel® BV in a range of countries. VivaGel® BV is currently registered in more than 45 countries. A number of new marketing materials are currently being finalised by Mundipharma and Starpharma for VivaGel® BV for use in Europe and elsewhere, and these include various outputs of advisory committee meetings attended by key opinion leaders in Europe and UK. The product continues to attract very positive customer reviews and feedback from clinicians.

Dr Jackie Fairley, Starpharma CEO, commented: "We are excited to see VIRALEZE™ launched in pharmacies and retail outlets in Italy and Vietnam soon. The overwhelming feedback from our distribution partners confirms the significant need for a product like VIRALEZE™ in addition to vaccines, and particularly for countries where vaccination rates are low. We continue to progress negotiations for multiple other supply and distribution arrangements in further countries and regions, while we undertake international regulatory activities to expedite launch wherever possible. We look forward to announcing these commercial partnerships as they come on board."

Dr Fairley added, "In addition, Starpharma continued to progress its three clinical stage DEP® assets, with a number of new and impressive tumour responses. Our partnered DEP® programs, including those with AstraZeneca, Merck and Chase Sun, are going well and we are really excited to see AZD0466 being presented by AstraZeneca at the ASH meeting in December. We continue to see strong commercial interest in our internal DEP® portfolio, including DEP® ADCs and DEP® radiopharmaceuticals, and we continue to advance commercial discussions for these products."

The closing cash balance as at 30 September 2021 was $53.4 million. Net operating cash outflows of $7.0 million for the quarter includes significant investment in R&D ($2.9 million) and product manufacturing and operating expenses ($1.1 million), reflecting investment in multiple phase 2 DEP® clinical programs, further DEP® candidates, such as DEP® gemcitabine, DEP® ADC and DEP® radiopharmaceutical products, and product manufacture of VIRALEZE™. Receipts from customers and grants in the quarter totalled $0.8 million, with $0.7 million outflow for product returned to Starpharma from LloydsPharmacy. This product is currently undergoing repackaging for sale. Staffing costs of $2.0 million, include non-executive and executive directors' fees of $233,000. Administration and corporate costs of $1.2 million reflect the traditionally higher amounts in the first quarter due to expenses insurance, and ASX and audit fees.

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 respiratory viruses, DEP® drug delivery and VivaGel®. Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered for sale in the UK/Europe and India, and available 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® BV has been licensed in >160 countries, is registered in >45

countries and available for sale in the UK, Europe, Japan, South East 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 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 Cashflow and Activities Report 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-Sep-21**

	Consolidated statement of cash flows	**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	634	634
1.2	Payments for		
	(a) research and development	(2,865)	(2,865)
	(b) product manufacturing and operating costs	(1,094)	(1,094)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,960)	(1,960)
	(f) administration and corporate costs	(1,229)	(1,229)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	65	65
1.5	Interest and other costs of finance paid	(12)	(12)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	177	177
1.8	Other (Lloyds product sales returns of VIRALEZE™)	(729)	(729)
1.9	**Net cash from / (used in) operating activities**	**(7,013)**	**(7,013)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(153)	(153)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets		
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(153)**	**(153)**
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)	(176)	(176)
3.10	**Net cash from / (used in) financing activities**	**(176)**	**(176)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	60,500	60,500
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,013)	(7,013)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(153)	(153)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(176)	(176)
4.5	Effect of movement in exchange rates on cash held	215	215
4.60	**Cash and cash equivalents at end of period**	**53,373**	**53,373**

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	2,346	3,201
5.2	Call deposits	51,027	57,299
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)**	**53,373**	**60,500**

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	236
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	800	695
7.2	Credit standby arrangements	150	13
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**950**	**708**

7.5	**Unused financing facilities available at quarter end**	**242**

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 is a National Australia Bank master asset finance facility for leased laboratory equipment, the facility is secured against equipment and a term deposit. 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)	(7,013)
8.2	Cash and cash equivalents at quarter end (item 4.6)	53,373
8.3	Unused finance facilities available at quarter end (item 7.5)	242
8.4	Total available funding (item 8.2 + item 8.3)	53,615
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**7.6**

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 October 2021

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.