

Quarterly Cashflow and Activities Report

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

Starpharma's cash balance as at 30 June 2021 was \$60.5 million. The net cash-burn for the financial year was \$16.5 million (FY20: \$11.2 million) excluding the \$46.9 million of equity raising proceeds.

Receipts for the quarter from customers and grants totalled \$2.4 million. Receipts from customers for the quarter of \$1.9 million included VIRALEZE™ and VivaGel® BV product sales as well as royalties for VivaGel® BV. Government grants of \$0.5 million in the quarter included the Australian Medical Research Future Fund (MRFF) Biomedical Translation Bridge (BTB) program grant for VIRALEZE™. Cash outflows for the quarter include expenditure related to VIRALEZE™ launch activities including product manufacture, and also clinical costs and antiviral testing for VIRALEZE™. Expenditure also included trial costs for Starpharma's three phase 2 DEP® clinical programs, as well as further development of multiple preclinical DEP® candidates, such as DEP® radiopharmaceuticals and DEP® ADCs.

Key recent activities and events:

- VIRALEZE™ was registered for sale in India and Starpharma is in advanced discussions for local distribution arrangements in India with potential commercial partners into both the private (consumer) and Government markets. In the interim, consumers in India can purchase VIRALEZE™ online.
- VIRALEZE™ was launched in Europe in May 2021 through a dedicated webstore, which followed the product launch in LloydsPharmacy and online in the UK earlier in the year.
- VIRALEZE™ sales in the UK via LloydsPharmacy are temporarily paused while Starpharma and its distribution partner address correspondence from the MHRA in relation to promotional claims. In parallel, Starpharma is undertaking contingencies in relation to packaging in the event changes are required.
- Starpharma is negotiating distribution and marketing arrangements for VIRALEZE™ in a number of countries in addition to India, including various European countries and other international regions. In parallel, Starpharma continued to progress regulatory activities for VIRALEZE™ for a number of other markets, including in Australia where a submission has been made to the TGA.¹
- Impressive data established that SPL7013, the antiviral agent in VIRALEZE™ nasal spray, has potent virucidal activity (>99.99%) against the globally significant Delta variant of SARS-CoV-2. Antiviral testing at Scripps Research Institute has now confirmed that SPL7013 has >99% virucidal activity against all four of the WHO-designated SARS-CoV-2 *variants of concern*² (Alpha, Beta, Gamma, Delta) in laboratory studies, as well as the closely related Kappa variant.

¹ VIRALEZE™ is not registered for sale or supply in Australia.

² The Delta, Alpha, Beta and Gamma variants of SARS-CoV-2 are all classified 'Variants of Concern' by global health authorities due to their increased transmissibility, increased disease severity (COVID-19), and/or reduced effectiveness of current treatments or vaccines.

- Extensive antiviral data for SPL7013 (the antiviral agent in VIRALEZE™) was published in the prestigious international scientific journal, Antiviral Research³.
- Starpharma secured a partnership between VIRALEZE™ and 2021 English Premiership rugby union champions, Harlequins.
- VIRALEZE™ clinical trial: Starpharma completed a double-blinded, placebo-controlled safety study to support marketing of VIRALEZE™. The study involved 40 healthy volunteers, using the product 4 times a day for 14 consecutive days. All participants have completed the study. VIRALEZE™ was extremely well tolerated by all participants and study results will be released following final analysis of all blood samples and trial data.
- During the quarter, AstraZeneca commenced recruitment into a multi-region combined phase 1/2 trial in advanced haematological malignancies as part of its expedited clinical development program for DEP® AZD0466. The new phase 1/2 trial design is aimed at seamless transition to phase 2, to facilitate marketing approval. Data was also recently published showing the potent anti-cancer effects of AZD0466 in a malignant mesothelioma model.⁴
- DEP® irinotecan phase 2 trial continues to progress well, with 53 patients now recruited. Encouraging efficacy signals observed include significant tumour shrinkage maintained for up to 26 weeks, prolonged stable disease for up to 71 weeks in breast cancer, impressive tumour shrinkage and reductions in tumour marker levels for a number of tumour types, including breast, colorectal, ovarian, pancreatic, lung and oesophageal cancer. A patient with heavily pre-treated metastatic ovarian cancer also experienced a 98% reduction of tumour marker (CA-125) following 5 cycles of DEP® irinotecan and follow up scans showed a complete disappearance of her target tumour.
- DEP® docetaxel clinical trials continue to progress well, with 49 patients now recruited and encouraging efficacy signals observed, including prolonged stable disease and significant tumour shrinkage including in patients with hard-to-treat tumours such as pancreatic, oesophageal, cholangiocarcinoma, and gastric cancer. These impressive tumour responses in heavily pre-treated include stable disease for up to 40 weeks and significant tumour shrinkage in an oesophageal cancer patients, maintained for more than 28 weeks.
- DEP® cabazitaxel phase 2 trial continues to progress well, with 42 patients now recruited and multiple efficacy signals observed, including radiological responses, significant reductions in prostate-specific antigen (PSA) and lack of new bone metastases, seen in multiple prostate cancer patients. These observations have been reported for patients who have been previously heavily treated with chemotherapy and radiation. Responses included patients previously treated with conventional cabazitaxel or conventional docetaxel (taxanes). One patient who had previously received multiple cycles of conventional docetaxel and several other anticancer agents achieved three responses - significant tumour shrinkage, a PSA response and a reduction in the number of bone metastases. Other notable efficacy signals in heavily pre-treated patients include longstanding significant shrinkage in two different types of gastro-oesophageal cancers, as well as ovarian, cholangiocarcinoma, lung, thymic and head and neck cancers.
- Starpharma was invited to present its DEP® technology at the prestigious, international Controlled Release Society (CRS) Virtual Annual Meeting, during a session called 'Success Stories from Bench to Trials to Market'. There was also a presentation on new

³ Paull, J.R.A. et al. Virucidal and antiviral activity of astodrimmer sodium against SARS-CoV-2 in vitro (2021). Antiviral Research. <https://doi.org/10.1016/j.antiviral.2021.105089>

⁴ Research paper on AZD0466 published: "A novel BH3-mimetic, AZD0466, targeting BCL-XL and BCL-2 is effective in a pre-clinical model of malignant pleural mesothelioma".

data on AZD0466 generated under a research collaboration between AstraZeneca, Starpharma, and Monash Institute of Pharmaceuticals Sciences.

- Further DEP[®] candidates continue to be progressed toward the clinic, including progress with DEP[®] gemcitabine. Additional development was undertaken for multiple DEP[®] candidates in the area of radiopharmaceuticals and antibody drug conjugates (ADCs).
- Starpharma has initiated a number of new radiopharmaceutical and ADC commercial discussions, and continued to progress its disclosed/undisclosed partnered programs, including with AstraZeneca, Merck Sharpe & Dohme (MSD) and Chase Sun.
- For VivaGel[®] BV, Starpharma and Mundipharma teams continued to progress regulatory activities in a range of countries, as well as marketing activities with key opinion leaders in Europe. VivaGel[®] BV is currently registered in more than 45 countries.
- LifeStyles launched the VivaGel[®] condom in countries in Europe during the quarter, marketed under LifeStyles' Manix and Akuel brands of condoms as the Absolute™ Dual Protection condom.

Dr Jackie Fairley, Starpharma CEO, commented: “During the quarter Starpharma achieved a further product registration for VIRALEZE™, in India, launched the product in Europe and also confirmed impressive antiviral activity of SPL7013 against the problematic Delta variant. Recent testing at Scripps Research Institute confirmed virucidal activity >99.99% for SPL7013 (VIRALEZE™ antiviral agent) against all four SARS-CoV-2 *variants of concern* including the Delta variant. Given its potent and broad spectrum of activity, VIRALEZE™ could prove to be particularly beneficial as an additional protective measure against these variants. We are rapidly progressing other registrations and distribution arrangements in further countries and regions.”

Dr Fairley added, “In addition, Starpharma continued to progress our partnered DEP[®] programs, including with MSD in the exciting area of ADCs, and the expansion of AstraZeneca's clinical program for DEP[®] AZD0466. We also progressed our three clinical stage DEP[®] assets which continued to recruit well and report impressive tumour responses in heavily pre-treated patients who otherwise would have limited options.”

The closing cash balance as at 30 June 2021 was \$60.5 million. Net operating cash outflows of \$3.6 million for the quarter includes significant investment in R&D (\$2.6 million) and product manufacturing and operating expenses (\$1.7 million), this reflects investment in multiple phase 2 DEP[®] clinical programs and launch, promotion and manufacture of VIRALEZE™. Receipts from customers and grants in the quarter totalled \$2.4 million. Staffing costs remained stable with quarterly staff costs of \$1.6 million, including non-executive and executive directors' fees of \$233,000.

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-Jun-21

Consolidated statement of cash flows		Current quarter	Year to date (12 months)
		\$A'000	\$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	1,861	2,436
1.2	Payments for		
	(a) research and development	(2,576)	(13,456)
	(b) product manufacturing and operating costs	(1,676)	(3,642)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,622)	(6,426)
	(f) administration and corporate costs	(208)	(1,128)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	96	362
1.5	Interest and other costs of finance paid	(12)	(57)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	541	7,103
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(3,596)	(14,808)
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(94)	(246)
	(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	(94)	(246)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	48,862
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	-	(1,931)
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)	(166)	(628)
3.10	Net cash from / (used in) financing activities	(166)	46,303
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	64,292	30,054
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,596)	(14,808)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(94)	(246)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(166)	46,303
4.5	Effect of movement in exchange rates on cash held	64	(803)
4.60	Cash and cash equivalents at end of period	60,500	60,500

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	3,201	2,660
5.2	Call deposits	57,299	61,632
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)	60,500	64,292

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	233
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	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>			
7.1	Loan facilities	800	196
7.2	Credit standby arrangements	150	13
7.3	Other (please specify)	-	-
7.4	Total financing facilities	950	209

7.5 Unused financing facilities available at quarter end **741**

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)	(3,596)
8.2	Cash and cash equivalents at quarter end (item 4.6)	60,500
8.3	Unused finance facilities available at quarter end (item 7.5)	741
8.4	Total available funding (item 8.2 + item 8.3)	61,241
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	17.0

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: 30 July 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.