

Quarterly Cashflow and Activities Report

Melbourne, Australia; 28 January 2022 Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 31 December 2021.

Starpharma's cash balance as at 31 December 2021 was \$51.3 million. This does not include the \$7.7 million R&D tax incentive that was recently received and announced in January.

Receipts from customers for the quarter were up 188% from the prior quarter, to \$1.8 million. Receipts included sales of VIRALEZE™ to Vietnam following product launch in December.

Net operating cash outflows for the quarter were \$4.2 million, down from \$7.0 million last quarter. Cash outflows include clinical trial costs for Starpharma's three phase 2 DEP® clinical programs, as well as scale-up and development costs for preclinical DEP® candidates, including DEP® gemcitabine, DEP® radiopharmaceutical candidates and DEP® ADCs. Other cash outflows include expenditure related to VIRALEZE™ product manufacture.

Key recent activities and events:

- Starpharma reported positive interim results from the prostate cancer cohort of its phase 2 DEP® cabazitaxel trial. 100% of patients assessed for efficacy following DEP® cabazitaxel-treatment experienced one or more encouraging efficacy signals. These included reductions in tumour size, decreased PSA levels, and lack of progression of metastases in the bone. These very positive interim results compare favourably to conventional cabazitaxel (Jevtana®) and are particularly significant given all patients in this cohort had late-stage prostate cancer and had failed multiple anti-cancer treatments (including taxanes), in addition to surgeries and radiation, prior to entering the DEP® cabazitaxel trial. 55 patients have now been recruited across all cancer types in the phase 2 DEP® cabazitaxel trial. Recruitment of a small number of additional ovarian and gastro-oesophageal cancer patients is ongoing following promising efficacy signals in both these tumours as well as prostate. Full results for the trial will be reported in the coming months once ongoing patients have completed treatment.
- [On 7 December 2021](#), Starpharma signed a new DEP® Research Agreement with one of the world's largest biopharmaceutical companies. This new partnered DEP® program is in addition to previously disclosed partnerships with Merck & Co., Inc., AstraZeneca, and Chase Sun.
- AstraZeneca continues to recruit patients with advanced haematological malignancies (refractory AML- acute myeloid leukemia and ALL- acute lymphoblastic leukemia) into its global, phase 1/2 trial for DEP® AZD0466, which is currently recruiting at sites in the USA, South Korea, and in Melbourne.
- AstraZeneca recently advised that they expect to commence, in February, an additional international trial for AZD0466 in patients with non-Hodgkin's lymphoma - a blood cancer that accounts for more than 80,000 cancer diagnoses annually in the US and is one of the top 10 most commonly occurring cancers in most countries worldwide.
- AstraZeneca and MD Anderson Cancer Center researchers presented new data for AZD0466 in two scientific poster presentations ([Poster 1](#) and [Poster 2](#)) 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 haematology

and these poster presentations highlighted impressive activity of AZD0466 in different types of blood cancer.

- On 3 December 2021, Starpharma signed a 5-year sales and distribution agreement for VIRALEZE™ antiviral nasal spray in Vietnam. The agreement includes a minimum commitment of at least 1 million units in the first year.
- VIRALEZE™ was successfully launched in Vietnam in December following confirmation of the product's registration. Several launch events were held across Vietnam and attended by clinicians, healthcare professionals, politicians, and media networks. Starpharma has already supplied three large orders to Vietnam during the quarter, with further orders expected to be fulfilled shortly.
- Following the signing of a sales and distribution agreement for VIRALEZE™ in Italy with leading pharmaceutical retail and wholesale distribution company, ADMENTA Italia Group, VIRALEZE™ was launched through ADMENTA's LloydsFarmacia. ADMENTA's LloydsFarmacia comprises ~260 retail pharmacies and an online platform.
- VIRALEZE™ was recently registered for sale in Saudi Arabia, Vietnam, and New Zealand, adding to existing registrations for the product in Europe and India taking the number of countries where VIRALEZE™ is registered to more than 30 countries. The registration of VIRALEZE™ in Saudi Arabia is the first in the Middle East and will support further registrations in the region. Starpharma continues to liaise closely with the MHRA in the UK in relation to their query regarding promotional claims. Dialogue with the TGA continues, following our submission for registration in Australia. A number of other regulatory submissions for VIRALEZE™ in further countries and regions have also been made.
- Negotiations are nearing completion for a distribution agreement for VIRALEZE™ in Saudi Arabia and other countries in the Middle East. This is in addition to commercial discussions for distribution of the product elsewhere, including in Europe, Asia, and other regions.
- Testing of SPL7013, the antiviral agent in VIRALEZE™, against the Omicron variant of SARS-CoV-2 is underway at The Scripps Research Institute. Antiviral and virucidal testing in laboratory studies has previously demonstrated that SPL7013 inactivates >99.9% of the Delta, Alpha, Beta, Gamma and Kappa variants of the coronavirus SARS-CoV-2.
- DEP® irinotecan clinical trial continues to progress well, with 68 patients now recruited, and multiple patients exhibiting encouraging efficacy signals, such as impressive and prolonged tumour shrinkage and reductions in tumour marker levels for multiple tumour types, including colorectal, breast, ovarian, pancreatic, lung and oesophageal cancer.
- In parallel with ongoing phase 2 monotherapy investigations for DEP® irinotecan, Starpharma is progressing a phase 1/2 combination arm that will investigate DEP® irinotecan in combination with 5-FU + Leucovorin ('FOLFIRI'). FOLFIRI is a commonly used combination treatment regimen in colorectal cancer. Enrolment of patients in the DEP® irinotecan combination arm is expected to commence shortly.
- The DEP® docetaxel clinical program continues to progress, with 66 patients now recruited (monotherapy and combination arms). Encouraging efficacy signals have been observed including prolonged stable disease and significant tumour shrinkage in heavily pre-treated patients with lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers.
- Additional DEP® candidates are being progressed towards the clinic, including DEP® gemcitabine. Final preclinical work is being completed, including scale-up, to facilitate

DEP[®] gemcitabine's entry into a phase 1/2 trial. The company also continues to develop multiple other preclinical DEP[®] candidates, including in the area of DEP[®] radiopharmaceuticals and DEP[®] ADCs.

- Starpharma continued to progress multiple partnered programs, including its DEP[®] Antibody Drug Conjugate (ADC) program with Merck & Co Inc., DEP[®] anti-infective program with Chase Sun and other DEP[®] programs with named and unnamed partners. Additionally, further partnered DEP[®] programs are at an advanced stage of negotiation with other leading pharmaceutical companies, including in the area of radiopharmaceuticals.
- Starpharma continues to support marketing and regulatory activities for its VivaGel[®] BV partners, Mundipharma and Aspen. VivaGel[®] BV is currently registered in more than 45 countries.

Dr Jackie Fairley, Starpharma CEO, commented: "Starpharma was very excited to announce the positive interim results for DEP[®] cabazitaxel in prostate cancer from our phase 2 trial this quarter. Likewise, the recent decision by our partner, AstraZeneca, to expand its clinical program for AZD0466 to include non-Hodgkins lymphoma marks more exciting progress for this important oncology agent. In addition, we also announced the signing of a new DEP[®] Research Agreement with one of the world's largest biopharmaceutical companies, adding to our existing partnerships with industry leaders AstraZeneca and Merck & Co., Inc., and Chase Sun. Each of these important milestones provide further validation for our DEP[®] platform and illustrates the broad optionality of Starpharma's DEP[®] technology.

"In parallel to our progress with DEP[®], Starpharma's antiviral nasal spray, VIRALEZE[™], was successfully launched in Vietnam, with Starpharma having received orders totalling more than \$2 million to date. We were excited to see the product so well received and pleased to see VIRALEZE[™] playing a role in the fight against COVID-19 in that region. The product was also launched in Italy, and registered in Saudi Arabia, Vietnam, and New Zealand, with further regulatory submissions in progress in other countries. Testing of SPL7013, the antiviral agent in VIRALEZE[™], against the globally important Omicron variant of SARS-CoV-2 is also underway at The Scripps Research Institute, following impressive results in the Delta variant. A key advantage of VIRALEZE[™] is its mechanism of action, which appears to not be adversely impacted by mutations in the spike proteins of SARS-CoV-2 that make the virus more infectious, as has occurred in the Delta and Omicron variants."

The closing cash balance as at 31 December 2021 was \$51.3 million. Receipts from customers and grants in the quarter totalled \$2.0 million, with net operating cash outflows of \$4.2 million. The quarter includes significant investment in R&D (\$2.6 million), product manufacturing and operating expenses (\$0.6 million), reflecting investment in three phase 2 DEP[®] clinical programs, scale-up and development of further DEP[®] candidates, including DEP[®] gemcitabine, DEP[®] ADCs and DEP[®] radiopharmaceutical products, and product manufacture of VIRALEZE[™]. Staffing costs of \$3.0 million, include non-executive and executive directors' fees of \$438,000.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHY) 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 Europe, Vietnam, India, Saudi Arabia, and New Zealand, 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[®] 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

20 078 532 180

Quarter ended ("current quarter")

31-Dec-21

Consolidated statement of cash flows	Current quarter	Year to date (6 months)
	\$A'000	\$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,824	2,458
1.2 Payments for		
(a) research and development	(2,570)	(5,435)
(b) product manufacturing and operating costs	(591)	(1,685)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(3,029)	(4,989)
(f) administration and corporate costs	(19)	(1,248)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	29	94
1.5 Interest and other costs of finance paid	(12)	(24)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	138	315
1.8 Other	-	(729)
1.9 Net cash from / (used in) operating activities	(4,230)	(11,243)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(40)	(193)
(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	(40)	(193)
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	2,400	2,400
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)	(194)	(370)
3.10 Net cash from / (used in) financing activities	2,206	2,030
4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	53,373	60,500
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(4,230)	(11,243)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(40)	(193)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	2,206	2,030
4.5 Effect of movement in exchange rates on cash held	(55)	160
4.60 Cash and cash equivalents at end of period	51,254	51,254

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	5,718	2,346
5.2 Call deposits	45,536	51,027
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)	51,254	53,373

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current quarter \$A'000
438
-

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.

- 7.1 Loan facilities
7.2 Credit standby arrangements
7.3 Other (please specify)
7.4 **Total financing facilities**

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
4,800	3,061
150	9
-	-
4,950	3,070

7.5 Unused financing facilities available at quarter end

1,880

- 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 newly approved 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 0.265%. A\$2.4M 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)	(4,230)
8.2 Cash and cash equivalents at quarter end (item 4.6)	51,254
8.3 Unused finance facilities available at quarter end (item 7.5)	1,880
8.4 Total available funding (item 8.2 + item 8.3)	53,134
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	12.6

- 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: 28 January 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.