

Quarterly Cashflow and Activities Report

Melbourne, Australia; 29 January 2021: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 31 December 2020.

Starpharma's cash balance as at 31 December 2020 was \$70.3 million.

Net operating cash outflows for the quarter were \$0.7 million, compared to \$5.4 million last quarter, with the R&D tax incentive refund of \$5.7 million received in October 2020. Cash flows from financing activities include net proceeds of \$47.0 million from the equity raising in the quarter.

Cash outflows for the quarter include expenditure relating to the pre-launch activities for the VIRALEZE™ antiviral nasal spray, including preparation for the manufacture of launch batches, completion of required testing and documentation requirements and commercialisation activities. Cash outflows also included expenditure on Starpharma's three DEP® product phase 2 clinical programs.

Key recent activities and events:

- **VIRALEZE™ European dossier has been completed and is undergoing final review ahead of submission shortly; VIRALEZE™ is on track to be registered in Europe and ready for market Q1 CY2021.** VIRALEZE™ is an easy to use broad-spectrum antiviral nasal spray which can be stored at room temperature. Initial launch batches of VIRALEZE™ are currently being manufactured to support rapid European launch following approval. Launch preparations and commercial activities are advancing well, including discussions with pharmacy chains, B2B customers, and online platforms. Licensing discussions are continuing in parallel.
- **SPL7013 demonstrated potent activity in respiratory pathogen RSV (respiratory syncytial virus) – further antiviral testing underway to expand the potential use for VIRALEZE™.** Following confirmation of the activity of SPL7013 in RSV, further antiviral testing continues to be conducted at the Scripps Research Institute in other respiratory viruses to further broaden the product claims for VIRALEZE™ and expand its utility, post-approval. Based on the effectiveness of VIRALEZE™ against multiple viruses, including drug-resistant strains, the product is expected to retain activity against the coronavirus strains being reported in the UK, South Africa and elsewhere.
- **Starpharma commenced a human study for VIRALEZE™ and dosing of the first cohort is complete.** This study is being undertaken to support commercialisation activities for VIRALEZE™, but is not a requirement to achieve EU product registration. The study, which is being conducted in Perth, Western Australia, is expected to be completed during Q1 CY2021.
- **DEP® irinotecan phase 2 trial continues to progress well.** Encouraging efficacy signals have been observed for a number of tumour types, including breast, colorectal, ovarian, pancreatic, lung and oesophageal cancer. Efficacy signals include tumour shrinkage and stable disease – including 72 weeks' stable disease in a breast cancer patient. These efficacy signals are particularly encouraging given the heavy pre-treatment in trial patients, who average ~30 dosing cycles of anti-cancer therapy and an average of four different types of treatment before entering the DEP® irinotecan trial.

Preparations continue for the addition of clinical combinations with DEP[®] irinotecan, thereby expanding the market opportunity.

- **DEP[®] docetaxel clinical trials continue to progress well**, with encouraging efficacy signals observed, including prolonged stable disease and tumour shrinkage in patients with pancreatic, oesophageal and gastric cancer. Patients treated with DEP[®] docetaxel continue to experience less neutropenia than is usually associated with the standard version of docetaxel (Taxotere[®]) and have not required pre-treatment with cortisone.
- **DEP[®] cabazitaxel phase 2 trial continues to progress well**, with encouraging efficacy signals observed, including stable disease, significant target tumour shrinkage and substantial tumour marker reductions (e.g. PSA), in cancers including prostate, ovarian, lung, gastro-oesophageal, head and neck and other cancers. Patients treated with DEP[®] cabazitaxel continue to experience less neutropenia than is usually associated with the standard version of cabazitaxel (Jevtana[®]) and have not required pre-treatment with cortisone.
- The impact of COVID-19 in the UK, where DEP[®] trials are taking place, has had a variable effect on the DEP[®] clinical programs depending on site-specific factors including the location and type of hospital. Existing DEP[®] trial patients continue to receive treatment; however, new patient recruitment has slowed in some trial sites, especially those in general hospitals in large cities. Recruitment at other sites, including dedicated cancer hospitals, has been faster than usual. An Australian site has been initiated for both the DEP[®] irinotecan and DEP[®] cabazitaxel trials and recruitment there has been relatively unaffected by COVID-19 restrictions.
- **AstraZeneca's phase 1 clinical trial for DEP[®] AZD0466** continues to progress well, with potential expansion in the coming months.
- Further pharmacokinetic testing confirmed the **enhanced benefits of DEP[®] remdesivir**, including low injection volume (2-3 mL), and long-acting, controlled release when administered both subcutaneously and intravenously. These DEP[®] benefits represent a significant improvement over the large volume and repeated intravenous infusions required by current remdesivir formulation (Gilead's Veklury[®]).
- Active commercial discussions in relation to several **new DEP[®] partnered programs are advancing, including in the area of Antibody Drug Conjugates (ADCs)**. Starpharma also has a number of other ongoing partnered DEP[®] programs, which continued to make progress, including the DEP[®] anti-infective program with Chase Sun.
- Aspen's **Fleurstat BVgel** campaign was awarded the 2020 Diamond Award for *Best Launch of a Consumer Healthcare Product*. **VivaGel[®] BV** continues to receive positive product reviews by BV patients. Mundipharma continued with regulatory submissions and launch activities for VivaGel[®] BV in multiple regions. Reduced consumer activity (e.g. social activity and workplace attendance) due to COVID-19 lockdowns have impacted consumer demand and sales activities. Formal FDA review process for the US market is ongoing.
- Progress with several internal DEP[®] programs being developed, including ADCs and radiopharmaceutical candidates for both therapeutic and diagnostic applications. Radiopharmaceuticals are a rapidly developing area in oncology which has recently generated several high-value deals.
- Starpharma's laboratory and internal operations continued to operate with minimal disruption, under a COVID safe plan.

Dr Jackie Fairley, Starpharma CEO, commented: “Considering the current situation in Europe, we are pleased to see our oncology trial sites continuing to treat and recruit DEP[®] patients, and to see positive patient outcomes with our DEP[®] drugs, including a range of impressive efficacy signals and improved safety profile. We also continued to actively progress our partnered DEP[®] programs and we look forward to new additions in the coming months, including in the area of ADCs.”

In relation to the Company’s VIRALEZE™ nasal spray, Dr Fairley said: “We have just completed the regulatory dossier for Europe and expect to submit this shortly. We are also manufacturing the first batches of VIRALEZE™ in readiness for launch. We continue to test the active ingredient in VIRALEZE™ against further important respiratory viruses, and indeed, further strains of the coronavirus. Not surprisingly, our consumer research in Europe indicates very strong demand for VIRALEZE™, including after the roll-out of efficacious vaccines, and we are on track for the product to be launched during Q1 CY2021, which is ahead of the original schedule.”

The closing cash balance as at 31 December 2020 was \$70.3 million, including the net proceeds of \$47.0 million from the equity placement and share purchase plan in the quarter. Net operating cash outflows of \$0.7 million for the quarter includes the receipt of \$5.7 million for the R&D tax incentive refund. Investment in R&D (\$4.0 million) and product manufacturing and operating expenses (\$0.9 million) reflects investment in multiple phase 2 DEP[®] clinical programs and increased expenditure on the VIRALEZE™ nasal spray in preparation for launch. Starpharma’s VIRALEZE™ nasal spray program is also supported by a \$1.0 million Australian MRFF grant, with \$0.2 million received subsequent to the end of the quarter. Staffing levels remained stable with quarterly staff costs of \$1.6 million, including non-executive and executive directors’ fees of \$242,000. There was an unfavorable foreign exchange loss of \$0.7 million in the quarter on the declining value of US dollars held.

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 COVID-19, DEP[®] drug delivery and VivaGel[®]. Starpharma is developing VIRALEZE™, an antiviral nasal spray for COVID-19 which is complementary to vaccines and other preventative measures such as distancing and PPE. VIRALEZE™ also has potential use in future pandemics and is afforded expedited development because it is repurposing an already-marketed, broad-spectrum antiviral dendrimer, SPL7013. SPL7013 is utilised in approved products - the VivaGel[®] condom and VivaGel[®] BV. VivaGel[®] BV has been licensed in >160 countries, is approved in >40 countries and available in for sale in the UK, Europe, South East Asia, Australia and New Zealand.

As a leading company in dendrimer based drug delivery, Starpharma’s proprietary drug delivery platform technology, DEP[®], which 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 programs with AstraZeneca and other world leading pharmaceutical companies, which 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 December 2020

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	189	253
1.2	Payments for		
(a)	research and development	(3,991)	(6,625)
(b)	product manufacturing and operating costs	(879)	(1,237)
(c)	advertising and marketing	-	-
(d)	leased assets	-	-
(e)	staff costs	(1,592)	(3,225)
(f)	administration and corporate costs	(325)	(986)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	118	160
1.5	Interest and other costs of finance paid	(15)	(31)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	5,835	6,318
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(660)	(5,373)
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
(a)	entities	-	-
(b)	businesses	-	-
(c)	property, plant and equipment	(103)	(108)
(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	(103)	(108)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	48,862	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	(1,899)	(1,899)
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)	(152)	(298)
3.10	Net cash from / (used in) financing activities	46,811	46,665
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	24,906	30,054
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(660)	(5,373)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(103)	(108)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	46,811	46,665
4.5	Effect of movement in exchange rates on cash held	(680)	(964)
4.60	Cash and cash equivalents at end of period	70,274	70,274

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1 Bank balances	1,754	3,487
5.2 Call deposits	68,520	21,419
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)	70,274	24,906

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
242
-

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
800	217
150	29
-	-
950	246

7.5 Unused financing facilities available at quarter end

704

- 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, when utilised the facility is secured against equipment and a term deposit. Item 7.2 is a National Australia Bank business credit card facility (rate 15.5%) predominantly used for business travel.

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(660)
8.2 Cash and cash equivalents at quarter end (item 4.6)	70,274
8.3 Unused finance facilities available at quarter end (item 7.5)	704
8.4 Total available funding (item 8.2 + item 8.3)	70,978
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	107.5

- 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 January 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.