starpharma

ASX Announcement

Quarterly Cashflow and Activities Report

Melbourne, Australia; 27 April 2021: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 31 March 2021.

Starpharma's cash balance as at 31 March 2021 was $64.3 million.

Net operating cash outflows for the quarter were $5.8 million, including significant investment in DEP®/VIRALEZE™ clinical trials and product manufacture of VIRALEZE™, and launch-related items, e.g., EU taxation costs (expected to be refundable). Expenditure during the quarter also includes costs associated with VIRALEZE™ registration, further antiviral testing and the small safety study undertaken to support commercialisation activities, as well as expenditure on Starpharma's three phase 2 clinical programs – for DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan.

Key recent activities and events:

- **Starpharma announced a new Research Agreement with leading global pharma company Merck utilising Starpharma's proprietary DEP® technology for dendrimer-based ADCs.** Starpharma's DEP® partner, Merck, is ranked 4th globally by total sales revenue and is a recognised leader in oncology.
- **AstraZeneca advised a significant expansion of its clinical program for DEP® AZD0466, to include a multi-centre global phase 1 study with a focus on haematological tumours.** The clinical expansion facilitates patient recruitment and is aimed at rapid development and approval of AZD0466.
- **On 25 March Starpharma signed an exclusive commercial arrangement for VIRALEZE™ with LloydsPharmacy/McKesson UK,** one of the largest pharmacy groups in the UK with around 1,400 LloydsPharmacy stores across the UK and servicing a further 14,000 independent UK pharmacies.
- **On 29 March, VIRALEZE™ was launched in the UK by LloydsPharmacy, initially online and in its first week was the fastest selling product on record on LloydsPharmacy.com.** Whilst it is not expected that this rate of sales will necessarily be maintained, both Starpharma and LloydsPharmacy have been very pleased with the launch of the product. VIRALEZE™ has been well received by UK consumers, and the product is now also available at LloydsPharmacy outlets in-store.
- **To date, Starpharma has invoiced LloydsPharmacy $1.2 million, for the launch supply of VIRALEZE™ in the UK**, with further orders to be filled between now and the end of FY21.
- Starpharma has been progressing arrangements to facilitate the launch of VIRALEZE™ in other parts of Europe in the coming weeks via www.viraleze.co, as well as commercial discussions with pharmacy groups.
- As outbreaks of COVID-19 continue around the world, commercial interest in VIRALEZE™ remains strong and discussions for distribution of the product in a number of markets actively continue in parallel. Starpharma is also engaged in discussions with organisations, including various sporting teams which have expressed interest in the product.

- Starpharma is leveraging the European registration of VIRALEZE™ to expedite further marketing approvals for the product as soon as practicable in other countries, including Australia.
- Dosing was completed in the VIRALEZE™ double-blinded, placebo-controlled safety study, which was undertaken to support commercialisation activities. The study involved 40 healthy volunteers, using VIRALEZE™ or placebo 4 times a day for 14 consecutive days. All participants have now completed the study. Whilst the data is not yet unblinded, both VIRALEZE™ and the placebo nasal spray were extremely well tolerated by all participants.
- Further antiviral testing of SPL7013 (VIRALEZE™ active) at the Scripps Research Institute has confirmed it is active in two additional pandemic coronaviruses - severe acute respiratory syndrome coronavirus (SARS-CoV) or "SARS" and Middle East respiratory syndrome coronavirus (MERS-CoV) or "MERS". **SPL7013's broad-spectrum antiviral activity is a compelling feature for the role of VIRALEZE™ today and further testing is underway in multiple COVID strains.**
- **DEP® irinotecan phase 2 trial continues to progress well,** with more than 40 patients now recruited. Encouraging efficacy signals observed include prolonged stable disease, 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 experienced a 98% reduction of tumour marker (CA-125) following 7 cycles of DEP® irinotecan, and follow up scans showed a complete disappearance of her ovarian target tumour.
- **DEP® docetaxel clinical trials continue to progress well, with more than 40 patients now recruited and encouraging efficacy signals observed**, including prolonged stable disease and tumour shrinkage in patients with pancreatic, oesophageal, and gastric cancer. These impressive tumour responses include stable disease for up to 40 weeks and significant tumour shrinkage in a heavily pre-treated oesophageal cancer patient, maintained for more than 28 weeks. In addition to the monotherapy of DEP® docetaxel, **Starpharma is also recruiting into a study combining DEP® docetaxel with gemcitabine.** This study follows compelling data for this combination in pre-clinical human pancreatic cancer models.
- **DEP® cabazitaxel phase 2 trial continues to progress well,** with more than 35 patients now recruited. Encouraging efficacy signals have been 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. These impressive tumour responses include significant tumour shrinkage including in prostate and ovarian cancer, in patients who have failed multiple other lines of cancer treatment.
- **Starpharma's second radiopharmaceutical candidate, DEP® HER2-lutetium outperformed in human breast cancer model -** achieving complete tumour regression, outperforming Herceptin® (trastuzumab) labelled with lutetium, in a human breast cancer model (BT474).
- Further DEP® candidates are being progressed toward the clinic, including DEP® gemcitabine.
- Starpharma is engaged in active discussions with further partners in relation to DEP® programs. The Company's disclosed/undisclosed partnered programs continued to progress, including with AstraZeneca, Merck and Chase Sun. **Following the Merck ADC partnership, Starpharma has also initiated a number of new ADC discussions.**

- **Mundipharma has continued its rollout of VivaGel® BV with the launch of Betadine™ BV Gel in South Africa in March 2021.** The Starpharma and Mundipharma teams continue to work together on expanding the breadth of regulatory submissions for VivaGel® BV, which has **now been approved in more than 45 countries**. Further regulatory submissions are underway to support additional launches of VivaGel® BV in Mundipharma's territories.

Dr Jackie Fairley, Starpharma CEO, commented: "It has been an important quarter for Starpharma, with multiple value-adding milestones achieved in the DEP® portfolio, in addition to the commercialisation and launch of VIRALEZE™. Starpharma signed with leading global pharma company Merck, in the cutting-edge area of ADCs. We were also delighted that AstraZeneca is significantly expanding its clinical program for AZD0466 globally to support rapid development and approval of this product".

Dr Fairley added, "Alongside these partnered DEP® programs, we also progressed our internal DEP® assets, including our three clinical stage assets which continued to recruit further patients and report impressive tumour responses, in heavily pre-treated patients who have limited options".

"Starpharma was excited to launch VIRALEZE™ in the UK in March, ahead of our original schedule. We were pleased to partner with Lloyds/McKesson to bring this important product to consumers in the UK. We are rapidly advancing the launch of VIRALEZE™ in other parts of Europe and look forward to pursuing registrations in further countries and regions".

The closing cash balance as at 31 March 2021 was $64.3 million. Net operating cash outflows of $5.8 million for the quarter includes significant investment in R&D ($4.3 million) and product manufacturing and operating expenses, this reflects investment in multiple phase 2 DEP® clinical programs and manufacture of VIRALEZE™. Receipts from customers and grants in the quarter totalled $0.6 million. Staffing levels 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 COVID-19, DEP® drug delivery and VivaGel®. Starpharma has developed VIRALEZE™, an antiviral nasal spray for COVID-19, which is complementary to vaccines and other preventative measures such as distancing and PPE. VIRALEZE™ is registered for sale in the UK/Europe and available in the UK through LloydsPharmacy. SPL7013 is utilised in approved products - the VivaGel® condom and VivaGel® BV. VivaGel® BV has been licensed in >160 countries, is approved in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, 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.

Starpharma.com | Twitter | LinkedIn

Media: Sumit Media
Grant Titmus
Mob: +61 419 388 161
grant@sumitmedia.com.au

Starpharma Holdings Limited
Dr Jackie Fairley, Chief Executive Officer
Nigel Baade, CFO and Company Secretary
+61 3 8532 2704
investor.relations@starpharma.com
4-6 Southampton Crescent
Abbotsford Vic 3067

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	**31-Mar-21**

	Consolidated statement of cash flows	**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	322	575
1.2	Payments for		
	(a) research and development	(4,255)	(10,880)
	(b) product manufacturing and operating costs	(729)	(1,966)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,579)	(4,804)
	(f) administration and corporate costs	66	(920)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	106	266
1.5	Interest and other costs of finance paid	(14)	(45)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	244	6,562
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(5,839)**	**(11,212)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(44)	(152)
	(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**	**(44)**	**(152)**
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	(32)	(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)	(164)	(462)
3.10	**Net cash from / (used in) financing activities**	**(196)**	**46,469**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	70,274	30,054
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,839)	(11,212)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(44)	(152)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(196)	46,469
4.5	Effect of movement in exchange rates on cash held	97	(867)
4.60	**Cash and cash equivalents at end of period**	**64,292**	**64,292**

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	2,660	1,754
5.2	Call deposits	61,632	68,520
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)**	**64,292**	**70,274**

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 *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	210
7.2	Credit standby arrangements	150	16
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**950**	**226**

7.5	Unused financing facilities available at quarter end	724

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)	(5,839)
8.2	Cash and cash equivalents at quarter end (item 4.6)	64,292
8.3	Unused finance facilities available at quarter end (item 7.5)	724
8.4	Total available funding (item 8.2 + item 8.3)	65,016
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**11.1**

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: 27 April 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.