ASX Announcement

Quarterly Cashflow and Activities Report

Melbourne, Australia; 30 July 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 30 June 2020.

Starpharma's cash balance as at 30 June 2020 was $30.1 million. The net cash-burn for the financial year was $11.2 million (FY19: $10.1 million). Receipts for the quarter totalled $0.9 million. Receipts from customers included product sales, royalties and an approval milestone for VivaGel® BV. Cash outflows for the quarter include expenditure on Starpharma's clinical trials, including its three phase 2 DEP® programs. Expenditure also included development of multiple preclinical candidates, including DEP® lutetium and DEP® ADC programs, as well as costs associated with VivaGel® BV.

Starpharma continues to maintain its strong balance sheet, and is well placed to advance its three phase 2 DEP® assets, alongside its commercial products, and to progress its development activities including the new COVID-19 nasal spray.

Key recent activities and events:

- **DEP® irinotecan** phase 1 trial was successfully completed ahead of schedule and moved immediately into phase 2. In phase 1, DEP® irinotecan was well-tolerated and patients generally experienced fewer and less severe side effects, including no cases of the problematic severe diarrhoea, which is common with the conventional form of irinotecan (and has a FDA black box warning). Encouraging efficacy signals were observed in 50% of evaluable patients. A number of patients have already been dosed in phase 2, which is actively recruiting at five sites, including The Kinghorn Cancer Centre (Sydney) and the Beatson (Glasgow), both of which recently opened for recruitment.
- Starpharma successfully developed **DEP® lutetium,** a radiotherapeutic candidate that showed statistically significant and durable anticancer activity and was extremely well tolerated in a human prostate cancer model (DU-145). DEP® lutetium is one of several promising DEP® radiotherapeutic candidates in development.
- AstraZeneca continued to progress its phase 1 clinical trial for **DEP® AZD0466**, opening the prestigious MD Anderson Cancer Center (Houston, Texas) as an additional trial site.
- Following positive results with SPL7013 against the COVID-19 SARS-CoV-2 (coronavirus), Starpharma commenced rapidly developing an **SPL7013 COVID nasal spray** that has the potential to prevent acquisition and transmission of SARS-CoV-2, and to complement vaccine-based prevention strategies.
    - Starpharma has patented the COVID-19 nasal spray and is expediting its development by leveraging existing regulatory approvals, clinical and nonclinical data for marketed products containing SPL7013, stocks of material, supply chains and existing relationships. Starpharma is also pursuing grant funding, and has commenced commercialisation discussions.
    - During the quarter, Starpharma confirmed with regulators the classification of the COVID-19 nasal spray, and that minimal re-development is required for the product. Starpharma's strategy is to leverage its vast body of existing technical data for SPL7013 and existing regulatory approvals, to fast-track development and to expedite product launch.
    - Given SPL7013 has broad spectrum antiviral activity, Starpharma is also exploring the nasal spray's application beyond COVID-19 for common respiratory viruses and as a pandemic preparedness product.

- **VivaGel® BV** was launched in the Central and Eastern European region. This launch follows launches in Germany, the UK and several other European countries. Mundipharma is continuing with activities to expand its geographic footprint of VivaGel® BV. Multiple additional regulatory applications were submitted for Betadine™ BV Gel and new approvals were granted. In Australia, Aspen continued its promotional activities for **Fleurstat BVgel**, maintaining its #1 position by market share of topical BV treatments in Australia.
- The formal review process with the US FDA for approval of **VivaGel® BV** continued and is ongoing, with the expectation that COVID-19 will continue to impact the timeline.
- Recruitment has resumed in all DEP® clinical trials following some disruption to new patient recruitment associated with the impact of COVID-19 on UK hospitals. There are some trial sites including in London where recruitment resumption has been slower than in regional centres.
- **DEP® docetaxel** – DEP® docetaxel + gemcitabine combination study commenced at the Christie, with further sites to open in the coming weeks. This combination study will run in parallel with the ongoing phase 2 study and will further enhance the commercial potential of DEP® docetaxel. The ongoing phase 2 study continues to progress following slowed recruitment due to COVID-19. Patients treated with DEP® docetaxel in the trial have experienced impressive results including stable disease and substantial target tumour shrinkage in cancers including pancreatic, lung, prostate, gastric and oesophageal.
- **DEP® cabazitaxel** – recruitment is progressing well following COVID-19 interruption, and a fifth site has been added to this trial at the Kinghorn Cancer Centre in Sydney. Impressive data continues to emerge, with demonstration of encouraging efficacy signals, including stable disease, significant target tumour shrinkage and substantial tumour marker reductions (e.g. PSA[1]), in cancers including prostate, gastro-oesophageal, breast, ovarian and cholangiocarcinoma.
- **DEP® irinotecan** in combination with an immuno-oncology (IO) agent (anti PD-1 antibody) showed improvement in survival and efficacy in human colorectal cancer (CRC) models when compared to anti PD-1 antibody alone. This impressive data and results from our phase 1 DEP® irinotecan trial have already attracted the attention of industry players and have triggered discussions regarding potential clinical combinations.
- Starpharma signed up a new DEP® program with an existing partner in an exciting and novel area of cancer therapeutics.
- An agreement is currently being finalised for a DEP® program in a new therapeutic area with a new commercial partner. The first DEP® program is for an anti-infective, and the agreement will be structured to allow for expansion into other therapy areas.
- Commercial discussions are underway with two further major pharmaceutical companies for several partnered DEP® drug delivery programs in oncology and non-oncology areas.
- Five posters featuring the DEP® platform were presented at the AACR (American Association for Cancer Research) Annual Meeting. Three featured AstraZeneca's DEP® oncology product, AZD0466, which consistently outperformed venetoclax in multiple preclinical tumour models. Two posters showcased Starpharma's three clinical-stage DEP® products, demonstrating superior performance in a range of tumour models, both alone and in combination with other agents.
- Several preclinical programs progressed, including advancing DEP® gemcitabine towards the clinic, and initiating new internal programs, including a DEP® based antiviral treatment for COVID-19.

[1] PSA – Prostate Specific Antigen

Dr Jackie Fairley, Starpharma CEO, commented: “We are pleased to have maintained good progress during this past quarter including completion of the DEP® irinotecan trial ahead of schedule, despite the challenges presented by COVID-19. Whilst the quarter has been impacted by several one-off clinical expenses and the expansion of our internal DEP® portfolio to three phase 2 programs, we are pleased to have been able to maintain our annual cash burn at similar levels as previous years”.

“We quickly identified an opportunity for a preventative SPL7013 COVID-19 nasal spray, confirmed an expedited regulatory pathway with regulators and have rapidly progressed its development. Specialist clinical feedback has confirmed that a preventative nasal spray would be highly valued and play an important role in reducing transmission, complementing vaccine-based prevention strategies”, added Dr Fairley.

“We continued to advance our three phase 2 DEP® assets and to build our pipeline, adding DEP® lutetium, which showed impressive efficacy and survival benefit. These impressive results in this rapidly expanding area further illustrate the versatility of Starpharma’s DEP® platform,” concluded Dr Fairley.

Receipts for the quarter of $0.9 million included product supply, royalties and milestone payments for VivaGel® BV, as well as government grants. Operating cash outflows for the quarter reflects the investment in product R&D ($3.8 million), including one-off costs related to the completion of the DEP® irinotecan phase 1, trial start-up cost including clinical trial supplies, and one-off regulatory costs. Staffing levels were stable with staff costs for the quarter slightly lower at $1.6 million, including directors’ fees and CEO remuneration of $232,000. The closing cash balance of $30.1 million was adversely impacted by a foreign exchange loss of $1.1 million in the quarter.

COVID-19

During the quarter, Starpharma continued to employ a broad range of measures to protect the health and safety of staff and clinical trial patients. Starpharma continues to actively monitor and review the situation, and measures are updated as appropriate.

Disruptions to the Company’s laboratory and office operations and its supply chain continue to be minimal, although, in Starpharma’s clinical trials, there was disruption to new patient recruitment associated with the impact of COVID-19 on UK hospitals. Recruitment has now resumed in all DEP® clinical trials and as previously advised, a number of new sites have been opened.

As experienced by companies around the world, Starpharma’s partners for VivaGel® BV have had some disruption to their sales and marketing activities, and the COVID-19 lockdowns have delayed some launches and may impact consumer demand.

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHRY), located in Melbourne Australia, is an ASX 300 company and is a world leader in the development of dendrimer products for pharmaceutical, life science and other applications.

Starpharma’s underlying technology is built around dendrimers – a type of synthetic nanoscale polymer that is highly regular in size and structure and well suited to pharmaceutical and medical uses. Starpharma has two core development programs: VivaGel® portfolio and DEP® drug delivery with the Company developing several products internally and others via commercial partnerships.

VivaGel®: Starpharma’s women’s health product - VivaGel® BV is based on SPL7013, astodrimer sodium, a proprietary dendrimer. VivaGel® BV for bacterial vaginosis (BV), is available for sale under the brand names Betafem® BV Gel (UK), Betadine BV™ (Europe), Betadine™ BV Gel (Asia) and Fleurstat BVgel (Australia and New Zealand) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa, and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel® condom (an antiviral condom which includes VivaGel® in the lubricant) in several regions, including Australia, Europe, Canada, China, and Japan (Okamoto). The VivaGel® condom has been launched in Japan under Okamoto’s 003 brand, and in Australia and Canada under the LifeStyles Dual Protect® brand. The VivaGel® condom is approved in Europe.

DEP® - Dendrimer Enhanced Product®: Starpharma's DEP® drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP® programs, including improved efficacy, safety, and survival. Starpharma has three internal DEP® products – DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan - in clinical development in patients with solid tumours. Starpharma's partnered DEP® programs include a multiproduct DEP® licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP® version of one of AstraZeneca's major marketed oncology medicines.

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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.

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 June 2020**

	Consolidated statement of cash flows	**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	456	7,229
1.2	Payments for		
	(a) research and development	(3,822)	(13,376)
	(b) product manufacturing and operating costs	(104)	(1,508)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,611)	(7,610)
	(f) administration and corporate costs	(127)	(1,042)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	98	562
1.5	Interest and other costs of finance paid	(17)	(79)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	363	5,261
1.8	Other (provide details if material)	-	(213)
1.9	**Net cash from / (used in) operating activities**	**(4,764)**	**(10,776)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(31)	(125)
	(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**	**(31)**	**(125)**
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)	(149)	(584)
3.10	**Net cash from / (used in) financing activities**	**(149)**	**(584)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	36,086	41,251
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,764)	(10,776)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(31)	(125)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(149)	(584)
4.5	Effect of movement in exchange rates on cash held	(1,088)	288
4.60	**Cash and cash equivalents at end of period**	**30,054**	**30,054**

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	4,070	3,968
5.2	Call deposits	25,984	32,118
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)**	**30,054**	**36,086**

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	232
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	200	-
7.2	Credit standby arrangements	150	14
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**350**	**14**

7.5	Unused financing facilities available at quarter end	336

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)	(4,764)
8.2	Cash and cash equivalents at quarter end (item 4.6)	30,054
8.3	Unused finance facilities available at quarter end (item 7.5)	336
8.4	Total available funding (item 8.2 + item 8.3)	30,390
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**6.4#**

 # Note: The above 'estimated quarters of funding' metric is subject to significant variability as a result of cash inflows varying quarter by quarter, such as milestones and the receipt of R&D tax incentive which is usually received in the December quarter.

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 2020

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.