

Quarterly Cashflow and Activity Report

Melbourne, Australia; 7 April 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 31 March 2020.

Starpharma's cash balance as at 31 March 2020 was \$36.1 million, an increase of \$0.2 million compared to the previous quarter's cash balance. Net operating cash outflows for the quarter were \$0.9 million, or \$6.0 million for the nine months to 31 March 2020. Starpharma's strong cash reserves and clean balance sheet places the Company in a strong position to continue to progress its commercial and R&D activities in the current uncertain global environment of the COVID-19 pandemic.

Receipts for the quarter of \$4.7 million included a US\$3 million payment from AstraZeneca in relation to the DEP[®] milestone for commencement of patient enrolment in the clinical trial of AZD0466, and cash receipts for VivaGel[®] products. Cash outflows relate to product manufacturing and regulatory/commercialisation costs for VivaGel[®] BV products as well as R&D-related expenditure, including for Starpharma's three internal DEP[®] clinical programs.

From the outset of COVID-19 emerging, Starpharma has implemented a comprehensive range of measures to protect the health and safety of its workforce while continuing to deliver and develop medicines for patients in need. The laboratory and on-site GMP manufacturing facility are currently fully operational and non-lab staff all continue to work on products and programs remotely during this time.

Key recent activities and events:

- Receipt of US\$3 million milestone payment from AstraZeneca for the successful dosing of the first patient in the phase 1 DEP[®] clinical trial for AZD0466. AstraZeneca recently indicated this trial is continuing, and they are progressing activities in preparation for opening additional sites in the US.
- Starpharma's three DEP[®] clinical trials progressed and further encouraging efficacy signals were observed. Significant developments in the ongoing trials, include:
 - **DEP[®] docetaxel** – continued observation of further encouraging efficacy signals including stable disease and substantial target tumour shrinkage in patients with cancers including pancreatic, gastric and oesophageal cancer.
 - **DEP[®] cabazitaxel** – demonstration of encouraging efficacy signals, including stable disease, significant target tumour shrinkage and substantial tumour marker reductions (e.g. PSA¹), in cancers including prostate, gastro-oesophageal, breast and cholangiocarcinoma.
 - **DEP[®] irinotecan** – dosing continues in the escalation phase and the product continues to be well-tolerated with encouraging efficacy signals observed, not only in patients with colorectal cancer, for which conventional Irinotecan is approved, but also in patients with breast and pancreatic cancer, for which it is not. For instance, one advanced breast cancer patient with extensive liver metastases has achieved 27 weeks' stable disease. This impressive result is despite the patient having been heavily pre-treated - with more than 100 cycles of 11 different breast cancer

¹ PSA – Prostate Specific Antigen

treatments previously. DEP[®] irinotecan has been well-tolerated, with no patients exhibiting the severe diarrhoea that is particularly problematic with the marketed form of irinotecan, Camptosar[®].

Consistent with previously reported clinical results, patients treated with these DEP[®] products typically exhibited fewer and/or less severe side-effects, than are observed with the conventional therapies.

- VivaGel[®] BV was launched in Asia under the brand name BETADINE[™] BV Gel (available Over-The-Counter). Preparations continued for product roll-out of BETADINE[™] BV Gel across Asia, in readiness for further regulatory approvals as they are granted. Regulatory activities are progressing for multiple countries across other Mundipharma regions. Starpharma also manufactured product to support Mundipharma's international roll-out of VivaGel[®] BV.
- Promotional activities for Fleurstat BVgel were expanded across Australia, with strong support from physicians and pharmacists, and the product now ranks as the #1 topical BV treatment in Australia.
- Okamoto's licensed territory was expanded to include marketing rights for the VivaGel[®] condom in a further 11 countries in Asia, which include South Korea, Indonesia, Malaysia, Thailand, Singapore and the consumer (non-government) China market.
- Regulatory activities to pursue US FDA approval of VivaGel[®] BV continued, including the formal review process.
- Aspen recently launched Fleurstat BVgel in New Zealand, and advertising and promotion activities have commenced, although launch activities may be somewhat impacted by COVID-19 related restrictions.
- Progress with several preclinical programs, including advancing DEP[®] gemcitabine towards the clinic.
- Starpharma is currently finalising arrangements with potential partners prior to commencement of new Targeted (ADC) and non-ADC DEP[®] programs, following successful meetings at the JP Morgan Healthcare Conference in San Francisco in January.
- As part of Starpharma's DEP[®] pipeline development strategy the Company continues to explore therapeutic areas outside oncology. In 2019, Starpharma initiated a range of antiviral DEP[®] programs with several market-leading antiviral products. Given the renewed importance of antiviral therapies in the current environment, Starpharma is prioritising further work on these programs, including partnering opportunities and is also exploring other antiviral strategies within in its portfolio.

Dr Jackie Fairley, Starpharma CEO, commented: "We're pleased to have ended the quarter in such a strong financial position. During the period we continued to make progress with programs across both product portfolios, including regulatory progress and further roll-out of VivaGel[®] BV internationally, expanding Okamoto's VivaGel[®] licence and advancing our clinical and preclinical DEP[®] programs".

"In the next few months, we look forward to the continued roll-out of products in the VivaGel[®] portfolio throughout multiple regions, and to supporting the regulatory, marketing and distribution activities of our partners", Dr Fairley added.

Operating cash outflows for the quarter reflects the investment in product R&D (\$3.4 million) on clinical and preclinical studies and regulatory activities, while product manufacturing and operating outflows (\$0.4 million) support the commercialisation of VivaGel[®] and DEP[®] product opportunities. Staff costs for the quarter were \$1.7 million, and staffing levels remain stable.

COVID-19 pandemic

Since the emergence of COVID-19, Starpharma has implemented a broad program of measures to protect the health and safety of staff and clinical trial patients, and to ensure product supply to customers. The company has established a range of strategies and controls to mitigate the impact of COVID-19 on its business and continues to update these as the situation evolves.

Starpharma's business operations continue to operate with minimal disruption, with stringent hygiene protocols in place to ensure that staff can continue in their roles in a safe and secure way, including work from home arrangements, virtual meetings, minimal onsite visitation and frequent cleaning/disinfecting on the premises. The Company's laboratory and in-house GMP manufacturing facilities are currently in full operation, and collaborations with various groups continue, which enables preclinical programs, other research and clinical trial support to progress as normal.

The burden of COVID-19 on healthcare resources globally is unprecedented, with a significant redirection of healthcare professionals to the care of COVID-19 patients. Industry-wide, this will impact the ability of many clinical research sites to enrol new trial patients, and may impact on the overall timing of Starpharma's clinical programs. Importantly, the design of the DEP[®] clinical programs is such that we do not anticipate COVID-19 to adversely affect the integrity of trial results.

In the face of COVID-19, patient safety continues to be of utmost importance. To minimise patient exposure to COVID-19, DEP[®] trial sites are implementing a number of strategies to enable patients already receiving DEP[®] treatment to continue doing so. While most enrolled patients are continuing DEP[®] treatment, recruitment of new patients is not currently occurring at most sites as hospitals prepare for the potential need to re-allocate staff to COVID-19 patient care. In view of the demands on the healthcare system, Starpharma has paused the commencement of new DEP[®] combination studies for the time being.

AstraZeneca has indicated that dosing in its phase 1 DEP[®] trial for AZD0466 continues.

With regard to VivaGel[®] BV, to date there has been no disruption to supply chain activities and key inventory levels remain adequate. VivaGel[®] BV product roll-out plans are continuing, though there may be some delays in certain countries, dependent upon partner's activities, such as sales representative visits.

As part of its strategy for FDA approval of VivaGel[®] BV, Starpharma continues to progress the FDA review process with input from a team of expert FDA consultants (regulatory, statistical, clinical, legal; several ex-FDA) and we are advised that it is possible that COVID-19 activities within the FDA may impact on timing. In view of the COVID-19 pandemic, and in particular, the potential disruption to the US healthcare system, the Company has paused activities relating to a potential BV treatment trial in the US, and this decision also supports Starpharma's objective to preserve its strong cash position. Starpharma will continue to monitor the situation in the coming months.

Dr Jackie Fairley, Starpharma CEO, commented: "Whilst COVID-19 is impacting companies around the world, Starpharma is in a very favourable position with \$36.1 million in cash and

is currently fully operational with laboratory and in-house manufacturing facilities unaffected. Starpharma is well-positioned with programs continuing to operate across each portfolio, including commercial partnering activities.”

“With regard to our DEP® clinical trials, we continue to support all of our programs, to minimise potential impact. Given the COVID-19 burden on healthcare systems around the world, we have taken the responsible step not to initiate new clinical studies at this time. The past few months has been a very busy time for Starpharma as we implemented continuity plans across the business in relation to COVID-19 and we thank staff for their exceptional dedication over this period”, concluded Dr Fairley.

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, astodimer 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 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.

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

20 078 532 180

Quarter ended ("current quarter")

31 March 2020

Consolidated statement of cash flows		Current quarter	Year to date (9 months)
		\$A'000	\$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	4,705	6,773
1.2	Payments for		
(a)	research and development	(3,427)	(9,554)
(b)	product manufacturing and operating costs	(390)	(1,404)
(c)	advertising and marketing	-	-
(d)	leased assets	-	-
(e)	staff costs	(1,709)	(5,999)
(f)	administration and corporate costs	(140)	(915)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	128	464
1.5	Interest and other costs of finance paid	(19)	(62)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	4,898
1.8	Other (provide details if material)	-	(213)
1.9	Net cash from / (used in) operating activities	(852)	(6,012)
2.	Cash flows from investing activities		
2.1	Payments to acquire:		
(a)	entities	-	-
(b)	businesses	-	-
(c)	property, plant and equipment	(22)	(94)
(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	(22)	(94)
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)	(435)
3.10	Net cash from / (used in) financing activities	(149)	(435)
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	35,876	41,251
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(852)	(6,012)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(22)	(94)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(149)	(435)
4.5	Effect of movement in exchange rates on cash held	1,233	1,376
4.60	Cash and cash equivalents at end of period	36,086	36,086

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1 Bank balances	3,968	4,814
5.2 Call deposits	32,118	31,062
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)	36,086	35,876

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
233
-

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
200	4
150	10
-	-
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, the annual interest rate is 5.8%, repayments end in May 2020, and the facility is secured against equipment and a term deposit. Item 8.2 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)	(852)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	36,086
8.3 Unused finance facilities available at quarter end (Item 7.5)	336
8.4 Total available funding (Item 8.2 + Item 8.3)	36,422
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	43

- 8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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

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

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

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: 7 April 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.