starpharma

ASX Announcement

Quarterly Cashflow Report

Melbourne, Australia; 29 April 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 31 March 2019.

Starpharma's cash balance as at 31 March 2019 was $44.7 million, with a positive net operating and investing cash inflow for the quarter of $0.3 million. The cash inflows for the quarter included the $4.0 million R&D tax incentive, with outflows including costs related to Starpharma's DEP® clinical programs and the manufacture of product for the VivaGel® BV launch.

Starpharma's strong cash balance and upcoming expected receipts associated with the international roll-out of VivaGel® products enables the Company to support the ongoing regulatory activities for VivaGel® BV while continuing to build its high-value DEP® portfolio.

Key events during the quarter:

- VivaGel® BV launch activities (Australia): VivaGel® BV has been officially launched in Australia by Aspen as Fleurstat BVgel. The product has undergone distribution across Australia and is available from pharmacies.
- VivaGel® BV launch activities (Europe): Mundipharma's preparations are well advanced for the launch of VivaGel® BV in Europe before the end of FY19, and product for launch has been manufactured.
- VivaGel® BV regulatory activities: a meeting was held with the US FDA as part of the process to clarify and address FDA's request for confirmatory data prior to the approval of VivaGel® BV in the US. Further information is expected once formal outcomes of the meeting and the subsequent follow up has been confirmed in writing by the FDA, which is expected within several weeks. In addition, regulatory activities have advanced in multiple countries within Mundipharma's territory.
- VivaGel® BV commercial discussions continue in the remaining countries not licensed, including India, Canada and Israel.
- VivaGel® condom: Starpharma obtained first receipts from Okamoto in April and Okamoto are progressing well with their launch plans for the VivaGel® condom in Japan which is expected mid-year; regulatory activities in other regions have continued.
- DEP® docetaxel: More than 70% of the initial cohort in the monotherapy arm have been enrolled and encouraging efficacy signals have been observed (stable disease and tumour shrinkage) together with a notable lack of bone marrow toxicity. Patients in the combination arm also continue to show encouraging efficacy signals and recruitment continues to progress well.
- DEP® cabazitaxel: Dose escalation continues. Several patients have now been dosed with multiple cycles, and no dose-limiting toxicities or other significant toxicities associated with DEP® cabazitaxel have been observed. Efficacy signals have been observed in prostate and other tumour types and at doses several fold lower than usually prescribed for cabazitaxel (due to the trial being in the escalation phase).
- Commencement of the DEP® irinotecan trial is expected mid-year; the Clinical Research Organisation (CRO) has been appointed, sites have been selected and the ethics and regulatory submissions are well advanced. Starpharma and the CRO are currently finalising trial documents ahead of trial start.

- Partnered programs progressed well during the quarter, including preparations for clinical trial commencement of AstraZeneca's AZD0466, which is expected this year. Additional partnering discussions have advanced for new DEP® projects.
- Recent patent grants include: an additional US patent granted for DEP® docetaxel, bringing the total US patents for the product to six, with an expiry date of 2032.

Dr Jackie Fairley, Starpharma CEO, commented: "We were extremely excited to see the launch of Fleurstat BVgel in Australia – it's fitting that the first launch in the world of VivaGel® BV is in the very country it was developed. During this time, we've also been working closely with Mundipharma to finalise preparations for the launch of VivaGel® BV in Europe, as well as progressing registrations for multiple other territories".

"Our internal DEP® products - DEP® docetaxel and DEP® cabazitaxel both continue to generate positive clinical results, including the observation of efficacy signals in a range of tumour types. It's also really pleasing to see the enthusiasm from clinicians and potential partners regarding DEP® irinotecan entering the clinic. In parallel, we are engaged in discussions for a number of high-value commercial partnering opportunities for our DEP® platform and look forward to reporting on these," concluded Dr Fairley.

Outlook

- Launch of VivaGel® BV in Europe and other markets
- Work together with FDA to address request for confirmatory data for VivaGel® BV
- Further VivaGel® BV licences with India, Canada and Israel currently under discussion
- Further regulatory approvals for VivaGel® BV
- Revenue from VivaGel® BV - milestones and sales/royalties
- Launch of VivaGel® condom in Japan and approvals/launch in additional regions, such as Europe and China
- Progress with DEP® docetaxel and DEP® cabazitaxel clinical trials
- DEP® irinotecan trial commencement - possible combination studies
- Other DEP® program developments, including new DEP® candidates, DEP® radiotherapeutics
- AstraZeneca program developments, AZD0466 advanced to the clinic and revenue from milestones; deals for further compounds
- Other partnered DEP® deals and program developments, including for Targeted DEP® (which includes Antibody Drug Conjugates or ADCs)
- Ophthalmic development / co-development (SPL7013 ophthalmic drops)

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 is approved for marketing in the EU for treatment and prevention of bacterial vaginosis (BV) and available for sale in Australia for treatment of BV and relief of symptoms. A marketing 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 Australia and Canada under the Lifestyles® Dual Protect™ brand.

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 two internal DEP® products – DEP® docetaxel and DEP® cabazitaxel - in clinical development in patients with solid tumours, and further DEP® products approaching clinical development. 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.

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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 report for entities subject to Listing Rule 4.7B

Introduced 31/03/00, Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

Starpharma Holdings Limited

ABN	Quarter ended ("current quarter")
20 078 532 180	**31 March 2019**

	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	58	2,181
1.2	Payments for		
	(a) research and development	(1,646)	(6,280)
	(b) product manufacturing and operating costs	(444)	(1,108)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,730)	(5,820)
	(f) administration and corporate costs	(133)	(709)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	264	827
1.5	Interest and other costs of finance paid	(1)	(2)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	4,019	4,019
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**387**	**(6,892)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(130)	(283)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(a) intellectual property	-	-
	(b) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	8
	(d) intellectual property	-	-
	(e) 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**	**(130)**	**(275)**
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
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 (provide details if material)	(7)	(20)
3.10	**Net cash from / (used in) financing activities**	**(7)**	**(20)**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter/year to date	44,401	51,319
4.2	Net cash from / (used in) operating activities (item 1.9 above)	387	(6,892)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(130)	(275)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(7)	(20)
4.5	Effect of movement in exchange rates on cash held	96	615
4.6	**Cash and cash equivalents at end of quarter**	**44,747**	**44,747**

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	2,346	2,659
5.2	Call deposits	42,401	41,742
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)**	**44,747**	**44,401**

6.	Payments to directors of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	224
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	

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.	Payments to related entities of the entity and their associates	Current quarter $A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
7.3	Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

8.	Financing facilities available	Total facility amount at quarter end $A'000	Amount drawn at quarter end $A'000
8.1	Loan facilities	200	29
8.2	Credit standby arrangements	150	15
8.3	Other (please specify)	-	-

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

Item 8.1 is a National Australia Bank master asset finance facility for leased laboratory equipment, the annual interest rate is 5.8% and the facility is secured against equipment and a term deposit. Item 8.2 is a National Australia Bank business credit card facility predominantly used for business travel, the facility is secured against a term deposit.

9.	Estimated cash outflows for next quarter	$A'000
9.1	Research and development	(2,400)
9.2	Product manufacturing and operating costs	(750)
9.3	Advertising and marketing	-
9.4	Leased assets	-
9.5	Staff costs	(1,650)
9.6	Administration and corporate costs	(180)
9.7	Other (provide details if material)	-
9.8	**Total estimated cash outflows *(excluding cash inflows)***	**(4,980)**

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

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.

N J Baade
Company Secretary
29 April 2019

Notes

1 The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.

2 If this quarterly 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 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.