starpharma

ASX Announcement

Quarterly Cashflow Report

Melbourne, Australia; 16 July 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 30 June 2019.

Starpharma's cash balance as at 30 June 2019 was $41.3 million. The net cash-burn for the financial year was $10.1 million (FY18: $9.9 million). The net operating and investing cash outflows for the quarter was $3.5 million. Cash outflows for the quarter include the manufacture of VivaGel® BV to support launches in Australia and Europe and expenditure on Starpharma's three DEP® clinical programs, including final preparations and initiation of multiple sites for the DEP® irinotecan trial. Receipts for the quarter included supply receipts for VivaGel® BV and first receipts for the VivaGel® condom in Japan.

The cash balance does not include the $0.7 million (US$0.5 million) milestone payment from Mundipharma for the launch of VivaGel® BV in Europe, which was received in July 2019.

Key recent events:

- First global launches for VivaGel® BV: VivaGel® BV was launched in several European countries, including Germany, under the brand name Betadine™ BV, generating a milestone payment of US$0.5M to Starpharma. VivaGel® BV was also launched in Australia by Aspen as Fleurstat BVgel.
- Starpharma signed a Development and Option Agreement with AstraZeneca to progress development of a DEP® version of one of AstraZeneca's major marketed oncology medicines. This new commercial deal is separate to the existing multi-product licence with AstraZeneca, under which AZD0466 is being developed.
- AZD0466 (AstraZeneca's DEP® Bcl2/xL oncology product): AstraZeneca's Senior Vice President and Head of Oncology, IMED Biotech Unit, Dr Susan Galbraith, presented AZD0466 to clinicians at ASCO as part of their oncology development update. US FDA investigational new drug application (IND) for AZD0466 is planned in the near future with the product expected to enter the clinic later this year.
- A US patent was granted for AstraZeneca's Bcl2/xL DEP® conjugates (including AZD0466), which provides US exclusivity until 2038, and the potential for up to 5 years' extension.
- Starpharma received formal feedback from the US FDA regarding approval of VivaGel® BV. The FDA feedback highlighted several potential options and Starpharma is currently working through these with the FDA and its expert consultants.
- Mundipharma has submitted regulatory applications for VivaGel® BV in multiple countries under their agreement, and Starpharma and Mundipharma have also compiled a number of other regulatory applications for submission in the coming months.
- VivaGel® BV commercial discussions continued in the remaining countries not licensed, including India, Canada and Israel.
- Okamoto launched the VivaGel® condom in Japan under its leading '003' brand and Starpharma received first receipts from Okamoto in April. Regulatory activities for the VivaGel® condom have progressed in other regions.
- Final preparations are being completed ahead of commencement of the DEP® irinotecan clinical trial in the near future. Initial UK sites include Guy's Hospital London, The Christie and The Royal Marsden, with other sites to be added in the expansion phase of the trial.

- DEP® docetaxel: Monotherapy and combination arms of the trial continue to show encouraging efficacy signals and a notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects including hair-loss, anaphylaxis and oedema.
- DEP® cabazitaxel: Patient recruitment continuing following multiple dose escalations and a number of patients being treated with more than 10 cycles of DEP® cabazitaxel. Encouraging efficacy signals continue to be observed in multiple patients in prostate cancer, for which cabazitaxel is approved, as well as other tumour types where efficacy would not necessarily be expected for the marketed form of cabazitaxel. These other tumour types include pancreatic cancer and ovarian cancer.
- Promising combination data were reported for DEP® irinotecan showing significant efficacy and safety benefits over leading colorectal cancer drugs, irinotecan (Camptosar®) and cetuximab (Erbitux®), in the irinotecan-refractory HT-29 human colon cancer nonclinical model.
- Other internal DEP® preclinical and partnered DEP® programs progressed well during the quarter.

Starpharma's strong balance sheet and expected revenue from VivaGel® products and partnered DEP® milestones places the Company in a strong position to support ongoing commercial roll-out and regulatory milestones for the VivaGel® portfolio, while continuing to expand and build value in the DEP® portfolio, including progressing clinical trials for its three internal DEP® products.

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to now have our VivaGel® BV products on the market in multiple regions, with the recent launches in Europe and Australia. We look forward to the further roll-out of VivaGel® BV internationally in the coming months."

"The next quarter will also be an exciting period for DEP® with the commencement of our clinical trial for DEP® irinotecan, our third DEP® product to enter the clinic. Our strategy is to build a valuable portfolio of clinical-stage assets for licensing. In our partnered DEP® area, we were delighted to sign a second commercial deal with AstraZeneca for one of their major oncology products and we also look forward to the near-term IND filing for AZD0466 and its clinical trial commencement later this year," 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, astodrimer sodium, a proprietary dendrimer. VivaGel® BV for bacterial vaginosis (BV), is available for sale under the brand name Betadine BV™ (Europe) 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.

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, with DEP® irinotecan due to commence clinical trials shortly. 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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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	**30 June 2019**

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	626	2,807
1.2	Payments for		
	(a) research and development	(2,263)	(8,543)
	(b) product manufacturing and operating costs	(336)	(1,444)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,615)	(7,435)
	(f) administration and corporate costs	(113)	(822)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	249	1,076
1.5	Interest and other costs of finance paid	-	(2)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	4,019
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,452)**	**(10,344)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(31)	(314)
	(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**	**(31)**	**(306)**
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)	(6)	(26)
3.10	**Net cash from / (used in) financing activities**	**(6)**	**(26)**
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	44,747	51,319
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,452)	(10,344)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(31)	(306)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(6)	(26)
4.5	Effect of movement in exchange rates on cash held	(7)	608
4.6	**Cash and cash equivalents at end of quarter**	**41,251**	**41,251**

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	2,945	2,346
5.2	Call deposits	38,306	42,401
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)**	**41,251**	**44,747**

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	225
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	23
8.2	Credit standby arrangements	150	23
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	(2,600)
9.2	Product manufacturing and operating costs	(1,000)
9.3	Advertising and marketing	-
9.4	Leased assets	-
9.5	Staff costs	(1,640)
9.6	Administration and corporate costs	(700)
9.7	Other (provide details if material)	-
9.8	**Total estimated cash outflows *(excluding cash inflows)***	**(5,940)**

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
16 July 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.