

### **Quarterly Cashflow Report**

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

Starpharma's cash balance as at 30 September 2019 was \$36.8 million, with net operating cash outflows for the quarter of \$4.6 million. The cash balance does not include the anticipated \$4.9 million R&D tax incentive which is expected to be received during the December quarter.

Receipts from customers for the quarter totalled \$1.1 million, which includes launch/regulatory milestones, product supply and royalty receipts from partners for VivaGel® BV. Cash outflows for the quarter include the manufacture of VivaGel® BV product following launches in Australia and Europe as well as expenditure on Starpharma's three DEP® clinical programs, including trial commencement and site setup costs for DEP® irinotecan in the quarter.

### Key recent events:

- FDA authorised the IND for a phase 1 clinical trial of AstraZeneca's first DEP® product, AZD0466. The AZD0466 clinical program is expected to commence later this year following site set-up and ethics committee/IRB approvals.
- Starpharma commenced its phase 1/2 clinical trial for DEP<sup>®</sup> irinotecan. The trial will be conducted at multiple sites, with initial sites already opened including leading UK cancer centres The Christie, The Royal Marsden and Newcastle Freeman Hospital.
- The first Asian regulatory approvals were received for VivaGel<sup>®</sup> BV and these approvals will facilitate and accelerate further registrations in Asia. The launch of Betadine<sup>™</sup> BV Gel in Asia is expected in the coming months and further regulatory submissions have been made in countries across Asia and other Mundipharma regions.
- Marketing and promotional activities for VivaGel<sup>®</sup> BV continued following the launch of Betadine BV<sup>™</sup> in Europe (June) and Fleurstat BVgel in Australia, where the product is currently for sale. In Australia, Fleurstat BVgel is available in major pharmacy chains (Chemist Warehouse, Terry White, Amcal, Priceline, etc).
- Starpharma continues to progress with a dual strategy to achieve US approval for VivaGel® BV with input from its team of expert FDA consultants, statisticians and legal advisors. In parallel with seeking further review of some of the FDA's initial conclusions, Starpharma has also undertaken significant preparations for a possible BV treatment trial, if required.
- Promising efficacy signals were observed in the DEP® cabazitaxel and DEP® docetaxel trials, as well as a notable lack of bone marrow toxicity and other common side effects.
   The dose escalation phase for DEP® cabazitaxel is approaching completion with multiple patients displaying efficacy signals, including stable disease of more than 47 weeks and significant reductions in specific tumour biomarkers, such as prostate specific antigen (PSA).



- Impressive data were reported for DEP<sup>®</sup> irinotecan, alone and in combination with Merck and AstraZeneca's Lynparza<sup>®</sup>, in a refractory human colon cancer model. DEP<sup>®</sup> irinotecan showed significant anti-tumour efficacy and synergy compared with standard irinotecan (Camptosar<sup>®</sup>) and Lynparza<sup>®</sup> (olaparib). These data have been shared with a number of interested partners and will also inform the conduct of the DEP<sup>®</sup> irinotecan clinical program.
- A novel HER-2 Targeted DEP® conjugate (ADC) from Starpharma's internal Targeted DEP® program demonstrated significant tumour regression and 100% survival in a preclinical human ovarian cancer model. Starpharma's novel HER-2 Targeted DEP® drug conjugate significantly outperformed leading products Kadcyla®, a HER-2 targeted antibody-drug conjugate (ADC), and Herceptin® itself.
- Two new DEP® patents were filed covering new DEP® candidates currently in preclinical development.

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to see our first AstraZeneca partnered DEP® product, AZD0466, cleared by the FDA to enter human clinical trials. This is an important milestone for the Company and provides further industry validation for the utility of the DEP® platform. This candidate will be the fourth DEP® product to enter the clinic following the commencement of Starpharma's DEP® irinotecan during the quarter".

"We were also pleased to see the roll-out of VivaGel® BV into Europe as well as Australia, and to receive the first regulatory approvals in Asia where the product is expected to be launched later this calendar year. The next quarter will be an exciting period for Starpharma with the anticipated commencement of a phase 1 trial for AZD0466, and further progress with our three internal DEP® clinical trials, further regulatory approvals and launches for VivaGel® BV," 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 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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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 fillings 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 e

# 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

| ABN            | Quarter ended ("current quarter") |
|----------------|-----------------------------------|
| 20 078 532 180 | 30 September 2019                 |
|                |                                   |

| Con | solidated statement of cash flows              | Current quarter | Year to date<br>(3 months) |
|-----|--|-----------------|----------------------------|
|     |  | \$A'000         | \$A'000                    |
| 1.  | Cash flows from operating activities           |                 |                            |
| 1.1 | Receipts from customers                        | 1,132           | 1,132                      |
| 1.2 | Payments for                                   |                 |                            |
|     | (a) research and development                   | (2,823)         | (2,823)                    |
|     | (b) product manufacturing and operating costs  | (576)           | (576)                      |
|     | (c) advertising and marketing                  | -               | -                          |
|     | (d) leased assets                              | -               | -                          |
|     | (e) staff costs                                | (1,680)         | (1,680)                    |
|     | (f) administration and corporate costs         | (630)           | (630)                      |
| 1.3 | Dividends received (see note 3)                | -               | -                          |
| 1.4 | Interest received                              | 193             | 193                        |
| 1.5 | Interest and other costs of finance paid       | (22)            | (22)                       |
| 1.6 | Income taxes paid                              | -               | -                          |
| 1.7 | Government grants and tax incentives           | -               | -                          |
| 1.8 | Other (provide details if material)            | (213)           | (213)                      |
| 1.9 | Net cash from / (used in) operating activities | (4,619)         | (4,619)                    |

| 2.  | Cash flows from investing activities           |      |      |
|-----|--|------|------|
| 2.1 | Payments to acquire:                           |      |      |
|     | (a) property, plant and equipment              | (38) | (38) |
| •   | (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                                | -    | -    |
|     | (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 | (38) | (38) |

| 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 (principal repayments on lease liability in compliance with AASB16)   | (142) | (142) |
| 3.10 | Net cash from / (used in) financing activities                              | (142) | (142) |

| 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        | 41,251  | 41,251  |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above)       | (4,619) | (4,619) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above)       | (38)    | (38)    |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above)      | (142)   | (142)   |
| 4.5 | Effect of movement in exchange rates on cash held                     | 330     | 330     |
| 4.6 | Cash and cash equivalents at end of quarter                           | 36,782  | 36,782  |

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| 5.  | Reconciliation of cash and cash equivalents   | Current quarter | Previous quarter |
|-----|---|-----------------|------------------|
|     | at the end of the quarter (as shown in the consolidated statement of cash flows) to the | \$A'000         | \$A'000          |
| İ   | related items in the accounts   |                 |                  |
| 5.1 | Bank balances   | 4,304           | 2,945            |
| 5.2 | Call deposits   | 32,478          | 38,306           |
| 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)               | 36,782          | 41,251           |

## 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

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

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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<br>at quarter end | Amount drawn at quarter end |
|-----|--------------------------------|---|-----------------------------|
|     |                                | \$A'000                                 | \$A'000                     |
| 8.1 | Loan facilities                | 200                                     | 17                          |
| 8.2 | Credit standby arrangements    | 150                                     | 25                          |
| 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                               | (2,750) |
| 9.2 | Product manufacturing and operating costs              | (700)   |
| 9.3 | Advertising and marketing                              | -       |
| 9.4 | Leased assets  | -       |
| 9.5 | Staff costs  | (2,600) |
| 9.6 | Administration and corporate costs                     | (150)   |
| 9.7 | Other (provide details if material)                    | -       |
| 9.8 | Total estimated cash outflows (excluding cash inflows) | (6,200) |

| 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 30 October 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.
- 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.