

Quarterly Activities Report & Appendix 4C

Highlights

- **Second DEP® Research Agreement signed with MSD involving DEP® antibody drug conjugates (ADC), building on the successful MSD program signed in 2021, which is ongoing**
- **New Phase 2 DEP® cabazitaxel data in prostate cancer presented at global oncology meeting, ESMO Congress in Paris**
 - **DEP® cabazitaxel demonstrated longer progression-free survival and a lower incidence of key side effects, including severe neutropenia, anaemia and thrombocytopenia, compared to previously published data for conventional cabazitaxel (Jevtana®)**
- **Continued commercial rollout of VIRALEZE™ with the signing of a sales and distribution agreement for Hong Kong and Macau with Hengan International Group**
- **Well-funded with a cash balance of \$42.3 million as at 30 September 2022**

Melbourne, Australia; 26 October 2022: Starpharma (ASX: SPL, OTCQX: SPHRY) today releases its Quarterly Activities Report and Appendix 4C for the period ended 30 September 2022.

Starpharma's closing cash balance as at 30 September 2022 was \$42.3 million. Net operating cash outflows for the quarter were \$7.3 million, which is similar to the corresponding period in FY22 of \$7.0 million. The cash balance of \$42.3 million excludes the anticipated ~\$7.0 million refundable Research and Development (R&D) tax incentive, expected to be received in the next 2-3 months. Receipts from customers for the quarter totaled \$0.6 million, including product sales.

Commenting on the quarter, Dr Jackie Fairley, Starpharma CEO, said:

"We were very pleased to present new clinical results at ESMO Congress in Paris during the quarter, which highlighted longer progression-free survival and lower incidence of key side effects in patients treated with DEP® cabazitaxel compared to previously published data for conventional cabazitaxel (Jevtana®). DEP® cabazitaxel is one of three clinical-stage oncology candidates being developed by Starpharma, along with DEP® docetaxel and DEP® irinotecan. These three Phase 2 trials are approaching completion and business development activities are already underway.

"This quarter, Starpharma also expanded its relationship with MSD through a second DEP® ADC agreement, building on our ongoing first program that began in 2021. The potential and broad applicability of our DEP® technology has attracted partnerships with three of the top 10 global pharmaceutical companies and we look forward to progressing these and further expanding our partnerships.

"The company recently expanded the distribution of VIRALEZE™ nasal spray into northern Asia, with the signing of a new sales and distribution agreement for Hong Kong and Macau with Hengan International Group. VIRALEZE™ will be available in these new markets through Hengan Group's extensive distribution network to retail stores and other channels, including via leading pharmacy chains, in the coming months."

DEP® Programs

Starpharma signed a new DEP® Research Agreement with MSD, a recognised leader in the global biopharmaceutical industry. Starpharma now has two active ADC programs with MSD, with Starpharma generating a number of novel DEP® dendrimer conjugates for evaluation by MSD. In parallel, Starpharma's partnered DEP® programs with AstraZeneca, Genentech, and Chase Sun continued to progress during the quarter. AstraZeneca continued recruitment into two clinical trials of their DEP® nanoparticle formulation AZD0466. The Phase 1/2 Advanced Haematological Malignancies trial continued to expand with 12 sites now open of an expected >30 sites. The Phase 1/2 Study of AZD0466 in Advanced Non-Hodgkin Lymphoma has opened a number of sites in the US and Korea with ~20 sites planned globally.

Starpharma presented new clinical data for **DEP® cabazitaxel** in prostate cancer at the ESMO Congress in Paris, France (see [company announcement dated 12 September 2022](#)). DEP® cabazitaxel showed a number of key advantages for patients compared to previously published data for conventional cabazitaxel, including longer progression-free survival and a lower incidence of key side effects, despite this patient cohort being relatively more heavily pre-treated, including prior treatment with taxanes.

In addition, encouraging efficacy signals have been observed in DEP® cabazitaxel treated patients with other cancer types, including platinum resistant ovarian cancer and other hard-to-treat cancers such as gastroesophageal cancer. Starpharma is recruiting a number of patients with these cancer types, thus expanding the potential clinical applications for DEP® cabazitaxel.

In total, the Phase 2 DEP® cabazitaxel trial has enrolled 72 patients with recruitment expected to complete within the next 2-3 months. Extensive data analyses and biostatistics activities are already underway and licensing discussions for the product continue.

The Phase 2 trial of **DEP® irinotecan** has continued to progress well, with 83 patients recruited to date for monotherapy treatment, with further recruitment focused on a specific indication where particularly impressive data have been observed. Encouraging efficacy signals with DEP® irinotecan have been observed in multiple tumour types, including colorectal, breast, ovarian (including platinum resistant), pancreatic, lung, and oesophageal cancer. Screening for the initial 6 patients for the combination arm, with DEP® irinotecan dosed in combination with fluorouracil (5-FU) + leucovorin, is well advanced. The combination of standard irinotecan + 5-FU + leucovorin, known as FOLFIRI, is a commonly used combination treatment in patients with colorectal cancer.

Starpharma's clinical program for **DEP® docetaxel** continued to progress well during the quarter, with a total of 74 patients enrolled across the monotherapy and combination arms. Encouraging efficacy signals have been observed, including in heavily pre-treated patients with lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers. The monotherapy trial is expected to complete recruitment within the next 2-3 months.

Business development activities for DEP® cabazitaxel, DEP® irinotecan, and DEP® docetaxel are ongoing. Other internal preclinical DEP® programs including DEP® radiotheranostics, DEP® ADCs, and DEP® gemcitabine continue to progress, with ongoing commercial discussions in parallel.

Marketed Products

Starpharma recently signed a sales and distribution agreement for its nasal spray product, **VIRALEZE™**, for Hong Kong and Macau with a Hong Kong Stock Exchange listed company,

Hengan International Group. VIRALEZE™ is expected to launch in Hong Kong and Macau within the next 2-3 months and will be available through an extensive network of retail stores and other channels, including via leading pharmacy chains.

Following the relaunch of VIRALEZE™ in the UK in June, LloydsPharmacy has implemented several marketing initiatives, including promoting the product instore and online as part of the pharmacy chain's 'winter wellness' and flu immunisation programs.

Starpharma continues to pursue registration and commercialisation for VIRALEZE™ in multiple other countries. In Australia, the review by the TGA for the nasal spray is ongoing as a medical device in accordance with the determination made in April 2022.

Starpharma continues to work together with its **VivaGel® BV** partners – Mundipharma and Aspen – to progress regulatory and commercial activities for the product. Regulatory approval for VivaGel® BV was achieved in Kuwait during the quarter. In Australia, consumer demand continues to trend positively, and Aspen is planning a new consumer campaign to support VivaGel® BV (Fleurstat BVgel).

Cash Flows

Starpharma's closing cash balance as at 30 September 2022 was \$42.3 million. Net operating cash outflows for the quarter were \$7.3 million, which is similar to the corresponding period in FY22 of \$7.0 million. The cash balance of \$42.3 million excludes the anticipated ~\$7.0 million refundable R&D tax incentive, expected to be received in the next 2-3 months. Receipts from customers for the quarter totaled \$0.6 million, including product sales. R&D outflows of \$3.3 million were higher than the prior corresponding period (FY22 Q1), reflecting the advanced stage of multiple clinical programs running in parallel. Product manufacturing and operating costs were \$1.6 million reflecting inventory, manufacturing and operational outflows associated with new markets and the continued rollout of VIRALEZE™ and ongoing supply of VivaGel® BV. As in prior years, the first quarter corporate and administration outflows are higher than other quarters due to one-off annual costs, including ASX listing fees, insurance premiums and audit fees, totalling \$1.1 million. Staffing costs were lower at \$1.9 million (FY22 Q1 \$2.0 million) and include non-executive and executive directors' fees of \$258,000.

This announcement is intended for investors and market participants only. VIRALEZE™ is not approved for use or supply in Australia.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for DEP® drug delivery, respiratory viruses and VivaGel®.

Starpharma's proprietary drug delivery platform technology, DEP®, is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP® versions of existing drugs, particularly in the area of anti-cancer therapies.

DEP® partnerships include oncology programs with AstraZeneca, with MSD in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives and other world leading pharmaceutical companies. Partnered DEP® programs have the potential to generate significant future milestones and royalties.

Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered in a number of countries, including in Europe and the UK. VIRALEZE™ is not approved for use or supply in Australia. SPL7013 is also

utilised in the following products - VivaGel® condom and VivaGel® BV. VivaGel® products have been licensed in >160 countries and are registered in >45 countries, including the UK, Europe, Japan, Southeast Asia, South Africa, Australia and New Zealand.

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Disclosure

This ASX Announcement was authorised for release by non-executive director, Ms Zita Peach.

The Quarterly Activities Report & Appendix 4C 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. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.

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")

30-Sep-22

Consolidated statement of cash flows		Current quarter	Year to date (3 months)
		\$A'000	\$A'000
1. Cash flows from operating activities			
1.1 Receipts from customers		615	615
1.2 Payments for			
(a) research and development		(3,298)	(3,298)
(b) product manufacturing and operating costs		(1,645)	(1,645)
(c) advertising and marketing		(67)	(67)
(d) leased assets		-	-
(e) staff costs		(1,866)	(1,866)
(f) administration and corporate costs		(1,143)	(1,143)
1.3 Dividends received (see note 3)		-	-
1.4 Interest received		167	167
1.5 Interest and other costs of finance paid		(56)	(56)
1.6 Income taxes paid		-	-
1.7 Government grants and tax incentives		11	11
1.8 Other		-	-
1.9 Net cash from / (used in) operating activities		(7,282)	(7,282)
2. Cash flows from investing activities			
2.1 Payments to acquire or for:			
(a) entities		-	-
(b) businesses		-	-
(c) property, plant and equipment		(101)	(101)
(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		(101)	(101)
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)		(169)	(169)
3.10 Net cash from / (used in) financing activities		(169)	(169)
4. Net increase / (decrease) in cash and cash equivalents for the period			
4.1 Cash and cash equivalents at beginning of period		49,918	49,918
4.2 Net cash from / (used in) operating activities (item 1.9 above)		(7,282)	(7,282)
4.3 Net cash from / (used in) investing activities (item 2.6 above)		(101)	(101)
4.4 Net cash from / (used in) financing activities (item 3.10 above)		(169)	(169)
4.5 Effect of movement in exchange rates on cash held		(23)	(23)
4.60 Cash and cash equivalents at end of period		42,343	42,343

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	2,180	4,126
5.2 Call deposits	40,163	45,792
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)	42,343	49,918

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
258
-

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
4,800	4,548
150	28
-	-
4,950	4,576

7.5 Unused financing facilities available at quarter end

374

- 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 consists of:

- \$0.8M existing National Australia Bank master asset finance facility for leased laboratory equipment, secured against equipment and a term deposit, interest rate 2.8%.
- \$4.0M Invest Victoria R&D cash flow loan with Treasury Corporation of Victoria maturing Oct-2023, secured against future refundable R&D tax incentives, current interest rate 2.8%. A\$4.0M drawn per item 3.5 above.
- Item 7.2 is a National Australia Bank corporate credit card facility (rate 12.65%).

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(7,282)
8.2 Cash and cash equivalents at quarter end (item 4.6)	42,343
8.3 Unused finance facilities available at quarter end (item 7.5)	374
8.4 Total available funding (item 8.2 + item 8.3)	42,717
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.9

- 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: 26 October 2022

Authorised by: Nigel Baade, Chief Financial Officer & Company Secretary
(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.