

# **Quarterly Cashflow Report**

**Melbourne, Australia; 19 July 2017:** Starpharma (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 30 June 2017.

The cash balance as at 30 June 2017 was \$61.8 million, with operating and investing cash inflows for the full year of \$15.7 million, placing Starpharma in a strong cash position to commercialise its VivaGel® products and accelerate the development of multiple DEP® programs. The 30 June balance includes the net proceeds from the recent sale of Starpharma's Agrochemicals business and the milestone payment received from AstraZeneca.

# Recent highlights:

- **Agrochemicals:** Starpharma sold its agrochemicals business to Agrium Inc, one of the largest agribusinesses in the world, for \$35 million greater than four times the book value of the assets and with no impact to the IP of the VivaGel® and DEP® portfolios.
- Partnered DEP®: Received \$2.6 million milestone payment from AstraZeneca for their first oncology compound under Starpharma's multiproduct DEP® license, triggered by the final preclinical milestone prior to commencing clinical trials. DEP® partnered programs continued to generate impressive results, consistent with the performance of DEP® more broadly.
- **DEP**<sup>®</sup> **docetaxel:** Continues to show promising efficacy signals, with no neutropenia among patients in the final expansion stage of the phase 1 trial. Preparations are well-advanced to use an adaptive trial design to facilitate rapid transition into phase 2 following completion of the final few patients in the phase 1 cohort. Phase 2 product manufacture and CRO selection are already complete.
- **DEP**<sup>®</sup> **cabazitaxel:** Final preclinical studies complete. Product manufacture, documentation, site and CRO selection are well-advanced ahead of the phase 1 trial start later this year. Starpharma used its new in-house scale-up facilities to manufacture DEP<sup>®</sup> cabazitaxel for the upcoming trial, resulting in a faster turnaround time and cost savings.
- DEP<sup>®</sup> irinotecan: Demonstrated significantly improved anti-tumour activity and increased survival compared with irinotecan in a variety of human colon cancer models, including irinotecan resistant HT-29 model. Activities are underway to expedite the development and scaling up of DEP<sup>®</sup> irinotecan for further preclinical studies prior to clinical trials.
- VivaGel® rBV phase 3 trials: Data collation and routine quality control review are complete, with the statistical analysis plan and bio-statistical programming in the process of being finalised, prior to unblinding the data. Trial results are expected to be released in late July/early August.
- FDA New Drug Application: Compilation of the first NDA for VivaGel® BV (for BV treatment) is well-advanced and expected to be submitted as early as possible in the second half of 2017, with rBV to follow. Starpharma is leveraging its QIDP designation and Fast Track status to support the NDA process.



- Appointed global healthcare investment bank: Licensing discussions in US, Europe, and global negotiations continue to progress positively following the coveted Fast Track and QIDP FDA designations granted earlier this year. Starpharma has appointed a leading global healthcare investment bank to facilitate the competitive process amongst several potential partners.
- **VivaGel**® **condom:** Ansell launched the VivaGel® condom in North America. Good regulatory progress has also been achieved in other key regions.

The net operating cash outflows of \$1.3 million for the quarter reflect the expenditure on the final stages of the phase 3 clinical trials for VivaGel® rBV, the DEP® docetaxel clinical programs, as well as preparations for the DEP® cabazitaxel clinical trial and other internal DEP® programs. Net cash inflows from investing activities of \$33.0 million include cash consideration from the successful sale of the agrochemicals business in June 2017.

Commenting on the Company's recent highlights and outlook, Dr Jackie Fairley, Chief Executive Officer of Starpharma said: "The past quarter has been a transformative period for the Company. The recent sale of our agrochemicals business and the AstraZeneca milestone payment demonstrate the value and optionality of our dendrimer products, where the value has been recognised and rewarded in significant commercial terms. Having successfully monetised our Priostar® IP, Starpharma is now in a particularly strong position to expedite and expand the development of internal DEP® candidates and broaden our pipeline to run more DEP® clinical trials in parallel, while continuing to commercialise the VivaGel® portfolio."

"The remainder of 2017 represents a particularly exciting period for Starpharma with several significant milestones expected, including the near-term reporting of VivaGel® rBV phase 3 results and regulatory activities for both VivaGel® BV indications; topline results for the phase 1 DEP® docetaxel trial/transition to phase 2; and commencement of our first clinical trial for DEP® cabazitaxel", added Dr Fairley.

## **Outlook**

- Results from the pivotal VivaGel<sup>®</sup> rBV phase 3 trials.
- NDA for VivaGel® BV expected as early as possible in 2H CY2017 for treatment, with the prevention of rBV indication to follow.
- Results from the phase 1 DEP<sup>®</sup> docetaxel trial and transition to phase 2.
- Commencement of DEP® cabazitaxel phase 1 clinical trial.
- Aspen's launch of VivaGel® BV for treatment of bacterial vaginosis upon TGA approval.
- Partnering deal(s) for VivaGel<sup>®</sup> BV.
- Further regulatory approvals and launch of VivaGel® condom in other regions.
- DEP<sup>®</sup> milestone payments and additional DEP<sup>®</sup> licenses.
- Progress and further data on DEP<sup>®</sup> internal candidates, such as DEP<sup>®</sup> irinotecan.



#### **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 a number of products internally and others via commercial partnerships.

VivaGel®: Starpharma's portfolio includes late stage women's health products based on VivaGel® (SPL7013, astodrimer sodium), a proprietary dendrimer. VivaGel® formulated as a water based gel and delivered vaginally - VivaGel® BV - has EU regulatory approval for topical treatment and rapid relief of bacterial vaginosis (BV) and is also under clinical development for the prevention of recurrent BV. Starpharma has signed a license agreement with Aspen Pharmacare Australia Pty Ltd for the sales and marketing of VivaGel® BV in Australia and New Zealand. Starpharma has also signed separate license agreements with Ansell Limited (ASX:ANN), Okamoto Industries. Inc., (TSE: JP3192800005), Sky and Land (China) and Koushan Pharmed (Iran) to market a value-added, VivaGel® condom. The VivaGel® condom is available for purchase in Australia and in Canada under Ansell's Lifestyles® Dual Protect™ brand. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles®, Manix®, ZERO® and SKYN®. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market.

**DEP®:** The other major part of Starpharma's pharmaceuticals business is its proprietary DEP® drug delivery platform. Starpharma has both partnered and internal DEP® programs in Drug Delivery. A number of dendrimer-enhanced, or DEP® versions of existing drugs are under development by the Company. The most advanced of these is DEP® docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere®), which is in clinical development in patients with solid tumours. In preclinical studies DEP® docetaxel has shown significant tumour-targeting and superior anti-cancer effects across a range of important cancer types including breast, prostate, lung and ovarian tumour, when compared to Taxotere® (docetaxel). In the partnered area, AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP® drug delivery platform in the development and commercialisation of a number of AstraZeneca oncology compounds.

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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 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

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ABN	Quarter ended ("current quarter")
20 078 532 180	30 June 2017

Con	solidated statement of cash flo	ws	Current quarter	Year to date (12 months)
			\$A'000	\$A'000
1.	Cash flows from operating activities	5		
1.1	Receipts from customers		2,668	3,309
1.2	Payments for			
	(a) research and development		(2,484)	(16,957)
	(b) product manufacturing and ope	rating costs	(26)	(290)
	(c) advertising and marketing		-	-
	(d) leased assets		-	-
	(e) staff costs		(1,481)	(6,453)
	(f) administration and corporate co	ests	(111)	(721)
1.3	Dividends received (see note 3)		-	-
1.4	Interest received		128	635
1.5	Interest and other costs of finance pai	d	-	(1)
1.6	Income taxes paid		-	-
1.7	Government grants and tax incentives		-	3,523
1.8	Other (provide details if material)		-	-
1.9	Net cash from / (used in) operating	activities	(1,306)	(16,955)

2.	Cash	of lows from investing activities		
2.1	Paym	nents to acquire:		
	(a)	property, plant and equipment	(306)	(625)
	(b)	businesses (see item 10)	-	-
	(c)	investments	-	-
	(a)	intellectual property	-	-
	(b)	other non-current assets	-	-
2.2	Proce	eeds from disposal of:		
	(a)	property, plant and equipment	-	-
	(b)	businesses (see item 10)	33,281	33,281
	(c)	investments	-	-
	(d)	intellectual property	-	-
	(e)	other non-current assets	-	-
2.3	Cash	flows from loans to other entities	-	-
2.4	Divid	ends received (see note 3)	-	-
2.5	Othe	r (provide details if material)	-	-
2.6	Net o	eash from / (used in) investing activities	32,975	32,656

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)	(3)	(21)
3.10	Net cash from / (used in) financing activities	(3)	(21)

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	29,659	45,972
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,306)	(16,955)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	32,975	32,656
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(3)	(21)
4.5	Effect of movement in exchange rates on cash held	(137)	(464)
4.6	Cash and cash equivalents at end of quarter	61,188	61,188

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
	related items in the accounts		
5.1	Bank balances	3,351	1,379
5.2	Call deposits	57,837	28,280
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)	61,188	29,659

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	213
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	

Financing facilities available Total facility amount Amount drawn at 8. at quarter end quarter end \$A'000 \$A'000 Loan facilities 8.1 200 70 Credit standby arrangements 150 63 8.3 Other (please specify)

3.4 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	(4,800)
9.2	Product manufacturing and operating costs	(150)
9.3	Advertising and marketing	-
9.4	Leased assets	-
9.5	Staff costs	(1,350)
9.6	Administration and corporate costs	(300)
9.7	Other	-
9.8	Total estimated cash outflows (excluding cash inflows)	(6,600)

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Disposals
10.1	Name of entity	Dendritic Nanotechnologies, Inc./
<u> </u>		Priostar Pty Ltd*
10.2	Place of incorporation or registration	Delaware, USA / Victoria, Australia
10.3	Consideration for acquisition or disposal	A\$35.0M
10.4	Total net assets	A\$7.5M
10.5	Nature of business	Agrochemicals

<sup>\*</sup>The transaction involved the sale of Starpharma's Agrochemical business comprising Dendritic Nanotechnologies, Inc. (USA), and Priostar Pty Ltd (a newly created subsidiary holding the Australian agrochemical assets).

## 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 19 July 2017

#### 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.