

# **Quarterly Cashflow Report**

**Melbourne, Australia; 31 January 2017:** Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 31 December 2016.

The cash balance as at 31 December 2016 was \$36.3 million, compared with a cash balance of \$37.6 million at 30 September 2016 placing Starpharma in a strong cash position with a number of important milestones upcoming in 2017.

## Highlights include:

- VivaGel<sup>®</sup> BV granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the US FDA for both treatment of bacterial vaginosis (BV) and prevention of recurrent BV;
- Progress with compiling a US marketing application for submission to the FDA for treatment of BV, with the prevention indication to follow;
- Enrolment completed for the pivotal phase 3 trials for VivaGel<sup>®</sup> BV for the prevention of recurrent BV; Trial completion expected Q1 CY2017, with top line results expected Q2 CY2017;
- Advanced commercial negotiations for VivaGel<sup>®</sup> BV in Europe and other territories; US negotiations accelerated by recent FDA designations;
- Preparations underway for Ansell's imminent launch of the VivaGel<sup>®</sup> condom in Canada;
- DEP<sup>®</sup> docetaxel phase 1 clinical trial progressing well in the final expansion phase including enrolment of several new patients at Guy's and St Thomas' Hospital, London with specific tumour types of interest;
- Preparations for phase 2 trials for DEP<sup>®</sup> docetaxel continue to advance with product manufacture complete; site and CRO selection well advanced;
- Partnered DEP<sup>®</sup> programs continue to perform extremely well, including the most recent AstraZeneca program and Targeted DEP<sup>®</sup> partnerships;
- DEP<sup>®</sup> cabazitaxel preclinical program now in its final stages ahead of the planned phase 1 clinical trial in CY2017;
- DEP<sup>®</sup> irinotecan showed near complete tumour regression in multiple human tumour models; preclinical results reproduced in two different cell lines of human colon cancer;
- Expand in-house DEP<sup>®</sup> scale-up facilities to facilitate rapid development of internal candidates and expedite partnered programs;
- Signed a license and supply agreement for a VivaGel<sup>®</sup> condom with one of Iran's fastest growing pharmaceutical companies, Koushan Pharmed;

- Additional positive Priostar<sup>®</sup> glyphosate field-trial results and a further patent allowed in the US; and
- Receipt of \$3.5M from R&D tax incentive refund.

The net operating cash outflows of \$1.9 million for the quarter reflect the expenditure on the final stages of phase 3 clinical trials for VivaGel<sup>®</sup> BV, the DEP<sup>®</sup> docetaxel clinical trial program and other programs across Starpharma's portfolio, offset by the receipt of the R&D tax incentive related to expenditure from the prior financial year.

"We anticipate a significant year in 2017 with numerous milestones to be reported as we approach the conclusion of our VivaGel<sup>®</sup> BV phase 3 trials, complete the DEP<sup>®</sup> docetaxel phase 1, gear up for phase 2 DEP<sup>®</sup> docetaxel and the phase 1 DEP<sup>®</sup> cabazitaxel program, in parallel with the development of our other internal and partnered DEP<sup>®</sup> programs" said Dr Jackie Fairley, Chief Executive Officer of Starpharma.

"The recent QIDP and Fast Track designations for VivaGel<sup>®</sup> BV, coupled with favourable changes to the FDA's guidance on BV treatment, open up a significant new market opportunity for Starpharma. We look forward to the upcoming launch of our VivaGel<sup>®</sup> BV treatment product in Australia, while we continue to negotiate deals abroad and progress regulatory filings in other territories."

"Our partnered and internal programs continue to validate the reproducible benefits of the DEP<sup>®</sup> platform including reduced toxicities, formulation enhancement and improved efficacy. The response to our DEP<sup>®</sup> platform and VivaGel<sup>®</sup> BV portfolio from existing and potential new partners has been extremely positive, with successful meetings held throughout the US and Europe following the recent JP Morgan Conference," Dr Fairley concluded.

## 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 three core development programs: VivaGel<sup>®</sup> portfolio, DEP<sup>®</sup> drug delivery, and agrochemicals with the Company developing a number of products internally and others via commercial partnerships.

Starpharma's lead products are based on VivaGel<sup>®</sup> (SPL7013, astodrimer sodium), a proprietary dendrimer which has antimicrobial properties. VivaGel<sup>®</sup> formulated as a water based gel and delivered vaginally now has EU regulatory approval for topical treatment and rapid relief of bacterial vaginosis (BV) and is 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<sup>®</sup> 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<sup>®</sup> condom. The VivaGel<sup>®</sup> condom is available for purchase in Australia under Ansell's Lifestyles<sup>®</sup> Dual Protect<sup>™</sup> brand. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles<sup>®</sup>, Manix<sup>®</sup>, ZERO<sup>®</sup> and SKYN<sup>®</sup>. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market.

In the wider pharmaceutical field, Starpharma has both partnered and internal programs in Drug Delivery. A number of dendrimer-enhanced, or DEP<sup>®</sup> versions of existing drugs are under development. The most advanced of these is DEP<sup>®</sup> docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere<sup>®</sup>), which is in clinical development in patients with solid tumours. In preclinical studies DEP<sup>®</sup> 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<sup>®</sup> (docetaxel). AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP<sup>®</sup> drug delivery platform in the development and commercialisation of an AstraZeneca oncology compound, with potential for follow on compounds directed at a defined family of targets.

In agrochemicals Starpharma has a series of partnerships with leading industry players including global leader Adama (formerly Makhteshim Agan) as well as internal programs including an enhanced version of glyphosate (the active ingredient in Roundup<sup>®</sup>).

For more information please visit: www.starpharma.com

## FOR FURTHER INFORMATION

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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	en	tity

## Starpharma Holdings Limited

ABN	Quarter ended ("current quarter")
20 078 532 180	31 December 2016

Con	solidated statement of cash flows	Current quarter	Year to date
			(6 months)
		\$A'000	\$A'000
۱.	Cash flows from operating activities		
.1	Receipts from customers	374	624
.2	Payments for		
	(a) research and development	(3,725)	(10,370)
	(b) product manufacturing and operating costs	(67)	(150
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(2,106)	(3,502
	(f) administration and corporate costs	(55)	(354)
.3	Dividends received (see note 3)	-	-
.4	Interest received	160	348
.5	Interest and other costs of finance paid	-	-
.6	Income taxes paid	-	-
.7	Government grants and tax incentives	3,523	3,523
.8	Other (provide details if material)	-	-
.9	Net cash from / (used in) operating activities	(1,896)	(9,881
2. 2.1	Cash flows from investing activities Payments to acquire:		
	(a) property, plant and equipment	(22)	(50
	(b) businesses (see item 10)	(22)	(50
	(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)		-
.5	Other (provide details if material)	_	-
2.6	Net cash from / (used in) investing activities	(22)	(50
		i	(00
B.	Cash flows from financing activities		
3.1	Proceeds from issues of shares		-

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)	(8)	(16)
3.10	Net cash from / (used in) financing activities	(8)	(16)

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	37,554	45,972
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,896)	(9,881)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(22)	(50)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(8)	(16)
4.5	Effect of movement in exchange rates on cash held	652	255
4.6	Cash and cash equivalents at end of quarter	36,280	36,280

Total facility amount

at quarter end

\$A'000

200

150

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the	Current quarter \$A'000	Previous quarter \$A'000
	related items in the accounts		
5.1	Bank balances	1,207	1,221
5.2	Call deposits	35,073	36,333
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)	36,280	37,554
	Payments to directors of the entity and their associates		Current quarter \$A'000
-	Payments to directors of the entity and their associates Aggregate amount of payments to these parties included in item 1.2		
6.1 6.2	Aggregate amount of payments to these parties included in item 1.2 Aggregate amount of cash flow from loans to these parties included in item 2.3		
6.1 6.2	Aggregate amount of payments to these parties included in item 1.2		\$A'000 398
6.1 6.2	Aggregate amount of payments to these parties included in item 1.2 Aggregate amount of cash flow from loans to these parties included in item 2.3 Include below any explanation necessary to understand the transactions included in items Item 6.1 consists of the following:		\$A'000 398
<b>6.</b> 6.1 6.2 6.3	Aggregate amount of payments to these parties included in item 1.2 Aggregate amount of cash flow from loans to these parties included in item 2.3 Include below any explanation necessary to understand the transactions included in items		\$A'000 398

#### 7. Payments to related entities of the entity and their associates

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

8.1	Loan facilities	

- 8.2 Credit standby arrangements
- 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 8.2% 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	(4,500)
9.2	Product manufacturing and operating costs	(150)
9.3	Advertising and marketing	-
9.4	Leased assets	-
9.5	Staff costs	(1,400)
9.6	Administration and corporate costs	(120)
9.7	Other (Capital expenditure - investment in scale-up facility)	(200)
9.8	Total estimated cash outflows (excluding cash inflows)	(6,370)

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	-	-

Current quarter \$A'000	•••
-	

Amount drawn at

quarter end

\$A'000

3

### **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.



Company Secretary 31 January 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.
- 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.