

# **Quarterly Cashflow Report**

**Melbourne, Australia; 28 April 2017:** Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 31 March 2017.

The cash balance as at 31 March 2017 was \$29.7 million placing Starpharma in a strong cash position to continue with the commercialisation of its products across the VivaGel<sup>®</sup>, DEP<sup>®</sup> drug delivery and agrochemicals portfolios.

The March balance does not include the recently announced AstraZeneca milestone payment of US\$2 million that is due to be received in the June quarter.

## **Recent operational highlights:**

- AstraZeneca triggered a US\$2 million (~AUD\$2.7 million) milestone payment for their first oncology compound under Starpharma's multiproduct DEP<sup>®</sup> license following achievement of the final preclinical milestone prior to commencing clinical development.
- Completion of the pivotal phase 3 clinical trials evaluating VivaGel<sup>®</sup> BV for the prevention of recurrent bacterial vaginosis (rBV); top-line results available in Q2 CY2017.
- US FDA granted QIDP designation and Fast Track status for VivaGel<sup>®</sup> BV, each carrying significant benefits for regulatory approval and commercialisation.
- US marketing submission for VivaGel<sup>®</sup> BV treatment well advanced with submission expected in the near future, with the rBV indication to follow.
- Advanced commercial negotiations for VivaGel<sup>®</sup> BV in multiple regions, including Europe; Global/US commercial negotiations positively impacted by Fast Track, QIDP and the favourable revision to FDA's guidance on BV.
- VivaGel<sup>®</sup> condom now available in North America, following the Canadian launch by Ansell under the LifeStyles<sup>®</sup> Dual Protect<sup>™</sup> brand; Starpharma will receive royalties based on sales.
- DEP<sup>®</sup> docetaxel continues to show promising efficacy signals with no neutropenia or hair loss reported in the final expansion phase of its phase 1 clinical trial; patients with specific cancer types recruited at Guy's and St Thomas' Hospital, in London to accelerate trial completion, and facilitate rapid transition to phase 2.
- Key preparation such as product manufacture, site and CRO selection well advanced for the DEP<sup>®</sup> docetaxel phase 2 trial.
- Expansion of Starpharma's in-house DEP<sup>®</sup> scale-up facilities and capabilities to accelerate the development of internal candidates (e.g. DEP<sup>®</sup> cabazitaxel) and partnered DEP<sup>®</sup> programs.
- Final preclinical DEP<sup>®</sup> cabazitaxel activities including manufacture of clinical trial material underway ahead of planned Phase 1 trial in CY2017.
- Other DEP<sup>®</sup> partnered programs, including with world-leading antibody drug conjugate companies, progressing extremely well.

The net operating cash outflows of \$5.8 million for the quarter reflect the expenditure on the closing stages of phase 3 clinical trials for VivaGel<sup>®</sup> rBV, the DEP<sup>®</sup> docetaxel clinical programs, as well as DEP<sup>®</sup> cabazitaxel, capital expenditure for in-house scale up facility and other programs across Starpharma's portfolio.

Commenting on the operational highlights, Dr Jackie Fairley, Chief Executive Officer of Starpharma said: "Starpharma has recently reported several important achievements including a further milestone triggered for AstraZeneca's first DEP<sup>®</sup> candidate, QIDP and Fast Track designations for VivaGel<sup>®</sup> BV, as well as completion of the phase 3 VivaGel<sup>®</sup> BV (rBV) trials. These are important and commercially relevant achievements for the company."

## Outlook

- Results from the pivotal VivaGel<sup>®</sup> BV phase 3 trials (rBV).
- Aspen's launch of VivaGel<sup>®</sup> BV for treatment of bacterial vaginosis upon TGA approval.
- US marketing submission for VivaGel<sup>®</sup> BV expected in the near future for the treatment, with the prevention of rBV indication to follow.
- Partnering deal(s) for VivaGel<sup>®</sup> BV.
- Results from the phase 1 DEP<sup>®</sup> docetaxel trial and initiation of phase 2.
- Commencement of DEP<sup>®</sup> cabazitaxel phase 1 clinical trial.
- Further regulatory approvals and launch of VivaGel<sup>®</sup> condom in other regions.
- Further Priostar<sup>®</sup> licenses and other commercial deal structures for Priostar<sup>®</sup> in Agrochemicals.

## 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. 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 and in Canada 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

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## Starpharma Holdings Limited

ADIN 20 078 532 180	
ABN	Quarter ended ("current guarter")

Con	solidated statement of cash flows	Current quarter	Year to date (9 months)
		\$A'000	\$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	17	641
1.2	Payments for		
	(a) research and development	(4,103)	(14,473
	(b) product manufacturing and operating costs	(114)	(264
	(c) advertising and marketing		-
	(d) leased assets		-
	(e) staff costs	(1,470)	(4,972
	(f) administration and corporate costs	(256)	(610
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	159	507
1.5	Interest and other costs of finance paid	(1)	(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	(5,768)	(15,649
	Cash flows from investing activities		
<b>2.</b> 2.1 2.2	Payments to acquire:   (a) property, plant and equipment   (b) businesses (see item 10)   (c) investments   (a) intellectual property   (b) other non-current assets   Proceeds from disposal of:	(269) - - - - -	(319 - - - -
2.1	Payments to acquire:   (a) property, plant and equipment   (b) businesses (see item 10)   (c) investments   (a) intellectual property   (b) other non-current assets   Proceeds from disposal of:   (a) property, plant and equipment	(269) - - - - - -	(319 - - - -
2.1	Payments to acquire:   (a) property, plant and equipment   (b) businesses (see item 10)   (c) investments   (a) intellectual property   (b) other non-current assets   Proceeds from disposal of:   (a) property, plant and equipment   (b) businesses (see item 10)	(269) - - - - - - - - - -	(319 - - - - -
2.1	Payments to acquire:(a) property, plant and equipment(b) businesses (see item 10)(c) investments(a) intellectual property(b) other non-current assetsProceeds from disposal of:(a) property, plant and equipment(b) businesses (see item 10)(c) investments	(269) - - - - - - - - - - - - - -	(319 - - - - - - -
2.1	Payments to acquire:   (a) property, plant and equipment   (b) businesses (see item 10)   (c) investments   (a) intellectual property   (b) other non-current assets   Proceeds from disposal of:   (a) property, plant and equipment   (b) businesses (see item 10)   (c) investments   (d) intellectual property	(269) - - - - - - - - - - - - - - - - - - -	(319 - - - - - - - - - - - -
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2.1 2.2 2.3	Payments to acquire:(a)property, plant and equipment(b)businesses (see item 10)(c)investments(a)intellectual property(b)other non-current assetsProceeds from disposal of:(a)property, plant and equipment(b)businesses (see item 10)(c)investments(d)intellectual property(e)other non-current assetsCash flows from loans to other entities	(269) - - - - - - - - - - - - - - - - - - -	(319 - - - - - - - - - - - - - - - -
2.1 2.2 2.3 2.4	Payments to acquire:   (a) property, plant and equipment   (b) businesses (see item 10)   (c) investments   (a) intellectual property   (b) other non-current assets   Proceeds from disposal of:   (a) property, plant and equipment   (b) businesses (see item 10)   (c) investments   (d) intellectual property   (e) other non-current assets   Cash flows from loans to other entities   Dividends received (see note 3)	(269) - - - - - - - - - - - - - - - - - - -	(319 - - - - - - - - - - - - - - - - - - -
2.1 2.2 2.3	Payments to acquire:(a)property, plant and equipment(b)businesses (see item 10)(c)investments(a)intellectual property(b)other non-current assetsProceeds from disposal of:(a)property, plant and equipment(b)businesses (see item 10)(c)investments(d)intellectual property(e)other non-current assetsCash flows from loans to other entities	(269) - - - - - - - - - - - - - - - - - - -	(319 - - - - - - - - - - - - - - - - - - -

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)	(2)	(18)
3.10	Net cash from / (used in) financing activities	(2)	(18)

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	36,280	45,972
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,768)	(15,649)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(269)	(319)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2)	(18)
4.5	Effect of movement in exchange rates on cash held	(582)	(327)
4.6	Cash and cash equivalents at end of quarter	29,659	29,659

Total facility amount

at quarter end

\$A'000

200

150

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	1,379	1,207
5.2	Call deposits	28,280	35,073
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)	29,659	36,280
6.	Payments to directors of the entity and their associates		Current quarter
6.	Payments to directors of the entity and their associates		Current quarter \$A'000
<b>6.</b> 6.1	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	Aggregate amount of payments to these parties included in item 1.2	6.1 and 6.2	
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 Include below any explanation necessary to understand the transactions included in items	6.1 and 6.2	
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 Include below any explanation necessary to understand the transactions included in items Item 6.1 consists of the following:	6.1 and 6.2	
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 Include below any explanation necessary to understand the transactions included in items	6.1 and 6.2	

#### 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

8.2 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	(4,000)
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	(150)
9.7	Other (Capital expenditure)	(200)
9.8	Total estimated cash outflows (excluding cash inflows)	(5,900)

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	-	-

C	Current quarter \$A'000	
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Amount drawn at

quarter end

\$A'000

55

#### **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 28 April 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.