



## ASX ANNOUNCEMENT

# **Quarterly Cashflow Report**

**Melbourne, Australia; 14 July 2016:** Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today released its Appendix 4C – Quarterly Cashflow Report for the period ended 30 June 2016.

The cash balance as at 30 June 2016 was \$46.0 million, with operating and investing cash outflows for the full year of \$17.8 million. The cash outflows for the year include expenditure related to the phase 3 clinical trials of VivaGel<sup>®</sup> for prevention of recurrent bacterial vaginosis (BV) and the phase 1 clinical trial of DEP™ docetaxel, as well as the wider drug delivery and agrochemical programs.

### Highlights for the quarter include:

- Achieving more than 90% recruitment in the phase 3 clinical trials of VivaGel<sup>®</sup> for prevention of recurrent BV;
- DEP<sup>™</sup> docetaxel phase 1 clinical trial advancing to the final expansion phase with no neutropenia or hair loss reported, whilst showing promising efficacy signals;
- Significant progression of commercial and regulatory activities for the VivaGel<sup>®</sup> condom in important markets;
- Extensive launch preparations and progress on commercial negotiations for VivaGel<sup>®</sup> BV;
- Expansion of the AstraZeneca DEP™ partnered program to evaluate new therapeutic applications outside the existing license agreement;
- Demonstration of potent antiviral activity of the VivaGel<sup>®</sup> active against the Zika virus in laboratory studies; and
- Demonstration of significantly improved efficacy and elimination of neutropenia with DEP™ cabazitaxel compared to Jevtana<sup>®</sup> (standard cabazitaxel) in preclinical studies.

The phase 3 clinical trials of VivaGel® for the prevention of recurrent BV are nearing the important milestone of full enrolment, with over 90% of required patients now recruited.

The DEP™ docetaxel phase 1 clinical trial is advancing into the final expansion phase with a large European site recently added to facilitate completion of phase 1 and in preparation for phase 2. Importantly, no cases of neutropenia or alopecia (hair loss) have been reported to date, and due to the formulation being polysorbate-80 free, patients have not required steroid pre-treatment or experienced any hypersensitivity reactions. There have been promising efficacy signals at a broad range of dose levels, including at levels lower than the usual Taxotere® clinical doses, in patients that have undergone many prior treatments, including with taxanes, and in a number of cancer types that are typically not sensitive to docetaxel, such as pancreatic, brain, and oesophageal cancers.

Significant progress has been made on the regulatory and commercialisation activities for the VivaGel<sup>®</sup> portfolio of products, both for VivaGel<sup>®</sup> BV for the topical treatment and rapid relief of BV and the VivaGel<sup>®</sup> condom. Starpharma looks forward to concluding some of these activities in the near future.

With the demonstration of potent antiviral activity against the Zika virus, Starpharma is now investigating the potential to include Zika in the list of viruses inactivated for the VivaGel® condoms – further improving the value-add of the product opportunity.

Further highlights in the quarter occurred in the drug delivery portfolio, where the partnered program with AstraZeneca is progressing well and now expanding to include additional DEP<sup>TM</sup> programs beyond the existing multi-product license agreement signed in September 2015. In addition, very promising preclinical results were achieved for Starpharma's internal development candidate, DEP<sup>TM</sup> cabazitaxel.

"There has been significant progress across the portfolio in the recent quarter, and we look forward to announcing some of these in the near future. The clinical, regulatory and commercial progress in the quarter has been extensive, positioning the Company well to execute on the global commercialisation strategy for VivaGel<sup>®</sup>. Meanwhile, we continue to advance the core drug delivery and agrochemicals development programs, with significant progress and generation of encouraging data. The strong cash balance means Starpharma is well positioned to support the development and commercialisation of our deep and broad portfolio," said Dr Jackie Fairley, Chief Executive Officer of Starpharma.

### 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® portfolio, DEP $^{TM}$  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® (SPL7013, astodrimer sodium), a proprietary dendrimer which has antimicrobial properties. VivaGel® 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® BV in Australia and New Zealand. Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries. Inc., (TSE: JP3192800005) to market a value-added, VivaGel® condom. The VivaGel® condom is available for purchase in Australia 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.

In the wider pharmaceutical field, Starpharma has both partnered and internal programs in Drug Delivery. A number of dendrimer-enhanced, or DEP® versions, of existing drugs are under development. 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). AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP® 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®).

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.

# Starpharma Holdings Limited

ABN	Quarter ended ("current quarter")	
20 078 532 180	30 June 2016	

## Consolidated statement of cash flows

Cash flows related to operating activities		Current Quarter \$A'000	Year to Date \$A'000
1.1	Receipts from customers and grants (including R&D Tax Incentive)	142	7,504
1.2	Payments for (a) staff costs	(1,294)	(5,856)
	(b) advertising and marketing	-	-
	(c) research and development	(4,746)	(20,126)
	(d) other working capital	-	-
1.3	Dividends received	-	-
1.4	Interest and other items of a similar nature received	239	670
1.5	Interest and other costs of finance paid	(1)	(3)
1.6	Income taxes paid	-	-
1.7	Other	-	-
	Net operating cash flows	(5,660)	(17,811)
	1100 operating entire 210 Hb	(2,000)	(11,011)
	ws related to investing activities		
1.9	Payment for acquisition of:		
	(a) businesses (item 5)	-	-
	(b) equity investments	-	-
	(c) intellectual property	-	- (0.5)
	(d) physical non-current assets	(57)	<b>(97</b> )
1 10	(e) other non-current assets	-	-
1.10	Proceeds from disposal of:		
	<ul><li>(a) businesses (item 5)</li><li>(b) equity investments</li></ul>	10	125
	(c) intellectual property	10	123
	(d) physical non-current assets	_	1
	(e) other non-current assets	_	_ 1
	(c) one non content access		
1.11	Loans to other entities	-	-
1.12	Loans repaid by other entities	-	-
1.13	Other	-	-
	Net investing cash flows	(47)	29
1.14	Total operating and investing cash flows	(5,707)	(17,782)
Cash flo	ws related to financing activities		
1.15	Proceeds from issues of shares (net)	-	32,596
1.16	Proceeds from sale of forfeited shares	-	-
1.17	Proceeds from borrowings	-	-
1.18	Repayment of borrowings	-	-
1.19	Dividends paid	-	-
1.20	Other - lease repayments	(8)	(32)
	Net financing cash flows	(8)	32,564
Net incr	ease (decrease) in cash held	(5,715)	14,782
1.21	Cash at beginning of quarter/year to date	51,106	30,848
1.22	Exchange rate adjustments	581	342
1.23	Cash at end of quarter	45,972	45,972

## Payments to directors of the entity and associates of the directors Payments to related entities of the entity and associates of the related entities

		Current quarter \$A'000	
1.24	Aggregate amount of payments to the parties included in item 1.2	(207)	
1.25	Aggregate amount of loans to the parties included in item 1.11	-	
1.26	Explanation necessary for an understanding of the transactions		
	Item 1.24 consists of the following:		
	(a) Remuneration paid to the Chief Executive Officer.		
	(b) Director's fees paid to non-executive directors.		
Non-cash	financing and investing activities		
2.1	Details of financing and investing transactions which have had a material effect on coassets and liabilities but did not involve cash flows	onsolidated	
2.2	Details of outlays made by other entities to establish or increase their share in busine	sees in	
2.2	which the reporting entity has an interest	3363 111	
	Nil		
_	s facilities available as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).		
		Amount Amount used	

Item 3.1	A \$200,000 master asset finance facility with National Australia Bank for
	laboratory equipment, guaranteed by term deposit.

200

150

18

43

Loan facilities - Finance facility for laboratory equipment

Credit standby arrangements - Credit card facility

## **Reconciliation of cash**

3.1

3.2

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		Current quarter \$A'000	Previous quarter \$A'000
4.1	Cash on hand and at bank	1,327	3,909
4.2	Deposits at call	44,645	47,197
4.3	Bank overdraft	-	_
4.4	Other (provide details)	-	-
	Total: cash at end of quarter (item 1.23)	45,972	51,106

### Acquisitions and disposals of business entities

- 5.1 Name of entity
- 5.2 Place of incorporation or registration
- 5.3 Consideration for acquisition or disposal
- 5.4 Total net assets
- 5.5 Nature of business

Acquisitions	Disposals
(Item 1.9(a))	(Item 1.10(a))
-	-
-	-
-	-
-	-
-	-

## **Compliance statement**

- This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Law (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2. This statement does give a true and fair view of the matters disclosed.

14 July 2016

N J Baade Company Secretary