

# Starpharma Interim Report and Half-Year Financial Results

**Melbourne, Australia; 27 February 2017:** Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today released its interim report and financial results for the half-year ended 31 December 2016.

# Financial Summary

- Reported loss of \$9.0M (Dec 2015: \$10.0M)
- R&D tax incentives of \$1.7M reported in the half-year (Dec 2015: \$1.8M)
- Cash position at 31 December 2016 of \$36.3M (June 2016: \$46.0M)
- Receipt of \$3.5M R&D tax incentive refund from FY16

# VivaGel<sup>®</sup>

- VivaGel<sup>®</sup> BV granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for both treatment of Bacterial Vaginosis (BV) and prevention of recurrent BV by US FDA;
- Favourable revision to FDA regulatory guidance for BV treatment opens up significant new commercial opportunities for VivaGel<sup>®</sup> BV;
- Enrolment completed for pivotal phase 3 trials: VivaGel® BV prevention of recurrent BV;
- Significant progress in commercial negotiations and launch preparations for VivaGel<sup>®</sup> BV for the treatment and rapid relief of BV;
- Progress with compiling a US marketing application for submission to the FDA for treatment of BV, with the prevention indication to follow;
- License and supply agreements for the VivaGel<sup>®</sup> condom in China and Iran; and
- Canadian regulatory approval for marketing of the VivaGel<sup>®</sup> condom, enabling Ansell to launch in early 2017.

# DEP® Drug Delivery

- AstraZeneca initiated a new (additional) DEP<sup>®</sup> drug delivery program with DEP<sup>®</sup> performing extremely well across the multiple programs underway;
- Two new Targeted DEP<sup>®</sup> partnerships with world-leading antibody-drug conjugate companies producing promising data;
- DEP<sup>®</sup> docetaxel phase 1 clinical trial in its final expansion phase continues to show promising efficacy signals with no neutropenia or hair loss reported;
- Guy's and St Thomas' Hospital in London added to the DEP<sup>®</sup> docetaxel trial to accelerate trial completion, to enrich the patient cohort with specific cancer types, and facilitate rapid transition to phase 2;
- Preparations well advanced for DEP<sup>®</sup> docetaxel phase 2 trial including product manufacture, site and CRO selection;
- Reproduced excellent preclinical results for DEP<sup>®</sup> cabazitaxel with planned phase 1 clinical trial in CY2017;

- DEP® irinotecan showed near complete tumour regression in multiple human colon cancer mouse xenograft models; and
- An expansion of in-house DEP<sup>®</sup> scale-up facilities to facilitate rapid development of internal candidates and expedite partnered programs.

# Agrochemicals

- New partnerships with leading agrochemical companies;
- Additional positive Priostar<sup>®</sup> glyphosate field-trial results; and
- US patent granted for a Priostar<sup>®</sup> glyphosate formulation.

Starpharma concluded the half-year in a strong financial position with a cash balance of \$36.3 million. The net loss after tax for the half-year of \$9.0 million (Dec 2015: \$10.0 million) reflects investment across the VivaGel<sup>®</sup>, DEP<sup>®</sup> drug delivery and agrochemical portfolios, including the conduct of two separate clinical programs – the VivaGel<sup>®</sup> BV phase 3 clinical trials for the prevention of recurrent BV and the phase 1 DEP<sup>®</sup> docetaxel trial. Revenue for the half-year is lower than the prior corresponding period (pcp), with the AstraZeneca upfront license milestone occurring in the pcp.

Commenting on the half-year's highlights and outlook, Starpharma CEO, Dr Jackie Fairley, said: "We are particularly pleased with the important commercial, regulatory and clinical milestones achieved in the half-year. It was most gratifying to be granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for both indications for VivaGel® BV by the FDA and to have achieved 100% enrolment in the phase 3 program for the prevention of recurrent BV. During this time, we are focussed on preparing our US FDA marketing application - in the first instance for treatment, and subsequently for the prevention indication and are pleased our application will be expedited and given priority review, a benefit of the QIDP status granted earlier this year."

"In drug delivery, we entered into several new DEP® partnerships, including with two world-leading antibody-drug conjugate companies and also a new and important program with AstraZeneca. Our DEP® platform continues to spark intense interest from global partners, based on the outstanding safety and efficacy benefits being reproduced in our internal and external programs. In the condom category, we announced deals for the large Chinese and Iranian markets. Meanwhile, Ansell is planning to launch the VivaGel® condom in Canada in the very near future following regulatory approval late last year."

"We expect the positive momentum from the half-year to keep building with catalysts throughout 2017, namely: the VivaGel® BV trial results, planned NDA filing for VivaGel® BV, commencement of a phase 2 DEP® docetaxel program, and further commercial deals and corporate developments to be announced across Starpharma's portfolio," said Dr Fairley.

# 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® 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 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 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 20 078 532 180

# **Interim Report – 31 December 2016**

Lodged with the ASX under Listing Rule 4.2A

This information should be read in conjunction with the 30 June 2016 Annual Report and any public announcements made by Starpharma Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

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# **Results for Announcement to the Market**

Starpharma Holdings Limited ABN 20 078 532 180

Half-year ended 31 December 2016

Previous corresponding period: Half-year ended 31 December 2015

|   |                          |     |    | \$          |
|---|--------------------------|-----|----|-------------|
| Revenue from ordinary activities (Appendix 4D item 2.1)                                       | Down                     | 84% | to | \$576,000   |
| <b>Loss</b> from ordinary activities after tax attributable to members (Appendix 4D item 2.2) | Down<br>(decreased loss) | 10% | to | \$9,017,000 |
| Net Loss for the period attributable to members (Appendix 4D item 2.3)                        | Down<br>(decreased loss) | 10% | to | \$9,017,000 |

| Dividends/distributions<br>(Appendix 4D items 2.4 and, 2.5) | Amount per security | Franked amount per security |
|---|---------------------|-----------------------------|
| Final dividend  | Nil                 | Nil                         |
| Interim dividend  | Nil                 | Nil                         |

**Record date** for determining entitlements to the dividend: Not Applicable

No dividends have been paid or declared by the entity since the beginning of the current reporting period. No dividends were paid for the previous corresponding period.

## Explanation of revenue

(Appendix 4D item 2.6)

Revenue from ordinary activities includes royalty, licensing and research revenue from commercial partners of \$231,000 (December 2015: \$3,483,000); and interest income on cash invested in term deposits of \$345,000 (December 2015: \$198,000). Revenue is lower primarily due to the signature payment of US\$2 million (A\$2.9 million) from AstraZeneca for the DEP® drug delivery license being reported in the prior half-year ending 31 December 2015.

# Explanation of net loss

(Appendix 4D item 2.6)

The consolidated loss after tax for the half-year to 31 December 2016 was \$9,017,000 (December 2015: \$10,034,000). Research and development expenses include the costs of the VivaGel®, drug delivery and agrochemical programs, with expenditure (including patenting costs) fully expensed in the current and previous corresponding periods. The research and development expenditure reflects the costs associated with the conduct of the VivaGel® Phase 3 clinical trials for the prevention of recurrent bacterial vaginosis, the DEP® docetaxel program and the wider DEP® drug delivery and agrochemical programs.

A contra research and development expense of \$1,746,000 (December 2015: \$1,784,000) has been recorded for research and development activities eligible under the Australian Government's R&D Tax Incentive program.

## Net tangible assets

(Appendix 4D item 3)

|   |        | Half-year ended<br>31 December |
|---|--------|--------------------------------|
|   | 2016   | 2015                           |
| Net tangible asset backing per ordinary share | \$0.09 | \$0.14                         |

The above NTA backing calculation is considered a non-IFRS value in accordance with Australian Accounting Standards and has not been audited or reviewed.

Additional Appendix 4D disclosure requirements can be found in the Directors' Report and the 31 December 2016 half-year financial statements. This report is based on the consolidated 2016 half-year financial statements which have been reviewed by PricewaterhouseCoopers (the company's auditors) with the Independent Auditor's Review Report included in the 31 December 2016 half-year financial statements.

# **Directors' Report**

The directors have pleasure in presenting this report on the consolidated entity (referred to hereafter as the group or the company) consisting of Starpharma Holdings Limited and the entities it controlled at the end of, or during, the half-year ended 31 December 2016.

## **Directors**

The following persons were directors of Starpharma Holdings Limited during the whole of the half-year and up to the date of this report:

R B Thomas (Chairman) J K Fairley (Chief Executive Officer) R A Hazleton

Z Peach P R Turvey

# Principal activities

The principal activities of the group consist of research, development and commercialisation of dendrimer products for pharmaceutical, life-science and other applications. Activities within the group are directed towards the development of precisely defined nano-scale materials, with a particular focus on the development of VivaGel® for the management and prevention of bacterial vaginosis, as a condom coating and for prevention of sexually transmitted infections. Starpharma is also applying its proprietary dendrimers to drug delivery, and in agrochemicals.

# Business strategy, future developments and prospects

There is no change to Starpharma's strategy from the previous period. The company aims to create value for shareholders through the commercial exploitation of proprietary products based on its dendrimer technology in pharmaceutical, life science and other applications. The company's key focus is to advance, broaden and commercialise its product development pipeline for VivaGel®, DEP® drug delivery and agrochemicals. It is intended to achieve this by continuing to utilise a combination of internally funded and partnered projects across the portfolio. The company commercialises its development pipeline with corporate partners via licensing agreements at various stages in a product's development lifecycle; depending on the product, patent opportunity, a partner's relative strength of product and market expertise, comparison of current and future potential returns, and the risks involved in advancing the product to the next value inflection point or milestone.

Starpharma remains well positioned to capture value from its technology in the short to medium term. Starpharma has deep expertise, strong intellectual property portfolio, deep product portfolio, a culture and ability to innovate and apply its technology platform to commercial opportunities, proven risk management practices, and a solid cash position. The company will continue using its cash resources to invest in selected research and development activities to achieve its objectives.

## Dividends

No dividends have been paid or declared by the company since the beginning of the current reporting period. No dividends were paid for the previous corresponding period.

## Review of operations

Key highlights and significant events until the date of this report included:

#### Commercial

- License and supply agreement with Shenyang Sky and Land Latex Co for the VivaGel® condom in China;
- License and supply agreement with Koushan Pharmed for the VivaGel<sup>®</sup> condom in Iran;
- Significant progress in commercial negotiations and launch preparations for VivaGel® BV for the treatment and rapid relief of BV;
- AstraZeneca initiated a new DEP® drug delivery program for a product in their portfolio, in addition to the existing multiproduct license;
- Two new Targeted DEP® partnerships with world leading antibody-drug conjugate companies;
- Several new partnerships with leading agrochemical companies including major a Japanese agrochemical business; and
- Allowance of a patent by the US Patent Office for a Priostar<sup>®</sup> glyphosate formulation, potentially increasing the patent's term to 2030.

### Regulatory

- Canadian regulatory approval for marketing of the VivaGel<sup>®</sup> condom, enabling Ansell to launch in early 2017;
- VivaGel® BV granted QIDP and Fast Track designations by the US FDA for both treatment of 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;
   and
- Favourable revision to FDA regulatory guidance for BV treatment opening up a significant new commercial opportunity for VivaGel® BV.

#### Clinical

- Enrolment completed for the pivotal phase 3 trials for VivaGel® BV prevention of recurrent BV;
- DEP® docetaxel phase 1 clinical trial showing promising efficacy signals with no neutropenia or hair loss reported;
- Major UK site added to the DEP® docetaxel trial in its final expansion phase to accelerate trial completion, enrich the patient cohort with specific cancer types, and to facilitate transition to phase 2; and
- Preparation has progressed for phase 2 trial of DEP® docetaxel including product manufacture, site and CRO selection.

#### Preclinical

- Partnered DEP<sup>®</sup> programs continue to perform extremely well, including the most recent AstraZeneca program and Targeted DEP<sup>®</sup> partnerships;
- Reproduced excellent preclinical results for Starpharma's internal development candidate, DEP® cabazitaxel ahead of planned phase 1 clinical trial in CY2017;
- New internal program, DEP<sup>®</sup> irinotecan, showed near complete tumour regression in multiple human colon cancer mouse xenograft models;
- An expansion of in-house DEP® scale-up facilities to facilitate rapid development of internal candidates and expedite partnered programs.

#### Financial

Receipt of A\$3.5M R&D tax incentive refund.

#### VivaGel® Program

# <u>VivaGel<sup>®</sup> BV – BV treatment and symptomatic relief (acute use)</u>

A significant market opportunity opened up in the half year for VivaGel<sup>®</sup> BV arising from a favourable revision to the US FDA's guidance on BV treatment. The revised draft guidance released by the FDA in July 2016, now recommends the primary endpoint for BV treatment to be 7-14 days after commencing treatment. This timing aligns with Starpharma's previous phase 3 clinical trial results of 2012, which showed a highly statistically significant benefit of VivaGel<sup>®</sup> BV at this time point. Starpharma has commenced compiling a VivaGel<sup>®</sup> BV marketing application for submission to the FDA and expects the application will be submitted in the near future.

Furthermore, VivaGel® BV received Qualified Infectious Disease Product (QIDP) and Fast Track designations by the US FDA in January 2017. These designations were for both the VivaGel® BV treatment and prevention indications for BV. These designations recognise the high unmet medical need in the management of BV and are designed to make new therapeutics available to patients as rapidly as possible. The benefits of QIDP and Fast Track are highly advantageous and include: priority regulatory review, an additional five years' of market exclusivity, more frequent interactions with the FDA and expedited review, leading to faster approval.

Outside the US, Viva $Gel^{\otimes}$  BV for the treatment of BV is approved for marketing in the EU, with advanced commercial negotiations underway for this region and other regions, to add to the current Aspen Pharmacare license for the Australian and New Zealand market. Negotiations in the US have been accelerated by the recent FDA designations.

#### VivaGel® BV – to prevent recurrent BV (chronic use)

Starpharma's double-blinded, placebo controlled phase 3 trials to evaluate the efficacy and safety of VivaGel<sup>®</sup> BV for the prevention of recurrent BV were fully enrolled in the half-year. Trial completion is expected in the first quarter of the calendar year 2017, with topline results anticipated in the second quarter. These pivotal clinical trials are designed to support a submission for marketing authorisation in the US, Europe and the world more generally. In addition to the QIDP and Fast Track designations outlined above, the clinical program design received a Special Protocol Assessment (SPA) with the FDA that reduces the regulatory risk in this important market.

# VivaGel® condom

Ansell plans to launch the VivaGel® condom in Canada in early CY2017, having received approval by the Canadian regulatory authority. In addition, Starpharma signed two commercially important deals in China and Iran during the half-year. The company firstly signed a license and supply agreement with Shenyang Sky and Land Latex Co (Sky & Land) for the manufacture and sale of VivaGel® condoms for the Chinese Government Sector. The Chinese Government provides around 3 billion condoms per annum to the public through various initiatives and Sky & Land are a major supplier to government. The second deal for the VivaGel® condom was with Koushan Pharmed - one of Iran's fastest growing pharmaceutical companies. Iran represents a commercially attractive market for condoms, with over 60% of the 80 million population under 30 years of age. Meanwhile, Starpharma continues to work with its Japanese partner, Okamoto, to finalise the regulatory process in Japan.

## **Drug Delivery Program**

Important progress has also been achieved in both the partnered and internal drug delivery programs.

During the half-year AstraZeneca initiated a new DEP® program, outside the scope of the existing multiproduct license and in addition to its current DEP® programs which continue to progress well. The new AstraZeneca program involves the application of the DEP® platform to an unrelated product from AstraZeneca's portfolio. Starpharma also signed two new Targeted DEP® partnerships with world leading antibody-drug conjugate (ADC) companies, which are progressing well. Importantly, Starpharma's DEP® platform remains largely unencumbered and available for licensing in the vast majority of oncology and other applications for additional deals.

In the company's internal DEP® portfolio, Starpharma advanced its phase 1 clinical trial for DEP® docetaxel into the final expansion phase, and has recruited new patients from Guy's and St Thomas' Hospital in London. This large UK site was added to accelerate recruitment for specific cancer types and facilitate rapid start-up of a phase 2 clinical trial. Early results from the DEP® docetaxel trial are showing efficacy signals in a significant proportion of patients, including in cancers not typically sensitive to the commercially available docetaxel. In addition, no cases of neutropenia or alopecia (hair loss) have been reported to date with DEP® docetaxel. Preparations for the phase 2 trial of DEP® docetaxel have progressed, with product manufacture, and site and CRO selection now well advanced.

A number of other dendrimer-enhanced, or DEP® versions of existing drugs are being developed by Starpharma, including DEP® cabazitaxel, DEP® irinotecan and antibody-Targeted DEP® conjugates. The results from preclinical studies undertaken for these internal programs are reproducing the benefits of DEP® in enhancing the therapeutic window of drugs, including reduced toxicities and enhanced efficacy.

### **Agrochemical Program**

During the half-year, Starpharma's Priostar® agrochemicals showed improved weed and insect control capabilities compared to standard marketed formulations, including in a recent trial in Asian rice crops which demonstrated that a Priostar® herbicide formulation increased rice seedling density by ~50% over the commercial formulation. Starpharma's intellectual property of Priostar® was also strengthened when an additional US patent was granted for a Priostar® glyphosate formulation, with an expected patent term to 2030. Starpharma's Priostar® partners also demonstrated further improvements in agricultural formulations, including with Adama, in the period.

## **Review of Financials**

For the half-year ended 31 December 2016 the consolidated entity incurred an operating loss after income tax of \$9,017,000 (December 2015: \$10,034,000).

|   |                | Half-Year Ended<br>31 December |
|---|----------------|--------------------------------|
| Summary of consolidated results                   | 2016<br>\$′000 | 2015<br>\$'000                 |
| Revenue from continuing operations                | 576            | 3,681                          |
| Other income, including grants                    | 1              | 59                             |
| Research & development (net of R&D tax incentive) | (6,868)        | (11,685)                       |
| Administration and finance costs                  | (2,726)        | (2,089)                        |
| Loss attributable to members                      | (9,017)        | (10,034)                       |

#### **Income statement**

Revenue consists of royalty, licensing and research revenue from commercial partners of \$231,000 (December 2015: \$3,483,000); and interest income on cash invested in term deposits of \$345,000 (December 2015: \$198,000). Revenue is lower primarily due to the signature payment of US\$2 million (A\$2.9 million) from AstraZeneca for the DEP® drug delivery license being reported in the prior half-year ending 31 December 2015.

The consolidated loss after tax for the half-year to 31 December 2016 was \$9,017,000 (December 2015: \$10,034,000). Research and development expenses include the costs of the VivaGel®, drug delivery and agrochemical programs, with expenditure (including patenting costs) fully expensed in the current and previous corresponding periods. The research and development expenditure reflects the costs associated with the conduct of the VivaGel® BV phase 3 clinical trials for the prevention of recurrent bacterial vaginosis as well as the DEP® docetaxel clinical program. The increase in administration expenses is due to movements in foreign exchange rates of \$365,000 and an increase of \$244,000 in non-cash share-based expenses associated with the employee performance rights plan.

A contra research and development expense of \$1,746,000 (December 2015: \$1,784,000) has been recorded for research and development activities eligible under the Australian Government's R&D Tax Incentive program.

#### **Balance sheet**

At 31 December 2016 the group's cash position was \$36,280,000 (June 2016: \$45,972,000). Trade and other receivables of \$2,084,000 (June 2016: \$4,304,000) includes \$1,746,000 accrued receivable from the Australian Government under the R&D Tax Incentive program. Trade and other payables of \$4,492,000 (June 2016: \$8,839,000) have reduced on lower accrued expenditure associated with the clinical trial programs.

# Statement of cash flows

Net operating cash outflows of \$9,881,000 (December 2015: \$7,632,000) includes costs associated with the company's VivaGel®, drug delivery and agrochemical programs, offset by the R&D tax incentive refund received of \$3,523,000 during the half-year (2015: \$3,422,000).

# Earnings per share

|                        |               | Half-year ended<br>31 December |
|------------------------|---------------|--------------------------------|
|                        | 2016<br>Cents | 2015<br>Cents                  |
| Basic loss per share   | (2.45)        | (3.10)                         |
| Diluted loss per share | (2.45)        | (3.10)                         |

# Matters subsequent to the end of the financial half-year

No matters or circumstances have arisen since 31 December 2016 that have significantly affected, or may significantly affects:

- (a) the consolidated entity's operations in future financial years, or
- (b) the results of the operations in future financial years, or
- (c) the consolidated entity's state of affairs in future financial years.

# Rounding of amounts

The company is of a kind referred to in ASIC Corporations (Rounding Financial/Directors' Reports) Instrument 2016/191, issued by the Australian Securities and Investments Commission, relating to the "rounding off" of amounts in the directors' report and financial report. Amounts in the directors' report and interim financial report have been rounded off to the nearest thousand dollars in accordance with that Instrument.

# Auditor's independence declaration

A copy of the auditor's independence declaration as required under section 307C of the *Corporations Act 2001* is set out on page 7.

This report is made in accordance with a resolution of the Directors.

Rob Thomas AM

Chairman

Melbourne, 27 February 2017

# **Auditor's Independence Declaration**



# **Auditor's Independence Declaration**

As lead auditor for the review of Starpharma Holdings Limited for the half-year ended 31 December 2016, I declare that to the best of my knowledge and belief, there have been:

- (a) no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- (b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Starpharma Holdings Limited and the entities it controlled during the period.

Jon Roberts

Partner PricewaterhouseCoopers Melbourne 27 February 2017

# **Interim Financial Report**

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This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2016 and any public announcements made by Starpharma Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

# **Consolidated income statement**

For the half-year ended 31 December 2016

|   |       |         | Half-year |
|---|-------|---------|-----------|
|   |       | 2016    | 2015      |
|   | Notes | \$'000  | \$'000    |
| Revenue from continuing operations  | 4     | 576     | 3,681     |
|   |       |         |           |
| Other income  | 4     | 1       | 59        |
| Administration expense  | 5     | (2,726) | (2,087)   |
| Research and development expense  | 5     | (6,868) | (11,685)  |
| Finance costs   |       | -       | (2)       |
| Loss before income tax  |       | (9,017) | (10,034)  |
| Income tax  |       | -       | -         |
| Loss from continuing operations   |       |         |           |
| attributable to members of Starpharma<br>Holdings Limited                       |       | (9,017) | (10,034)  |
| Loss per share for loss from continuing operations attributable to the ordinary |       |         |           |
| equity holders of the company   |       | Cents   | Cents     |
| Basic loss per share  | 8     | (2.45)  | (3.10)    |
| Diluted loss per share  | 8     | (2.45)  | (3.10)    |

The above consolidated income statement should be read in conjunction with the accompanying notes.

# **Consolidated statement of comprehensive income**

For the half-year ended 31 December 2016

|   |         | Half-year |
|---|---------|-----------|
|   | 2016    | 2015      |
|   | \$'000  | \$'000    |
| Loss for the period                               | (9,017) | (10,034)  |
| Other comprehensive income (loss)                 |         |           |
| Items that may be reclassified to profit or loss: |         |           |
| Foreign exchange differences on translation of    |         |           |
| foreign operations                                | 203     | 438       |
| Other comprehensive income (loss) for             |         |           |
| the half-year                                     | 203     | 438       |
|   |         |           |
| Total comprehensive loss for the half-            |         |           |
| year  | (8,814) | (9,596)   |

The above consolidated statement of comprehensive income should be read in conjunction with the accompanying notes.

# **Consolidated balance sheet**

As at 31 December 2016

|                                    | _     | 31 December | 30 June   |
|------------------------------------|-------|-------------|-----------|
|                                    |       | 2016        | 2015      |
|                                    | Notes | \$'000      | \$'000    |
| Current assets                     |       |             |           |
| Cash and cash equivalents          |       | 36,280      | 45,972    |
| Trade and other receivables        |       | 2,084       | 4,304     |
| Total current assets               |       | 38,364      | 50,276    |
| Non-current assets                 |       |             |           |
| Property, plant and equipment      |       | 588         | 690       |
| Intangible assets                  |       | 7,973       | 8,073     |
| Total non-current assets           |       | 8,561       | 8,763     |
| Total assets                       |       | 46,925      | 59,039    |
| Current liabilities                |       |             |           |
| Trade and other payables           |       | 4,492       | 8,839     |
| Finance lease liabilities          |       | 3           | 18        |
| Provisions (employee entitlements) |       | 766         | 718       |
| Total current liabilities          |       | 5,261       | 9,575     |
| Non-current liabilities            |       |             |           |
| Provisions (employee entitlements) |       | 53          | 40        |
| Total non-current liabilities      |       | 53          | 40        |
| Total liabilities                  |       | 5,314       | 9,615     |
| Net assets                         |       | 41,611      | 49,424    |
| Equity                             |       |             |           |
| Contributed equity                 | 6     | 193,512     | 193,512   |
| Reserves                           |       | 10,992      | 9,787     |
| Accumulated losses                 |       | (162,893)   | (153,875) |
| Total equity                       |       | 41,611      | 49,424    |

The above consolidated balance sheet should be read in conjunction with the accompanying notes.

# Consolidated statements of changes in equity

For the half-year ended 31 December 2016

|   |       |             |          | ſ           | Half-year<br>December 2016 |
|---|-------|-------------|----------|-------------|----------------------------|
|   |       | Contributed | Reserves | Accumulated | Total                      |
|   |       | equity      |          | losses      | equity                     |
|   | Notes | \$'000      | \$'000   | \$'000      | \$'000                     |
| Balance at 1 July 2016                                |       | 193,512     | 9,787    | (153,875)   | 49,424                     |
| Loss for the half-year                                |       | -           | -        | (9,017)     | (9,017)                    |
| Other comprehensive income                            |       |             |          |             |                            |
| Foreign exchange differences on                       |       |             | 202      |             | 202                        |
| translation of foreign operations                     |       | -           | 203      | -           | 203                        |
| Total comprehensive income (loss) for the half-year   |       | -           | 203      | (9,017)     | (8,814)                    |
| Transactions with owners, recorded directly in equity |       |             |          |             |                            |
| Contributions of equity, net of transaction costs     | 6     | -           | -        | -           | -                          |
| Employee performance rights plan                      |       | -           | 1,002    | -           | 1,002                      |
| Total transactions with owners                        |       | -           | 1,002    | -           | 1,002                      |
|   |       |             |          |             |                            |
| Balance at 31 December 2016                           |       | 193,512     | 10,992   | (162,893)   | 41,611                     |

For the half-year ended 31 December 2015

|   |       |                    |          | r                  | Half-year<br>December 2015 |
|---|-------|--------------------|----------|--------------------|----------------------------|
|   | _     | Contributed equity | Reserves | Accumulated losses | Total<br>equity            |
|   | Notes | \$'000             | \$'000   | \$'000             | \$'000                     |
| Balance at 1 July 2015  |       | 160,884            | 7,874    | (131,200)          | 37,558                     |
| Loss for the half-year  |       | -                  | -        | (10,034)           | (10,034)                   |
| Other comprehensive income  |       |                    |          |                    |                            |
| Foreign exchange differences on translation of foreign operations |       | -                  | 438      | -                  | 438_                       |
| Total comprehensive income (loss) for the half-year               |       | -                  | 438      | (10,034)           | (9,596)                    |
| Transactions with owners, recorded directly in equity             |       |                    |          |                    |                            |
| Contributions of equity, net of transaction costs                 | 6     | 30,697             | -        | -                  | 30,697                     |
| Employee performance rights scheme                                |       | -                  | 758      | -                  | 758                        |
| Total transactions with owners                                    |       | 30,697             | 758      | -                  | 31,455                     |
| Balance at 31 December 2015                                       |       | 191,581            | 9,070    | (141,234)          | 59,417                     |

The above consolidated statements of changes in equity should be read in conjunction with the accompanying notes.

# **Consolidated statement of cash flows**

For the half-year ended 31 December 2016

|   |       |          | Half-year |
|---|-------|----------|-----------|
|   |       | 2016     | 2015      |
|   | Notes | \$'000   | \$'000    |
| Cash flow from operating activities   |       |          |           |
| Receipts from trade and other debtors _(inclusive of GST)                           |       | 624      | 3,776     |
| Grant income and R&D incentives (inclusive of GST)                                  |       | 3,523    | 3,430     |
| Payments to suppliers and employees (inclusive of GST)                              |       | (14,376) | (15,016)  |
| Interest received   |       | 348      | 180       |
| Interest paid   |       | -        | (2)       |
| Net cash outflows from operating activities   |       | (9,881)  | (7,632)   |
| Cash flow from investing activities   |       |          |           |
| Payments for property, plant and equipment Proceeds from sale of available-for-sale |       | (50)     | (9)       |
| financial assets  |       | -        | 56        |
| Net cash outflows from investing activities   |       | (50)     | 47        |
| Cash flow from financing activities   |       |          |           |
| Proceeds from issue of shares   | 6     | -        | 32,000    |
| Share issue transaction costs   |       | -        | (1,298)   |
| Lease repayments  |       | (16)     | (16)      |
| Net cash inflows from financing activities  |       | (16)     | 30,686    |
| Net decrease in cash and cash equivalents held                                      |       | (9,947)  | 23,101    |
| Cash and cash equivalents at the beginning of                                       |       |          | ,         |
| the half-year  Effects of exchange rate changes on cash and                         |       | 45,972   | 30,848    |
| cash equivalents  |       | 255      | 739       |
| Cash and cash equivalents at the end of the half-year                               |       | 36,280   | 54,688    |

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

# Notes to the consolidated financial statements

# 31 December 2016

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# 1. Basis of preparation of half-year report

This condensed consolidated interim financial report for the half-year reporting period ended 31 December 2016 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2016 and any public announcements made by Starpharma Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

## 2. Critical accounting estimates and judgments

The preparation of financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the group's accounting policies.

The group's research and development activities are eligible under an Australian Government tax incentive for eligible expenditure from 1 July 2011. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive program. For the half-year to 31 December 2016, the group has recorded a contra research and development expense of \$1,746,000.

# 3. Segment information

The group has determined that on the basis of internal reporting and monitoring to the Chief Executive Officer, who is the chief operating decision maker, the group operates in one business segment, being the discovery, development and commercialisation of dendrimers for pharmaceutical, life science and other applications.

# 4. Revenue and other income

| 2016<br>\$′000 | Half-year<br>2015<br>\$'000 |
|----------------|-----------------------------|
|                |                             |
| \$′000         | \$'000                      |
|                |                             |
| 231            | 3,483                       |
| 345            | 198                         |
| 576            | 3,681                       |
|                |                             |
| 1              | 59                          |
| 577            | 3,740                       |
|                | 345<br>576                  |

Royalty, customer & license revenue is lower than the half-year ended 31 December 2015, due to the prior period including a signature payment of US\$2 million (A\$2.9 million) from the AstraZeneca DEP® drug delivery licencing agreement. Interest revenue relates to interest earned on cash deposits.

## Expenses

| Consolidated  |                |                |
|---|----------------|----------------|
|   |                | Half-year      |
|   | 2016<br>\$′000 | 2015<br>\$'000 |
| Loss from continuing operations before income tax expense includes the following items: |                |                |
| R&D Tax Incentive (contra expense)  | (1,746)        | (1,784)        |
| Employee benefits expenses (including share-based payments)                             | 4,081          | 3,628          |
| Depreciation  | 151            | 155            |
| Amortisation  | 299            | 312            |
| Rental expense on operating leases  | 274            | 266            |

# 6. Contributed equity

## (a) Share capital

|                              |                         | Consolidated        |                         | Consolidated        |
|------------------------------|-------------------------|---------------------|-------------------------|---------------------|
|                              | December 2016<br>Shares | June 2016<br>Shares | December 2016<br>\$'000 | June 2016<br>\$'000 |
| Share Capital                |                         |                     |                         |                     |
| Ordinary shares – fully paid | 368,536,766             | 367,107,521         | 193,512                 | 193,512             |

## (b) Movements in ordinary share capital

| Date        | Details  | Number of shares | <b>Issue Price</b> | \$′000  |
|-------------|--|------------------|--------------------|---------|
| 1 Jul 2014  | Opening balance                                    | 285,109,680      |                    | 140,349 |
| Various     | Share issue under Employee Performance Rights Plan | 1,018,400        | \$ -               | _       |
| 29 Sep 2014 | Share placement                                    | 27,692,308       | \$0.65             | 18,000  |
| 5 Nov 2014  | Share Purchase Plan                                | 5,259,937        | \$0.65             | 3,419   |
|             | less transaction costs                             |                  |                    | (916)   |
|             | Balance at 31 December 2014                        | 319,080,325      |                    | 160,852 |
| 22 Jan 2015 | Employee share plan (\$1,000) issue                | 58,176           | \$0.55             | 32      |
|             | Balance at 30 June 2015                            | 319,138,501      |                    | 160,884 |
| Various     | Share issue under Employee Performance Rights Plan | 1,466,810        | \$ <b>-</b>        | _       |
| 16 Dec 2015 | Share placement                                    | 43,835,617       | \$0.73             | 32,000  |
|             | less transaction costs                             |                  |                    | (1,303) |
|             | Balance at 31 December 2015                        | 364,440,928      |                    | 191,581 |
| 22 Jan 2016 | Share Purchase Plan                                | 2,623,361        | \$0.73             | 1,915   |
|             | less transaction costs                             |                  |                    | (16)    |
| 25 Jan 2016 | Employee share plan (\$1,000) issue                | 43,232           | \$0.74             | 32      |
|             | Balance at 30 June 2016                            | 367,107,521      |                    | 193,512 |
| Various     | Share issue under Employee Performance Rights Plan | 1,429,245        | \$ -               | _       |
|             | Balance at 31 December 2016                        | 368,536,766      |                    | 193,512 |

## (c) Ordinary shares

As at 31 December 2016 there were 368,536,766 issued ordinary shares. Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the company in proportion to the number of, and amounts paid, on the shares held. Ordinary shares have no par value and the company does not have a limited amount of authorised capital.

## (d) Employee Share Plan (\$1,000 Plan)

Shares issued under the Starpharma Holdings Limited Employee Share Plan (\$1,000 Plan) to eligible staff are granted for no consideration and are escrowed for 3 years while participants are employed by the company. An allocation of 51,023 shares was issued to eligible staff on 25 January 2017, subsequent to the reporting date.

#### (e) Employee Performance Rights Plan

There were 1,429,245 shares issued on the vesting on performance rights and 4,072,250 performance rights issued during the financial half-year.

As at 31 December 2016 the company had on issue the following Employee Performance Rights under the Starpharma Holdings Limited Employee Performance Rights Plan.

| Grant date                    | Vesting date      | Holding Lock date | Number under rights |
|-------------------------------|-------------------|-------------------|---------------------|
| 20 November 2014 <sup>1</sup> | 30 September 2017 | N/A               | 450,000             |
| 20 November 2014 <sup>1</sup> | 30 September 2017 | 30 September 2018 | 300,000             |
| 30 January 2015               | 30 September 2017 | N/A               | 944,125             |
| 30 January 2015               | 30 September 2018 | N/A               | 809,250             |
| 11 November 2015              | 30 June 2017      | N/A               | 469,213             |
| 11 November 2015              | 30 September 2018 | N/A               | 2,052,800           |
| 19 November 2015 <sup>2</sup> | 30 June 2017      | N/A               | 181,001             |
| 19 November 2015 <sup>2</sup> | 30 September 2018 | N/A               | 893,851             |
| 13 October 2016               | 30 June 2018      | N/A               | 594,450             |
| 13 October 2016               | 30 September 2019 | N/A               | 2,377,800           |
| 29 November 2016 <sup>3</sup> | 30 June 2018      | N/A               | 223,022             |
| 29 November 2016 <sup>3</sup> | 30 September 2019 | N/A               | 876,978             |

<sup>&</sup>lt;sup>1</sup> Approved by shareholders at the Annual General Meeting on 20 November 2014; securities allotted on 3 December 2014.

## (f) Capital risk management

The group's and the parent entity's objectives when managing capital are to safeguard their ability to continue as a going concern, so that they can continue to provide returns for shareholders and benefits for other stakeholders.

## 7. Events occurring after the balance sheet date

There are no significant events occurring since 31 December 2016 that have significantly affected or may significantly affect the operations of the group, the results of those operations, or the state of the group.

# 8. Earnings per share

|   |             | Half-year   |
|---|-------------|-------------|
|   | 2016        | 2015        |
| Basic loss per share (cents)  | (2.45)      | (3.10)      |
| Diluted loss per share (cents)  | (2.45)      | (3.10)      |
| Net loss attributable to members of Starpharma Holdings Limited used as the numerator in calculating diluted and basic earnings per share (\$'000)          | (9,017)     | (10,034)    |
| Weighted average number of ordinary shares outstanding during the year used as the denominator in calculating diluted and basic earnings per share (shares) | 368,120,526 | 323,420,707 |

As at 31 December 2016 the company had on issue 10,172,490 (30 June 2016: 7,826,746) performance rights that are not considered dilutive.

The rights have not been included in the determination of basic earnings per share. The rights granted are considered to be potential ordinary shares and have been included in the determination of diluted earnings per share to the extent to which they are dilutive. Given the entity is currently loss making, the potential shares are anti-dilutive and have therefore not been included in the diluted earnings per share calculation.

<sup>&</sup>lt;sup>2</sup> Approved by shareholders at the Annual General Meeting on 19 November 2015; securities allotted on 2 December 2015.

<sup>&</sup>lt;sup>3</sup> Approved by shareholders at the Annual General Meeting on 29 November 2016; securities allotted on 5 December 2016.

# **Directors' declaration**

In the directors' opinion:

- (a) the financial statements and notes set out on pages 8 to 17 are in accordance with the Corporations Act 2001, including:
  - (i) complying with Accounting Standards, the Corporations Regulations 2001 and other mandatory professional reporting requirements; and
  - (ii) giving a true and fair view of the consolidated entity's financial position as at 31 December 2016 and of its performance for the half-year ended on that date; and
- (b) there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the directors.

Rob Thomas *AM* Chairman

Melbourne, 27 February 2017

## Independent Auditor's Review Report to the Members



# Independent auditor's review report to the members of Starpharma Holdings Limited

# Report on the Half-Year Financial Report

We have reviewed the accompanying half-year financial report of Starpharma Holdings Limited (the company), which comprises the consolidated balance sheet as at 31 December 2016, the consolidated income statement and consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, selected explanatory notes and the directors' declaration for Starpharma Holdings Limited (the consolidated entity). The consolidated entity comprises the company and the entities it controlled during that half-year.

# Directors' responsibility for the half-year financial report

The directors of the company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement whether due to fraud or error.

## Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Australian Auditing Standard on Review Engagements ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the Corporations Act 2001 including giving a true and fair view of the consolidated entity's financial position as at 31 December 2016 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001. As the auditor of Starpharma Holdings Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

## *Independence*

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

#### Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Starpharma Holdings Limited is not in accordance with the *Corporations Act 2001* including:

PricewaterhouseCoopers, ABN 52 780 433 757

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- 1. giving a true and fair view of the consolidated entity's financial position as at 31 December 2016 and of its performance for the half-year ended on that date;
- 2. complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

PricewaterhouseCoopers

5.PA

Jon Roberts Partner Melbourne 27 February 2017