

## Starpharma Interim Report and Half-Year Financial Results

**Melbourne, Australia; 27 February 2019:** Starpharma (ASX: SPL, OTCQX: SPHRY) today released its interim report and financial results for the half-year ended 31 December 2018.

### Financial Summary

- Reported loss of \$7.3M (Dec 2017: \$6.2M); and
- Cash position at 31 December 2018 of \$44.4M (June 2018: \$51.3M), which excludes the expected \$4.0M FY18 R&D tax incentive to be received.

### VivaGel®

- VivaGel® BV was licensed to ITF Pharma, Inc., for the US for milestones of up to US\$101M in addition to escalating, double-digit royalties;
- Starpharma and its partners, Mundipharma and Aspen, undertook extensive preparations for the upcoming launches of VivaGel® BV in multiple regions scheduled for the first half of 2019. Extensive marketing activities such as packaging design, sales staff training, promotional material development, and launch meetings occurred in parallel with supply chain activities. Manufactured product has been delivered to Aspen subsequent to half-year end, and manufacturing of product for Europe is well-advanced;
- US FDA completed its review of the VivaGel® BV NDA and advised it requires confirmatory clinical data prior to approval. In preparation for a meeting with the FDA to discuss the data required, Starpharma has been working closely with expert FDA consultants and is currently awaiting confirmation of the meeting date;
- VivaGel® condom received final regulatory approval in Japan and Starpharma's partner, Okamoto, commenced launch activities; and
- Positive independent market research was conducted in the US for SPL7013 ophthalmic drops for viral conjunctivitis and a patent was granted for the product.

### DEP® Drug Delivery

- Recruitment activities progressed well for two DEP® clinical trials - for DEP® docetaxel (phase 2) and DEP® cabazitaxel (phase 1 / 2), with new sites opened to support recruitment. Efficacy signals have been observed in a number of patients and both products continue to exhibit a notable lack of bone marrow toxicity and other common side effects including hair-loss, anaphylaxis and oedema;
- Final preclinical work for the DEP® irinotecan phase 1 / 2 trial was completed, study product was manufactured, and other trial preparations, including CRO/site selection, are well advanced ahead of the planned trial commencement later in FY19;
- AstraZeneca's first patent application on DEP® Bcl2/xL inhibitor conjugates was published and included compelling efficacy data on DEP® Bcl2/xL inhibitor conjugates, both alone and in combination with market-leading anti-cancer treatments, in various human leukemia models;
- DEP® irinotecan showed impressive efficacy and safety benefits over standard irinotecan in combination with 5-FU in a human pancreatic cancer model;
- DEP® docetaxel & DEP® cabazitaxel outperformed both gemcitabine & Abraxane® in a human pancreatic cancer model; and

- A range of DEP<sup>®</sup> radiopharmaceutical and other DEP<sup>®</sup> candidates have been made and are currently undergoing testing in a variety of models.

Starpharma concluded the half-year in a strong financial position with a cash balance of \$44.4 million, which does not include the \$4.0M FY18 R&D tax incentive expected to be received after 31 December 2018. The net loss after tax for the half-year of \$7.3 million (Dec 2017: \$6.2 million) reflects investment across the VivaGel<sup>®</sup> and DEP<sup>®</sup> portfolio, including DEP<sup>®</sup> docetaxel, DEP<sup>®</sup> cabazitaxel, and DEP<sup>®</sup> irinotecan. Expenditure includes an increased investment in commercialisation, regulatory and operating costs associated with the US VivaGel<sup>®</sup> BV licence and the preparation for product launch in a number of territories.

Starpharma's CEO, Dr Jackie Fairley, commented: "We achieved several important milestones in the VivaGel<sup>®</sup> portfolio during the half-year, including signing a US licence for VivaGel<sup>®</sup> BV with ITF Pharma, Inc. We were clearly surprised and disappointed by the FDA's request for confirmatory data and we are working with expert FDA consultants to expedite this process. In non-US territories, launch activities are in the final stages as we approach the launch of VivaGel<sup>®</sup> BV in Australia and Europe (1H CY19). We also continue to work closely with our partner, Mundipharma, on further registrations to support launches in several other regions."

Commenting on the DEP<sup>®</sup> drug delivery portfolio, Dr Fairley said: "We're pleased to see efficacy signals once again in both our DEP<sup>®</sup> clinical trials as well as a notable lack of bone marrow toxicity and other common side effects. An abundance of positive data from the DEP<sup>®</sup> platform, both preclinical and clinical, continues to build amid partnered program discussions with a number of multinational and US pharmaceutical companies. Our first partnered program with AstraZeneca for AZD0466 is expected to commence clinical trials this year and preparations at AstraZeneca for this activity continue with priority. This partnered program is just one example of the value that can be generated from our unique DEP<sup>®</sup> platform."

Dr Fairley concluded: "We expect to announce a number of key milestones throughout 2019, in addition to the launch of VivaGel<sup>®</sup> BV in Australia and Europe, and regulatory progress across a range of markets, including the US; launch of the VivaGel<sup>®</sup> condom in Japan; regulatory approval of the VivaGel<sup>®</sup> condom in other regions; and progress across internal and partnered DEP<sup>®</sup> programs including commencement of the DEP<sup>®</sup> irinotecan and AZD0466 clinical trials."

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#### About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHRY), located in Melbourne Australia, is an ASX 300 company and is a world leader in the development of dendrimer products for pharmaceutical, life science and other applications.

Starpharma's underlying technology is built around dendrimers – a type of synthetic nanoscale polymer that is highly regular in size and structure and well suited to pharmaceutical and medical uses. Starpharma has two core development programs: VivaGel<sup>®</sup> portfolio and DEP<sup>®</sup> drug delivery with the Company developing several products internally and others via commercial partnerships.

**VivaGel<sup>®</sup>:** Starpharma's women's health product - VivaGel<sup>®</sup> BV is based on SPL7013, astodimer sodium, a proprietary dendrimer. VivaGel<sup>®</sup> BV is approved for marketing in the EU and Australia for bacterial vaginosis (BV) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel<sup>®</sup> BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel<sup>®</sup> condom (an antiviral condom which includes VivaGel<sup>®</sup> in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel<sup>®</sup> condom has been launched in Australia and Canada under the Lifestyles<sup>®</sup> Dual Protect™ brand.

**DEP<sup>®</sup> - Dendrimer Enhanced Product<sup>®</sup>:** Starpharma's DEP<sup>®</sup> drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP<sup>®</sup> programs, including improved efficacy, safety and survival. Starpharma has two internal DEP<sup>®</sup> products – DEP<sup>®</sup> docetaxel and DEP<sup>®</sup> cabazitaxel - in clinical development in patients with solid tumours, and further DEP<sup>®</sup> products approaching clinical development. Starpharma's partnered DEP<sup>®</sup> programs include a multiproduct DEP<sup>®</sup> licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more.

[Starpharma.com](http://Starpharma.com) | [Twitter](#) | [LinkedIn](#)

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[investor.relations@starpharma.com](mailto:investor.relations@starpharma.com)**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 2018

Lodged with the ASX under Listing Rule 4.2A

This information should be read in conjunction with the 30 June 2018 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 2018

Previous corresponding period: Half-year ended 31 December 2017

|   |                        |     |    | \$          |
|---|------------------------|-----|----|-------------|
| <b>Revenue</b><br><i>(Appendix 4D item 2.1)</i>   | Down                   | 46% | to | \$649,000   |
| <b>Loss after tax attributable to members</b><br><i>(Appendix 4D item 2.2)</i>          | Up<br>(increased loss) | 17% | to | \$7,266,000 |
| <b>Net Loss for the period attributable to members</b><br><i>(Appendix 4D item 2.3)</i> | Up<br>(increased loss) | 17% | to | \$7,266,000 |

| <b>Dividends/distributions</b><br><i>(Appendix 4D items 2.4 and, 2.5)</i> | 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 consists of royalty, licensing and research revenue from commercial partners of \$83,000 (December 2017: \$663,000); and interest income on cash invested in term deposits of \$566,000 (December 2017: \$544,000).

## Explanation of net loss

*(Appendix 4D item 2.6)*

The consolidated loss from ordinary activities after tax for the half-year to 31 December 2018 was \$7,266,000 (December 2017: \$6,231,000). The net loss is higher than the prior period predominantly on lower research revenue from commercial partners, and higher commercial and regulatory operating expenditure related to the commercialisation of both the VivaGel<sup>®</sup> and DEP<sup>®</sup> portfolios, including business development, legal, regulatory, supply chain and quality assurance activities. Research and product development expense includes the preclinical and clinical expenditure of the Company's internal DEP<sup>®</sup> drug delivery programs, including DEP<sup>®</sup> docetaxel, DEP<sup>®</sup> cabazitaxel, and DEP<sup>®</sup> irinotecan, as well as the VivaGel<sup>®</sup> program.

A contra research and product development expense of \$2,418,000 (December 2017: \$2,102,000) 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)*

|   | <b>Half-year ended<br/>31 December</b> |        |
|---|--|--------|
|   | <b>2018</b>                            | 2017   |
| Net tangible asset backing per ordinary share | <b>\$0.13</b>                          | \$0.15 |

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 2018 half-year financial statements.

This report is based on the consolidated 2018 half-year financial statements which have been reviewed by PricewaterhouseCoopers (the Company's auditor) with the Independent Auditor's Review Report included in the 31 December 2018 half-year financial statements.

## Directors' Report

The directors are pleased to present 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 2018.

### 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, AO (Chairman)  
Z Peach

J K Fairley (Chief Executive Officer)  
P R Turvey

R A Hazleton

### 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<sup>®</sup> for the management and prevention of bacterial vaginosis, and as a condom coating. Starpharma is also applying its proprietary dendrimers to drug delivery to create improved pharmaceuticals and has developed the valuable DEP<sup>®</sup> delivery platform.

### Business strategy, future developments and prospects

The Company aims to create value for shareholders through the commercial exploitation of proprietary products based on its patented dendrimer technology in pharmaceutical applications. The Company's key focus is to advance and broaden its product development pipeline, including internal and partnered DEP<sup>®</sup> programs and to commercially exploit VivaGel<sup>®</sup>. Starpharma intends 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, market dynamics, a partner's commercial strategy and 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's strategy remains consistent with the previous period. The Company continues to focus on the development of the high-value DEP<sup>®</sup> portfolio and Starpharma remains well positioned to capture value from its technology in the short to medium term. Starpharma has extensive expertise, a strong intellectual property portfolio, a deep product portfolio, a culture and ability to innovate and apply its technology platform to commercial opportunities, appropriate risk management practices, and a strong cash position. The Company will continue using its cash resources to invest in selected research and development and commercialisation 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:

#### *VivaGel<sup>®</sup>*

- VivaGel<sup>®</sup> BV was licensed to ITF Pharma, Inc for the US for milestones of up to US\$101M in addition to escalating, double-digit royalties;
- Starpharma and its partners, Mundipharma and Aspen, undertook extensive preparations for the upcoming launches of VivaGel<sup>®</sup> BV in multiple regions scheduled for the first half of 2019;
- US FDA completed its review of the VivaGel<sup>®</sup> BV NDA and advised it requires confirmatory clinical data prior to approval;
- VivaGel<sup>®</sup> condom received final regulatory approval in Japan and Starpharma's partner, Okamoto, commenced launch activities; and
- Positive independent market research was conducted in the US for SPL7013 ophthalmic drops for viral conjunctivitis and a patent was granted for the product.

#### *DEP<sup>®</sup> Drug Delivery Platform*

- Recruitment activities progressed well for two DEP<sup>®</sup> clinical trials - for DEP<sup>®</sup> docetaxel (phase 2) and DEP<sup>®</sup> cabazitaxel (phase 1 / 2), with new sites opened to support recruitment. Efficacy signals have been observed in a number of patients and both products continue to exhibit a notable lack of bone marrow toxicity and other common side effects including hair-loss, anaphylaxis and oedema;
- Final preclinical work for the DEP<sup>®</sup> irinotecan phase 1 / 2 trial was completed, study product was manufactured, and other trial preparations, including CRO/site selection, are well advanced ahead of the planned trial commencement later in FY19;
- AstraZeneca's first patent application on DEP<sup>®</sup> Bcl2/xL inhibitor conjugates was published and included compelling efficacy data on DEP<sup>®</sup> Bcl2/xL inhibitor conjugates, both alone and in combination with market-leading anti-cancer treatments, in various human leukemia models;
- DEP<sup>®</sup> irinotecan showed impressive efficacy and safety benefits over standard irinotecan in combination with 5-FU in a human pancreatic cancer model;
- DEP<sup>®</sup> docetaxel & DEP<sup>®</sup> cabazitaxel outperformed both gemcitabine & Abraxane<sup>®</sup> in a human pancreatic cancer model; and
- A range of DEP<sup>®</sup> radiopharmaceutical and other DEP<sup>®</sup> candidates have been made and are undergoing testing in a variety of models.

## VivaGel® Program

### *VivaGel® BV – Starpharma's breakthrough product for bacterial vaginosis (BV)*

During the half-year Starpharma made significant progress with commercialising VivaGel® BV, including signing a US licence with ITF Pharma, Inc, a speciality pharmaceutical company focused on Women's Health. The deal includes milestones of up to US\$101M in addition to escalating, double-digit royalties on sales.

VivaGel® BV is now licensed around the world, with launches in multiple territories planned for the first half of 2019. Starpharma and its partners, Mundipharma and Aspen, have advanced pre-launch activities for VivaGel® BV including extensive sales training, promotional activities and product manufacture, in readiness for these launches.

VivaGel® BV is already approved in the EU and Australia and registration activities for several Mundipharma territories continued to advance to support further launches in other non-US markets. In the US, the FDA completed its review of the VivaGel® BV NDA and advised that it requires confirmatory clinical data prior to approval. Starpharma is working with expert FDA consultants to expedite the path to approval for VivaGel® BV and has commenced the process of securing an FDA meeting to clarify what clinical data will be required. Starpharma is keen to work with the FDA to secure approval with minimal delay.

### *VivaGel® condom – World-first product and the only anti-viral condom with lubricant incorporating VivaGel®*

During the half-year, the VivaGel® condom received final regulatory approval in Japan. Starpharma's Japanese partner, Okamoto, is Japan's leading marketer of condoms and has already commenced launch preparations, and expects to launch the VivaGel® condom in the first half of 2019. The Company also made good regulatory progress in China, Europe and other markets, for which Starpharma has partnerships with LifeStyles® (previously Ansell) and Sky and Land Latex Co. (Sky & Land).

### *SPL7013 ophthalmic drops for viral conjunctivitis*

Following very encouraging efficacy data for SPL7013 (the VivaGel® active) in animal models of viral conjunctivitis, Starpharma completed formal market research with ophthalmologists, payers and primary care physicians in the US who confirmed a high level of interest in an anti-viral therapy, like SPL7013 ophthalmic drops. Findings from the research were extremely positive and have been of particular interest in discussions with potential partners. There are currently no products approved for viral conjunctivitis.

## DEP® Drug Delivery Platform

### *Internal DEP® programs*

The phase 2 DEP® docetaxel trial continued to progress well during the half-year, with further sites opened for recruitment (four sites in total). Starpharma completed recruitment in the first cohort of patients with lung cancer in the combination study trialling DEP® docetaxel + nintedanib (Vargatef®) and recruitment has been expanded in non-small cell lung cancer based on positive interim results. In the monotherapy arm, approximately 70% of patients in the initial cohort have been recruited. Early trial results include encouraging efficacy signals and a notable lack of bone marrow toxicity and other common side effects including hair-loss, anaphylaxis and oedema. The efficacy signals observed include stable disease and tumour shrinkage.

Recruitment has also progressed for the phase 1 / 2 DEP® cabazitaxel trial, which is currently underway at two sites. Positive interim results include a notable lack of bone marrow toxicity and other common side effects, and efficacy signals have been observed in prostate cancer despite a low dose of DEP® cabazitaxel (due to being in the dose escalation phase).

Starpharma expects to commence a phase 1 / 2 clinical trial for its third DEP® product, DEP® irinotecan, in FY19. During the period, Starpharma completed final preclinical and manufacturing activities and also has advanced trial preparations including CRO engagement, site selection and regulatory documentation in preparation for trial start. The DEP® irinotecan trial will be open to patients with a range of cancers, including colon and pancreatic, where impressive efficacy has been shown in preclinical models.

Further exciting preclinical results with Starpharma's DEP® products were achieved throughout the half-year, including DEP® in combination with other anti-cancer therapies, and in the area of pancreatic cancer. Data released in September showed impressive efficacy and safety benefits of DEP® irinotecan over standard irinotecan in combination with 5-FU in a human pancreatic cancer model. DEP® irinotecan achieved complete tumour regression and 100% survival. This was followed by new data showing DEP® docetaxel and DEP® cabazitaxel outperformed current treatments, gemcitabine (Gemzar®) alone, Abraxane® (Nab-paclitaxel) alone and in combination, in a human pancreatic cancer model. These impressive DEP® efficacy results were despite the fact that standard pancreatic cancer treatments, gemcitabine and/or Abraxane®, showed limited activity in this model. This data will feed into the clinical development programs for DEP® docetaxel and DEP® cabazitaxel.

A range of DEP® radiopharmaceutical and other DEP® candidates have been made and these are currently undergoing testing in a variety of models. The radiopharmaceutical area is a rapidly developing area of cancer treatment and diagnosis, and this area has recently generated several high-value deals. It also represents an expansion of the application of DEP®.

### *Partnered DEP® programs*

Starpharma's DEP® platform offers the opportunity to generate a significant number of additional high value licences.

During the period, AstraZeneca's first DEP® patent was published, which included the first disclosure of the compelling efficacy data on DEP® Bcl2/xL inhibitor conjugates, both alone and in combination with market-leading anti-cancer treatments including Rituximab, in various human leukemia models. The data published showed that the DEP® Bcl2/xL inhibitor conjugates were significantly more efficacious than the Bcl2/xL inhibitor alone, resulting in complete tumour regression in most animals and exhibited impressive synergy when used in combination. The DEP® Bcl2/xL inhibitor conjugates are being developed under Starpharma's multiproduct licence with AstraZeneca. The clinical trials for AstraZeneca's AZD0466 (a DEP® Bcl2/xL inhibitor conjugate) are fully funded by AstraZeneca and expected to commence in 2019.

The Company's other partnerships for Targeted DEP® also progressed during the half-year and several partnering discussions regarding new programs are also underway, including with major multinational and US pharmaceutical companies.

## Review of Financials

|   | Half-Year Ended<br>31 December |                |
|---|--------------------------------|----------------|
|   | 2018<br>\$'000                 | 2017<br>\$'000 |
| <b>Income statement</b>   |                                |                |
| Revenue   | 649                            | 1,207          |
| Other income  | 12                             | 37             |
| Research and product development expense (net of R&D tax incentive) | (4,976)                        | (5,406)        |
| Commercial and regulatory operating expense                         | (1,729)                        | (766)          |
| Corporate, administration and finance expense                       | (1,222)                        | (1,303)        |
| <b>Loss for the period</b>  | <b>(7,266)</b>                 | <b>(6,231)</b> |

### Income statement

For the half-year ended 31 December 2018 the consolidated loss after income tax was \$7,266,000 (December 2017: \$6,231,000).

Revenue consists of royalty, licensing and research revenue from commercial partners of \$83,000 (December 2017: \$663,000); and interest income on cash invested in term deposits of \$566,000 (December 2017: \$544,000). The prior period reflects higher revenue from scale-up activities associated with the AstraZeneca partnered DEP<sup>®</sup> program including project-based revenues that are not evenly spread throughout the year.

Research and product development expenses include the costs of the internal DEP<sup>®</sup> drug delivery programs, including DEP<sup>®</sup> docetaxel, DEP<sup>®</sup> cabazitaxel, and DEP<sup>®</sup> irinotecan, as well as the VivaGel<sup>®</sup> BV program. A contra research and product development expense of \$2,418,000 (December 2017: \$2,102,000) has been recorded for research and development activities eligible under the Australian Government's R&D Tax Incentive program.

Commercial and regulatory operating expense includes the expenditure related to the commercialisation of both VivaGel<sup>®</sup> and DEP<sup>®</sup> portfolios, including business development, legal, regulatory, supply chain and quality assurance activities. The increase over the prior corresponding period reflects the impact of increased activities in the commercialisation and launch of VivaGel<sup>®</sup> BV, with a greater proportion of expenses being allocated to commercial and regulatory operating expense, rather than to research and product development expense.

Corporate, administration and finance expense include corporate costs, as well as gains/losses on foreign currency held.

### Balance sheet

At 31 December 2018 the group's cash position was \$44,401,000 (June 2018: \$51,319,000). Trade and other receivables of \$6,741,000 (June 2018: \$6,134,000) include the accrued \$4,019,000 refundable Australian Government R&D tax incentive relating to year ended 30 June 2018 eligible activities and a further \$2,246,000 accrued R&D tax incentive receivable relating to half-year ended 31 December 2018 activities. Trade and other payables of \$2,800,000 (June 2018: \$3,801,000) have reduced primarily on lower accruals associated with the VivaGel<sup>®</sup> BV clinical program.

### Statement of cash flows

Net operating cash outflows for the half-year were \$7,279,000 (December 2018: \$11,261,000)

## Earnings per share

|                                | Half-year ended<br>31 December |               |
|--------------------------------|--------------------------------|---------------|
|                                | 2018<br>Cents                  | 2017<br>Cents |
| Basic / diluted loss per share | <b>(1.96)</b>                  | (1.69)        |

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

No matters or circumstances have arisen since 31 December 2018 that have significantly affected, or may significantly affect:

- the consolidated entity's operations in future financial years, or
- the results of the operations in future financial years, or
- the consolidated entity's state of affairs in future financial years.



## Rounding of amounts

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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

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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 AO  
Chairman  
Melbourne, 27 February 2019

# 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 2018, 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 entity it controlled during the period.

A handwritten signature in black ink, appearing to read 'S.P. A' with a stylized flourish at the end.

Jon Roberts  
Partner  
PricewaterhouseCoopers

Melbourne  
27 February 2019

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**PricewaterhouseCoopers, ABN 52 780 433 757**  
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# 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 2018 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 statement of comprehensive income

For the half-year ended 31 December 2018

|   | Notes | Half-year      |                |
|---|-------|----------------|----------------|
|   |       | 2018<br>\$'000 | 2017<br>\$'000 |
| Revenue   | 4     | 649            | 1,207          |
| Other income  | 4     | 12             | 37             |
| Research and product development expense  | 5     | (4,976)        | (5,406)        |
| Commercial and regulatory operating expense   | 5     | (1,729)        | (766)          |
| Corporate and administration expense  | 5     | (1,221)        | (1,301)        |
| Finance costs   |       | (1)            | (2)            |
| <b>Loss before income tax</b>   |       | <b>(7,266)</b> | <b>(6,231)</b> |
| Income tax expense  |       | -              | -              |
| <b>Loss attributable to the ordinary equity holders of the company</b>                                    |       | <b>(7,266)</b> | <b>(6,231)</b> |
| <b>Other comprehensive income (loss)</b>  |       | <b>-</b>       | <b>-</b>       |
| <b>Total comprehensive loss for the period attributable to the ordinary equity holders of the company</b> |       | <b>(7,266)</b> | <b>(6,231)</b> |
| <b>Loss per share for loss attributable to the ordinary equity holders of the company</b>                 |       | <b>Cents</b>   | <b>Cents</b>   |
| Basic loss per share  | 9     | (1.96)         | (1.69)         |
| Diluted loss per share  | 9     | (1.96)         | (1.69)         |

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

## Consolidated balance sheet

As at 31 December 2018

|                                      |       | 31 December   | 30 June   |
|--------------------------------------|-------|---------------|-----------|
|                                      |       | 2018          | 2018      |
|                                      | Notes | \$'000        | \$'000    |
| <b>Current assets</b>                |       |               |           |
| Cash and cash equivalents            |       | 44,401        | 51,319    |
| Trade and other receivables          | 6     | 6,741         | 6,134     |
| <b>Total current assets</b>          |       | <b>51,142</b> | 57,453    |
| <b>Non-current assets</b>            |       |               |           |
| Property, plant and equipment        |       | 1,054         | 1,058     |
| <b>Total non-current assets</b>      |       | <b>1,054</b>  | 1,058     |
| <b>Total assets</b>                  |       | <b>52,196</b> | 58,511    |
| <b>Current liabilities</b>           |       |               |           |
| Trade and other payables             |       | 2,800         | 3,801     |
| Finance lease liabilities            |       | 25            | 26        |
| Provision for employee benefits      |       | 948           | 930       |
| Deferred income                      |       | 449           | 407       |
| <b>Total current liabilities</b>     |       | <b>4,222</b>  | 5,164     |
| <b>Non-current liabilities</b>       |       |               |           |
| Finance lease liabilities            |       | 11            | 23        |
| Provision for employee benefits      |       | 60            | 47        |
| <b>Total non-current liabilities</b> |       | <b>71</b>     | 70        |
| <b>Total liabilities</b>             |       | <b>4,293</b>  | 5,234     |
| <b>Net assets</b>                    |       | <b>47,903</b> | 53,277    |
| <b>Equity</b>                        |       |               |           |
| Contributed capital                  | 7     | 193,583       | 193,583   |
| Reserves                             |       | 15,332        | 13,440    |
| Accumulated losses                   |       | (161,012)     | (153,746) |
| <b>Total equity</b>                  |       | <b>47,903</b> | 53,277    |

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 2018

|  | Notes | Half-year<br>December 2018      |                    |                                 |                           |
|--|-------|---------------------------------|--------------------|---------------------------------|---------------------------|
|  |       | Contributed<br>equity<br>\$'000 | Reserves<br>\$'000 | Accumulated<br>losses<br>\$'000 | Total<br>equity<br>\$'000 |
| Balance at 1 July 2018                                       |       | 193,583                         | 13,440             | (153,746)                       | 53,277                    |
| Loss for the period  |       | -                               | -                  | (7,266)                         | (7,266)                   |
| Other comprehensive income                                   |       | -                               | -                  | -                               | -                         |
| <b>Total comprehensive loss for the half-year</b>            |       | -                               | -                  | (7,266)                         | (7,266)                   |
| <b>Transactions with owners, recorded directly in equity</b> |       |                                 |                    |                                 |                           |
| Employee performance rights plan                             |       | -                               | 1,892              | -                               | 1,892                     |
| <b>Total transactions with owners</b>                        |       | -                               | 1,892              | -                               | 1,892                     |
| <b>Balance at 31 December 2018</b>                           |       | <b>193,583</b>                  | <b>15,332</b>      | <b>(161,012)</b>                | <b>47,903</b>             |

For the half-year ended 31 December 2017

|  | Notes | Half-year<br>December 2017      |                    |                                 |                           |
|--|-------|---------------------------------|--------------------|---------------------------------|---------------------------|
|  |       | Contributed<br>equity<br>\$'000 | Reserves<br>\$'000 | Accumulated<br>losses<br>\$'000 | Total<br>equity<br>\$'000 |
| Balance at 1 July 2017                                       |       | 193,549                         | 10,896             | (143,461)                       | 60,984                    |
| Loss for the period  |       | -                               | -                  | (6,231)                         | (6,231)                   |
| Other comprehensive income                                   |       | -                               | -                  | -                               | -                         |
| <b>Total comprehensive loss for the half-year</b>            |       | -                               | -                  | (6,231)                         | (6,231)                   |
| <b>Transactions with owners, recorded directly in equity</b> |       |                                 |                    |                                 |                           |
| Employee performance rights plan                             |       | -                               | 1,161              | -                               | 1,161                     |
| <b>Total transactions with owners</b>                        |       | -                               | 1,161              | -                               | 1,161                     |
| <b>Balance at 31 December 2017</b>                           |       | <b>193,549</b>                  | <b>12,057</b>      | <b>(149,692)</b>                | <b>55,914</b>             |

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 2018

|   | Notes | Half-year      |                 |
|---|-------|----------------|-----------------|
|   |       | 2018           | 2017            |
|   |       | \$'000         | \$'000          |
| <b>Cash flow from operating activities</b>                    |       |                |                 |
| Receipts from trade and other debtors (inclusive of GST)      |       | 2,123          | 426             |
| Grant income and R&D tax incentives (inclusive of GST)        |       | -              | -               |
| Payments to suppliers and employees (inclusive of GST)        |       | (9,964)        | (12,240)        |
| Interest received   |       | 563            | 555             |
| Interest paid   |       | (1)            | (2)             |
| <b>Net cash outflows from operating activities</b>            |       | <b>(7,279)</b> | <b>(11,261)</b> |
| <b>Cash flow from investing activities</b>                    |       |                |                 |
| Payments for property, plant and equipment                    |       | (153)          | (215)           |
| Proceeds from sale of available-for-sale financial assets     |       | 8              | -               |
| <b>Net cash outflows from investing activities</b>            |       | <b>(145)</b>   | <b>(215)</b>    |
| <b>Cash flow from financing activities</b>                    |       |                |                 |
| Lease repayments  |       | (13)           | (13)            |
| <b>Net cash inflows from financing activities</b>             |       | <b>(13)</b>    | <b>(13)</b>     |
| <b>Net decrease in cash and cash equivalents held</b>         |       | <b>(7,437)</b> | <b>(11,489)</b> |
| Cash and cash equivalents at the beginning of the half-year   |       | 51,319         | 61,188          |
| Effects of exchange rate changes on cash and cash equivalents |       | 519            | 203             |
| <b>Cash and cash equivalents at the end of the half-year</b>  |       | <b>44,401</b>  | <b>49,902</b>   |

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

## Notes to the consolidated financial statements

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31 December 2018

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## 1. Summary of significant accounting policies

### (a) Basis of preparation

This consolidated interim financial report for the half-year reporting period ended 31 December 2018 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 2018 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 except as set out in (b) below.

The financial statements have been prepared on a going concern basis.

### (b) Changes in accounting policies

#### *AASB 15 Revenue from Contracts with Customers*

AASB15 is based on the principle that revenue is recognised when control of a good or service transfers to a customer – so the notion of control replaces the existing notion of risks and rewards. The group has adopted AASB 15 effective from 1 July 2018 using the modified retrospective approach.

Management has assessed the impact of AASB 15 on the measurement and recognition of revenue from existing contractual arrangements. Based on the assessment, the adoption of AASB 15 has had no material impact on the group's profit or loss, nor has there been any adjustments to opening retained earnings as at 1 July 2018.

#### *AASB 9 Financial Instruments*

AASB 9 addresses the classification, measurement and derecognition of financial assets and financial liabilities. The group has adopted AASB 9 effective from 1 July 2018. There has been no material impact on the accounting for financial instruments as the group does not have any debt instruments classified as available-for-sale financial assets, financial liabilities that are designated at fair value through profit or loss or hedging instruments. AASB 9 introduces an expected credit loss model for impairment of financial assets such as trade receivables. The group has reviewed the requirements of the 'expected credit loss' model and did not identify any required provision.

#### *New accounting standard not yet effective*

#### *AASB 16 Leases (effective application date for the group 1 July 2019)*

AASB 16 will result in almost all leases being recognised on the balance sheet, as the distinction between operating and finance leases is removed. Under the new standard, an asset (the right to use the leased item) and a financial liability to pay rentals are recognised. The only exceptions are short-term and low-value leases.

The group has operating lease commitments, as disclosed in the 30 June 2018 annual report (see Note 20), primarily consisting of property and equipment leases. Management is currently assessing the impact of AASB 16 on the measurement and recognition of lease assets and liabilities. The new standard is mandatory for the group from 1 July 2019 and the group does not intend to adopt the standard before its effective date.

## 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 product 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 2018, the group has recorded a contra research and development expense of \$2,418,000.

## 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

|  | <b>Half-year</b> |               |
|--|------------------|---------------|
|  | <b>2018</b>      | 2017          |
|  | <b>\$'000</b>    | <b>\$'000</b> |
| <b>Revenue and other income</b>                  |                  |               |
| Royalty, customer & license revenue              | <b>83</b>        | 663           |
| Interest revenue                                 | <b>566</b>       | 544           |
| <b>Total revenue</b>                             | <b>649</b>       | 1,207         |
| Total other income (including government grants) | <b>12</b>        | 37            |
| <b>Total revenue and other income</b>            | <b>661</b>       | 1,244         |

## 5. Expenses

|   | Half-year      |                |
|---|----------------|----------------|
|   | 2018<br>\$'000 | 2017<br>\$'000 |
| Loss from before income tax expense includes the following items: |                |                |
| R&D Tax Incentive (contra expense) <sup>1</sup>                   | (2,418)        | (2,102)        |
| Employee benefits expenses (including share-based payments)       | 5,443          | 4,370          |
| Depreciation  | 155            | 154            |
| Rental expense on operating leases                                | 289            | 282            |

<sup>1</sup> Included within the research and product development expense line item in the consolidated statement of comprehensive income.

## 6. Current Assets – Trade and other receivables

Trade and other receivables primarily comprise of \$6,265,000 (30 June 2018: \$3,847,000) refundable under the Australian Government's R&D tax incentive scheme, of which \$4,019,000 relates to year ended 30 June 2018.

## 7. Contributed equity

### (a) Share capital

|                              | December 2018<br>Shares | June 2018<br>Shares | December 2018<br>\$'000 | June 2018<br>\$'000 |
|------------------------------|-------------------------|---------------------|-------------------------|---------------------|
| Share Capital                |                         |                     |                         |                     |
| Ordinary shares – fully paid | 371,620,542             | 370,544,775         | 193,583                 | 193,583             |

### (b) Ordinary shares

As at 31 December 2018 there were 371,620,542 issued ordinary shares. During the half-year to 31 December 2018 1,075,767 ordinary shares were issued on the vesting or exercising on employee performance rights. 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.

### (c) 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 34,542 shares was issued to eligible staff on 8 February 2019, subsequent to the reporting date.

### (d) Employee Performance Rights Plan

There were 1,075,767 shares issued on the vesting or exercise of performance rights and 2,988,135 performance rights issued during the financial half-year.

As at 31 December 2018 the company had on issue the following Employee Performance Rights under the Starpharma Holdings Limited Employee Performance Rights Plan.

| Grant date                    | Vesting date      | Number under rights | Grant date                    | Vesting date      | Number under rights |
|-------------------------------|-------------------|---------------------|-------------------------------|-------------------|---------------------|
| 11 November 2015              | 30 June 2017      | 307,293             | 10 August 2017 <sup>3</sup>   | 30 September 2020 | 2,622,880           |
| 11 November 2015              | 30 September 2018 | 1,389,758           | 29 November 2017 <sup>4</sup> | 30 June 2019      | 197,226             |
| 19 November 2015 <sup>1</sup> | 30 June 2017      | 181,001             | 29 November 2017 <sup>4</sup> | 30 September 2020 | 895,879             |
| 19 November 2015 <sup>1</sup> | 30 September 2018 | 836,260             | 16 August 2018 <sup>5</sup>   | 30 June 2020      | 203,500             |
| 13 October 2016               | 30 June 2018      | 357,176             | 16 August 2018 <sup>5</sup>   | 30 September 2021 | 814,000             |
| 13 October 2016               | 30 September 2019 | 2,022,600           | 2 November 2018 <sup>5</sup>  | 30 June 2020      | 259,147             |
| 29 November 2016 <sup>2</sup> | 30 June 2018      | 172,842             | 2 November 2018 <sup>5</sup>  | 30 September 2021 | 1,036,587           |
| 29 November 2016 <sup>2</sup> | 30 September 2019 | 876,978             | 29 November 2018 <sup>6</sup> | 30 June 2020      | 134,980             |
| 10 August 2017 <sup>3</sup>   | 30 June 2019      | 612,750             | 29 November 2018 <sup>6</sup> | 30 September 2021 | 539,921             |

<sup>1</sup> Approved by shareholders at the Annual General Meeting on 19 November 2015; securities allotted on 2 December 2015.

<sup>2</sup> Approved by shareholders at the Annual General Meeting on 29 November 2016; securities allotted on 5 December 2016.

<sup>3</sup> Securities allotted on 12 October 2017.

<sup>4</sup> Approved by shareholders at the Annual General Meeting on 29 November 2017; securities allotted on 11 December 2017.

<sup>5</sup> Securities allotted on 5 November 2018.

<sup>6</sup> Approved by shareholders at the Annual General Meeting on 29 November 2018; securities allotted on 11 December 2018.

## 8. Events occurring after the balance sheet date

There are no significant events occurring since 31 December 2018 that have significantly affected or may significantly affect the operations of the group, the results of those operations, or the state of the group.

## 9. Earnings per share

|  | Half-year   |             |
|--|-------------|-------------|
|  | 2018        | 2017        |
| <b>Basic loss per share / Diluted loss per share</b>   |             |             |
| From continuing operations attributable to the ordinary equity holders of the company (cents)                                    | (1.96)      | (1.69)      |
| <b>Reconciliations of loss used in calculating earnings per share</b>  |             |             |
| Profit attributable to the ordinary equity holders of the company used in calculating basic/diluted earnings per share (\$'000): | (7,266)     | (6,231)     |
| Weighted average number of ordinary shares used as the denominator in calculating basic/diluted earnings per share               | 370,920,956 | 369,739,376 |

As at 31 December 2018 the company had on issue 13,460,778 (30 June 2018: 11,876,199) performance rights. The rights are not included in the determination of basic earnings per share. The rights are also not included in the determination of diluted earnings per share. They are not considered dilutive as their conversion would not increase loss per share from continuing operations.

## Directors' declaration

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In the directors' opinion:

- (a) the financial statements and notes set out on pages 8 to 16 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 2018 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 AO  
Chairman  
Melbourne, 27 February 2019

## Independent Auditor's Review Report to the Members

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### **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 2018, the 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, a summary of significant accounting policies, selected other explanatory notes and the directors' declaration for Starpharma Holdings Limited. The consolidated entity comprises the Company and the entity 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 2018 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*.

---

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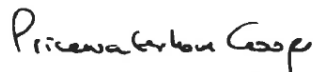
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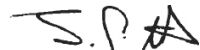


### *Conclusion*

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:

1. giving a true and fair view of the consolidated entity's financial position as at 31 December 2018 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

  
Jon Roberts  
Partner

Melbourne  
27 February 2019