

## Starpharma Interim Report and Half-Year Financial Results

**Melbourne, Australia; 24 February 2020:** Starpharma (ASX: SPL, OTCQX: SPHRY) today released its interim report and financial results for the half-year ended 31 December 2019.

Key Financials	1H FY20 (A\$M)	1H FY19 (A\$M)
Revenue and other income	5.7	0.7
Loss from period	(5.9)	(7.3)
Net operating cash outflows	(5.2)	(7.3)
<b>Net cash burn<sup>1</sup></b>	<b>(5.4)</b>	<b>(6.9)</b>
<b>Cash as at 31 Dec 2019</b>	<b>\$35.9M</b>	

### Financial Result

- Cash position at 31 December 2019 \$35.9M (June 2019 \$41.3M)
- Net cash burn<sup>1</sup> of \$5.4M for the half year, down 22% on prior corresponding period (pcp)
- Total revenue and other income of \$5.7M (pcp: \$0.7M), including US\$3M AstraZeneca milestone payment and more than \$1.0M for VivaGel<sup>®</sup> product sales and royalties
- Reported loss for half-year of \$5.9M (pcp: \$7.3M), down by 19%
- Net operating cash outflows of \$5.2M
- Receipt of \$4.9M R&D tax incentive received in December
- In February, Starpharma received US\$3.0M milestone payment from AstraZeneca

### VivaGel<sup>®</sup>

- VivaGel<sup>®</sup> BV was launched in the UK under the brand Betafem<sup>®</sup> BV Gel. Starpharma supplied product to support the roll-out of VivaGel<sup>®</sup> BV in Europe, including countries in Central and Eastern Europe, where launches are expected in the coming months.
- VivaGel<sup>®</sup> BV was recently launched in Asia under the brand Betadine<sup>™</sup> BV Gel, following the receipt of first Asian regulatory approvals and the supply of product during the half-year. Advanced marketing activities have been undertaken ahead of further launches in the Southeast Asian region.
- Aspen continued to advance their marketing and promotional activities for Fleurstat BVgel in Australia, and progressed with launch preparations for New Zealand. Starpharma has supplied product for the launch and conducted detailed sales representative training.
- Starpharma progressed its dual strategy regarding FDA approval of VivaGel<sup>®</sup> BV with ongoing support from a team of expert FDA consultants (regulatory, statistical, clinical, legal; several ex-FDA). This includes seeking formal review of some of the FDA's initial conclusions, as well as preparation for a possible BV treatment trial.

<sup>1</sup> Net cash burn is considered a non-IFRS value and has not been audited in accordance with Australian Accounting Standards. Net cash burn is calculated by the movement in cash and cash equivalents between reporting periods.

- VivaGel<sup>®</sup> condom was granted marketing approval in Europe. LifeStyles has commenced marketing preparations ahead of the launch of the VivaGel<sup>®</sup> condom under the brand name Absolute<sup>™</sup> DUAL PROTECTION.

#### DEP<sup>®</sup> Drug Delivery

- Recruitment progressed, and promising efficacy signals were observed in the DEP<sup>®</sup> docetaxel phase 2 trial in a variety of tumour types including non-small cell lung cancer, prostate cancer, and several hard to treat tumours. Two new sites, the Christie and the Beatson (Glasgow), were initiated and recruitment is continuing. Preparations advanced for the commencement of a DEP<sup>®</sup> docetaxel + gemcitabine (Gemzar<sup>®</sup>) combination arm with particular interest in pancreatic cancer.
- DEP<sup>®</sup> cabazitaxel trial progressed from phase 1 to phase 2 on positive results. The trial met its objective of evaluating safety, tolerability and preliminary efficacy data, and identifying a recommended phase 2 dose. The trial transitioned seamlessly into phase 2, with two new sites initiated and recruitment progressing well.
- Commenced phase 1/2 clinical trial for DEP<sup>®</sup> irinotecan, with recruitment continuing at three leading cancer sites, including the Christie, the Royal Marsden and Newcastle Freeman Hospital.
- AstraZeneca commenced the phase 1 clinical trial of its first DEP<sup>®</sup> product, AZD0466, after the US FDA authorised the IND. The successful dosing of the first patient in this trial triggered a US\$3 million milestone to Starpharma.
- Impressive data were reported for DEP<sup>®</sup> irinotecan, alone and in combination with Merck and AstraZeneca's Lynparza<sup>®</sup>, in a refractory human colon cancer model.
- New DEP<sup>®</sup> candidate, DEP<sup>®</sup> gemcitabine, was advanced for development after demonstrating significantly enhanced anti-tumour activity compared with Gemzar<sup>®</sup> (gemcitabine), both alone and in combination with Nab paclitaxel (Abraxane<sup>®</sup>), in a human pancreatic cancer model.
- A novel HER-2 Targeted DEP<sup>®</sup> conjugate (ADC) from Starpharma's internal Targeted DEP<sup>®</sup> program demonstrated significant tumour regression and 100% survival in a preclinical human ovarian cancer model.
- 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.
- Several new DEP<sup>®</sup> patents were filed covering new DEP<sup>®</sup> candidates and DEP<sup>®</sup> in combination with marketed anticancer agents and novel DEP<sup>®</sup> radiotherapeutics.

Starpharma concluded the half-year in a strong financial position with a cash balance of \$35.9 million, which does not include the US\$3.0 million milestone payment from AstraZeneca for the first successful dosing of AZD0466, which was subsequently received in February 2020.

Revenues for the half-year totalled \$5.9 million including a US\$3 million AstraZeneca milestone payment and more than \$1.0 million for VivaGel<sup>®</sup> product sales and royalties. The net loss after tax for the half-year was \$5.9 million (Dec 2018: \$7.3 million), which is lower than the prior period primarily due to the aforementioned increase in revenue from DEP<sup>®</sup> milestones and VivaGel<sup>®</sup> products. The increase in expenditure in the half-year was predominantly driven by higher research and product development expenses including expenditure on the Company's internal DEP<sup>®</sup> clinical programs and preparations for a possible VivaGel<sup>®</sup> BV treatment clinical trial. With the commencement of the DEP<sup>®</sup> irinotecan clinical trial in the half-year, the Company has three DEP<sup>®</sup> internal clinical trials underway, including DEP<sup>®</sup> docetaxel and DEP<sup>®</sup> cabazitaxel.

The increase in commercial and regulatory operating expense reflects internal and external costs related to US regulatory activities, commercial licences and the launch of VivaGel® BV in multiple markets. The increase in corporate, administration and finance expense over the prior corresponding period predominately reflects a lower foreign currency gain in the current period.

Starpharma's CEO, Dr Jackie Fairley, commented: "We achieved several significant milestones in the recent period, notably the launch of VivaGel® BV in Asia and the UK, regulatory approvals in Asia, and we supplied product to multiple regions for future launches of the product in 2020. In our DEP® portfolio, we announced positive interim results and advancement in our internal clinical trials, and AstraZeneca commenced a phase 1 trial for DEP® AZD0466 in the US. This was our first partnered DEP® product to enter the clinic, alongside our three internal clinical-stage DEP® products, DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan. AZD0466 is a great illustration of the benefits that can be created for novel agents using Starpharma's DEP® platform."

Dr Fairley concluded: "We expect to announce further milestones throughout the next period, including the launch of VivaGel® BV in New Zealand and additional countries in Central and Eastern Europe, as well as further regulatory approvals. We will continue to focus on advancing high potential DEP® candidates through development, accelerating our clinical trials, wherever possible, and pursuing partnerships to leverage our proprietary DEP® technology," concluded Dr Fairley.

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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® portfolio and DEP® drug delivery with the Company developing several products internally and others via commercial partnerships.

**VivaGel®:** Starpharma's women's health product - VivaGel® BV is based on SPL7013, astodimer sodium, a proprietary dendrimer. VivaGel® BV for bacterial vaginosis (BV), is available for sale under the brand names Betafem® BV Gel (UK), Betadine BV™ (Europe), Betadine™ BV Gel (Asia) and Fleurstat BVgel (Australia) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel® 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® condom (an antiviral condom which includes VivaGel® in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel® condom has been launched in Japan under Okamoto's 003 brand, and in Australia and Canada under the LifeStyles Dual Protect® brand. The VivaGel® condom is approved in Europe.

**DEP® - Dendrimer Enhanced Product®:** Starpharma's DEP® drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP® programs, including improved efficacy, safety and survival. Starpharma has three internal DEP® products – DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan - in clinical development in patients with solid tumours. Starpharma's partnered DEP® programs include a multiproduct DEP® licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP® version of one of AstraZeneca's major marketed oncology medicines.

[Starpharma.com](http://Starpharma.com) | [Twitter](https://twitter.com/Starpharma) | [LinkedIn](https://www.linkedin.com/company/starpharma)

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#### Disclosure

This ASX Announcement was authorised for release by the Board of Directors.

#### 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.

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# Starpharma Holdings Limited

ABN 20 078 532 180

## Interim Report – 31 December 2019

Lodged with the ASX under Listing Rule 4.2A

This information should be read in conjunction with the 30 June 2019 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 2019

Previous corresponding period: Half-year ended 31 December 2018

<b>Revenue</b> (Appendix 4D item 2.1)	Up	774%	to	\$5,671,000
<b>Loss</b> after tax attributable to members (Appendix 4D item 2.2)	Down (decreased loss)	19%	to	\$5,863,000
<b>Net Loss</b> for the period attributable to members (Appendix 4D item 2.3)	Down (decreased loss)	19%	to	\$5,863,000

<b>Dividends/distributions</b> (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 includes product sales, royalty, licensing and research revenue from commercial partners of \$5,353,000 (December 2018: \$83,000); and interest revenue on cash invested in term deposits of \$318,000 (December 2018: \$566,000). Revenue from commercial partners includes \$4,125,000 on AstraZeneca triggering a development milestone for the first dose of AZD0466 administered in the phase 1 trial of its first DEP® product, and the remaining \$1,228,000 predominately related to VivaGel® BV and VivaGel® condom product sales and royalties during the period.

## Explanation of net loss

(Appendix 4D item 2.6)

The consolidated loss after tax for the half-year to 31 December 2019 was \$5,863,000 (December 2018: \$7,266,000). The net loss is lower than the prior period due to the increase in revenue from commercial partners for DEP® and VivaGel® products, offset by increased expenditure, predominantly on research and product development expenses including clinical expenditure for the Company's internal DEP® drug delivery programs and preparations for a potential VivaGel® BV treatment clinical trial. With the commencement of the DEP® irinotecan clinical trial in the half-year, the Company has three DEP® internal clinical trials underway, including DEP® docetaxel and DEP® cabazitaxel.

Commercial and regulatory operating expense increase reflects internal and external costs related to US regulatory activities, commercial licences and the launch of VivaGel® BV in multiple markets. The increase in corporate, administration and finance expense over the prior corresponding period predominately reflects a lower foreign currency gain in the current period.

A contra research and product development expense of \$2,957,000 (December 2018: \$2,418,000) 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 31 December</b>	
	<b>2019</b>	2018
Net tangible asset backing per ordinary share	<b>\$0.10</b>	\$0.13

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 2019 half-year financial statements.

This report is based on the consolidated 2019 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 2019 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 2019.

### 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 focus on the development of VivaGel® 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® 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 deepen its product development pipeline, including internal and partnered DEP® programs and to commercially exploit VivaGel®. Starpharma achieves 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® 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®

- VivaGel® BV was launched in the UK under the brand Betafem® BV Gel. Starpharma supplied product to support the roll-out of VivaGel® BV in Europe, including countries in Central and Eastern Europe, where launches are expected in the coming months.
- VivaGel® BV was launched in Asia under the brand Betadine™ BV Gel, following the receipt of first Asian regulatory approvals and the supply of product during the half-year. Advanced marketing activities have been undertaken ahead of further launches in the Southeast Asian region.
- Aspen continued to advance their marketing and promotional activities for Fleurstat BVgel in Australia, and progressed with launch preparations for New Zealand. Starpharma has supplied product for the launch and conducted detailed sales representative training.
- Starpharma progressed its dual strategy regarding FDA approval of VivaGel® BV with ongoing support from a team of expert FDA consultants (regulatory, statistical, clinical, legal; several ex-FDA). This includes seeking formal review of some of the FDA's initial conclusions, as well as preparation for a possible BV treatment trial.
- VivaGel® condom was granted marketing approval in Europe. LifeStyles has commenced marketing preparations ahead of the launch of the VivaGel® condom under the brand name Absolute™ DUAL PROTECTION.

#### DEP® Drug Delivery Platform

- Recruitment progressed, and promising efficacy signals were observed in the DEP® docetaxel phase 2 trial in a variety of tumour types including non-small cell lung cancer, prostate cancer, and several hard to treat tumours. Two new sites, the Christie and the Beatson (Glasgow), were initiated and recruitment is continuing.
- DEP® cabazitaxel trial progressed from phase 1 to phase 2 on positive results. The trial met its objective of evaluating safety, tolerability and preliminary efficacy data, and identifying a recommended phase 2 dose. The trial transitioned seamlessly into phase 2, with two new sites initiated and recruitment progressing well.
- Commenced phase 1/2 clinical trial for DEP® irinotecan, with recruitment continuing at three leading cancer sites, including the Christie, the Royal Marsden and Newcastle Freeman Hospital.
- AstraZeneca commenced the phase 1 clinical trial of its first DEP® product, AZD0466, after the US FDA authorised the IND. The successful dosing of the first patient in this trial triggered a US\$3 million milestone to Starpharma.
- Impressive data were reported for DEP® irinotecan, alone and in combination with Merck and AstraZeneca's Lynparza®, in a refractory human colon cancer model.

- New DEP<sup>®</sup> candidate, DEP<sup>®</sup> gemcitabine, was advanced for development after demonstrating significantly enhanced anti-tumour activity compared with Gemzar<sup>®</sup> (gemcitabine), both alone and in combination with Nab-paclitaxel (Abraxane<sup>®</sup>), in a human pancreatic cancer model.
- A novel HER-2 Targeted DEP<sup>®</sup> conjugate (ADC) from Starpharma's internal Targeted DEP<sup>®</sup> program demonstrated significant tumour regression and 100% survival in a preclinical human ovarian cancer model.
- 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.
- Several new DEP<sup>®</sup> patents were filed covering new DEP<sup>®</sup> candidates and DEP<sup>®</sup> in combination with marketed anticancer agents and novel DEP<sup>®</sup> radiotherapeutics.

### VivaGel<sup>®</sup> Program

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

VivaGel<sup>®</sup> BV is currently on-market in the UK, Europe and Australia, and approved for launch in multiple countries in Asia, and New Zealand. The product has been licensed in more than 160 countries.

During the half-year Starpharma made significant progress with the roll-out of VivaGel<sup>®</sup> BV in several regions. VivaGel<sup>®</sup> BV was launched in the UK under the brand Betafem<sup>®</sup> BV Gel in October 2019 and Starpharma also supplied product to Mundipharma for further roll-out in Central and Eastern European countries. In February 2020 VivaGel<sup>®</sup> BV was launched in Asia, having received the first Asian regulatory approvals in August 2019. Multiple regulatory submissions were progressed during the half year, including a number of submissions completed for further countries in Asia and in other regions.

In Australia, Fleurstat BVgel is available in more than 2,700 Australian pharmacies and stocked in 100% of Chemist Warehouse, Priceline and Blooms pharmacies. Aspen expects to launch Fleurstat BVgel in New Zealand in the coming months, and launch preparations including product supply and extensive sales training has been completed.

Starpharma progressed its dual strategy regarding FDA approval of VivaGel<sup>®</sup> BV with ongoing support from a team of expert FDA consultants (regulatory, statistical, clinical, legal; several ex-FDA). This includes seeking formal review of some of the FDA's initial conclusions via an administrative review process, as well as preparation for a possible BV treatment trial. During the half-year Starpharma progressed significant activities, including protocol development, protocol review by the FDA, contingent CRO appointment and investigator/site selection, so that a trial could commence rapidly, if required.

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

During the half-year, Starpharma's Japanese condom partner, Okamoto, and the Japanese Ministry of Health, Labour & Welfare developed a joint STI prevention campaign using VivaGel<sup>®</sup> condoms. In Europe, the VivaGel<sup>®</sup> condom was granted marketing approval. Starpharma's European partner, LifeStyles, commenced marketing preparations ahead of the launch of the VivaGel<sup>®</sup> condom under the brand name Absolute™ DUAL PROTECTION.

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

#### *Internal DEP<sup>®</sup> programs*

The phase 2 DEP<sup>®</sup> docetaxel trial continued to progress well during the half-year, with two further sites, The Christie and The Beatson, opened for recruitment (six trial sites in total). In the monotherapy arm, DEP<sup>®</sup> docetaxel continued to show promising efficacy signals including prolonged stable disease (up to 40 weeks) and tumour shrinkage, as well as a notable lack of bone marrow toxicity and other common side effects. The efficacy signals observed were in a variety of tumour types including prostate cancer, non-small cell lung cancer and several hard-to-treat tumours including cholangiocarcinoma – the second most common liver cancer which is often fatal.

In the combination arm, DEP<sup>®</sup> docetaxel + nintedanib (Vargatef<sup>®</sup>), continued to show efficacy signals including prolonged stable disease and tumour shrinkage in non-small cell lung cancer and a notable lack of bone marrow toxicity and other common side effects including mouth ulcers, anaphylaxis and oedema. Further potential combinations are also being explored following interest from specialist oncologists, including DEP<sup>®</sup> docetaxel + gemcitabine (Gemzar<sup>®</sup>) which is expected to commence in the first half of 2020 targeting pancreatic cancer.

During the half-year, the phase 1 component of the phase 1/2 DEP<sup>®</sup> cabazitaxel trial met its objective of identifying a recommended Phase 2 Dose (RP2D) and transitioned seamlessly into phase 2. In phase 1, encouraging efficacy signals were observed in 67% of patients assessed and included prolonged stable disease in multiple tumour types, including prostate cancer. Efficacy signals were observed in cancers not usually responsive to conventional cabazitaxel (Jevtana<sup>®</sup>), such as ovarian cancer, and at doses lower than used for Jevtana<sup>®</sup>. Recruitment for the trial progressed well with two further sites (Imperial College London and Velindre Cancer Centre in Cardiff) opened for recruitment (four trial sites in total) for phase 2.

In August 2019, Starpharma commenced its phase 1/2 clinical trial for DEP<sup>®</sup> irinotecan for patients with advanced solid tumours, including colorectal cancer. The DEP<sup>®</sup> irinotecan trial is initially being conducted at multiple leading UK cancer centres including The Christie, The Royal Marsden and Newcastle Freeman Hospital. Recruitment progressed well during half-year in the escalation phase, with some patients having received up to seven cycles of treatment and efficacy signals observed. Additional sites in the UK and Australia are expected to open and commence recruitment as the trial progresses and for the phase 2 part of the trial. Starpharma is also exploring the use of DEP<sup>®</sup> irinotecan in other cancers, and in combination with other anti-cancer agents in preclinical models. In September 2019, Starpharma reported impressive data on DEP<sup>®</sup> irinotecan, alone and in combination with Merck and AstraZeneca's Lynparza<sup>®</sup>, in a refractory human colon cancer model, and these data will also inform the conduct of the phase 1/2 trial.

During the half-year, Starpharma progressed several important preclinical DEP<sup>®</sup> programs, including a DEP<sup>®</sup> version of Lilly's Gemzar<sup>®</sup> (gemcitabine). DEP<sup>®</sup> gemcitabine demonstrated significantly enhanced anti-tumour activity compared with Gemzar<sup>®</sup> (gemcitabine), both alone and in combination with Nab-paclitaxel (Abraxane<sup>®</sup>), in a human pancreatic cancer model. The Company also progressed a novel DEP<sup>®</sup> HER-2 ADC conjugate. In August 2019, Starpharma reported that this DEP<sup>®</sup> HER-2 ADC conjugate resulted in tumour regression and 100% survival, and significantly outperformed both Kadcylya<sup>®</sup> (T-DM1), a HER-2 targeted antibody-drug conjugate (ADC), and Herceptin<sup>®</sup> (Trastuzumab) itself, in a human ovarian cancer model.

A range of other DEP<sup>®</sup> candidates are being developed, including DEP<sup>®</sup> radiopharmaceuticals, with several patents filed during the half-year covering new candidates.



*Partnered DEP® programs*

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

During the half-year, the US FDA authorised the use of AstraZeneca's DEP® Bcl2/xL conjugate AZD0466 in clinical trials under an investigational new drug (IND) application. Following this approval, AstraZeneca commenced its first-in-human phase 1 clinical trial for AZD0466 in a range of cancers, to be conducted at 4-5 sites in the US. AZD0466 is being developed under Starpharma's multiproduct licence with AstraZeneca, whereby the development costs are funded by AstraZeneca, with Starpharma eligible for milestones and royalties on the product. The first dose of AZD0466 administered in the phase 1 trial triggered a milestone to Starpharma of US\$3 million.

The Company also progressed its other DEP® partnered programs during the half-year, including Targeted DEP® partnerships with world leading antibody-drug conjugate companies, and the new partnership signed with AstraZeneca in June 2019.

## Review of Financials

	Half-Year Ended 31 December	
	2019 \$'000	2018 \$'000
<b>Income statement</b>		
Revenue	5,671	649
Cost of goods sold	(650)	-
Other income	-	12
Research and product development expense (net of R&D tax incentive)	(7,316)	(4,976)
Commercial and regulatory operating expense	(1,989)	(1,729)
Corporate, administration and finance expense	(1,579)	(1,222)
<b>Loss for the period</b>	<b>(5,863)</b>	<b>(7,266)</b>

**Income statement**

For the half-year ended 31 December 2019 the consolidated loss after income tax was \$5,863,000 (December 2018: \$7,266,000).

Revenue includes product sales, royalty, licensing and research revenue from commercial partners of \$5,353,000 (December 2018: \$83,000); and interest income on cash invested in term deposits of \$318,000 (December 2018: \$566,000). Revenue from commercial partners includes \$4,125,000 on AstraZeneca triggering a development milestone for the first dose of AZD0466 administered in the phase 1 trial of its first DEP® product, and the remaining \$1,228,000 predominately related to VivaGel® BV and VivaGel® condom product sales and royalties during the period.

Research and product development expenses include the costs of the internal DEP® drug delivery programs, including DEP® docetaxel, DEP® cabazitaxel, and DEP® irinotecan, as well as the preparations for a potential VivaGel® BV treatment clinical trial. A contra research and product development expense of \$2,957,000 (December 2018: \$2,418,000) 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® and DEP® portfolios, including business development, legal, regulatory, supply chain and quality assurance activities. The increase in expense reflects internal and external costs related to US regulatory activities, commercial licences and the launch of VivaGel® BV in multiple markets.

Corporate, administration and finance expense include corporate costs, as well as gains/losses on foreign currency held. The increase over the prior corresponding period predominately reflects a lower foreign currency gain in the current period.

**Balance sheet**

At 31 December 2019 the group's cash position was \$35,876,000 (June 2019: \$41,251,000). Trade and other receivables of \$7,694,000 (June 2019: \$6,159,000) include \$2,957,000 for refundable Australian Government R&D tax incentive relating to half-year ended 31 December 2019 activities, and \$4,320,000 in customer receivables including the \$4,068,000 milestone receivable from AstraZeneca. Trade and other payables of \$5,193,000 (June 2019: \$4,917,000) have increased primarily on higher accruals associated with R&D expenditure on the DEP® and VivaGel® BV programs.

On the adoption of AASB 16 *Leases* from 1 July 2019, the group recognised lease liabilities and right-of-use assets in relation to leases which had previously been classified as 'operating leases' under AASB117 *Leases*. See Note 1(b) for further details.

**Statement of cash flows**

Net operating cash outflows for the half-year were \$5,160,000 (December 2018: \$7,279,000).

## Earnings per share

	Half-year ended 31 December	
	2019 Cents	2018 Cents
Basic / diluted loss per share	(1.58)	(1.96)

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

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No matters or circumstances have arisen since 31 December 2019 that have significantly affected, or may significantly affect:

- (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

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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, 24 February 2020

# 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 2019, 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.

A handwritten signature in black ink that reads 'Brad Peake'.

Brad Peake  
Partner  
PricewaterhouseCoopers

Melbourne  
24 February 2020

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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 2019 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 2019

	Notes	Half-year	
		2019 \$'000	2018 \$'000
Revenue	4	5,671	649
Cost of goods sold		(650)	
Other income	4	-	12
Research and product development expense (net of R&D tax incentive)		(7,316)	(4,976)
Commercial and regulatory operating expense		(1,989)	(1,729)
Corporate, administration and finance expense		(1,579)	(1,222)
<b>Loss before income tax</b>		<b>(5,863)</b>	<b>(7,266)</b>
Income tax expense		-	-
<b>Loss from continuing operations attributable to the ordinary equity holders of the company</b>		<b>(5,863)</b>	<b>(7,266)</b>
<b>Other comprehensive income (loss)</b>		<b>-</b>	<b>-</b>
<b>Total comprehensive income (loss) for the period</b>		<b>(5,863)</b>	<b>(7,266)</b>
<b>Loss per share for loss from continuing operations attributable to the ordinary equity holders of the company</b>		<b>Cents</b>	<b>Cents</b>
Basic loss per share	9	(1.58)	(1.96)
Diluted loss per share	9	(1.58)	(1.96)

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

## Consolidated balance sheet

As at 31 December 2019

		31 December	31 December
		2019	2018
	Notes	\$'000	\$'000
<b>Current assets</b>			
Cash and cash equivalents		35,876	41,251
Trade and other receivables	6	7,694	6,159
Inventories		275	399
<b>Total current assets</b>		<b>43,845</b>	47,809
<b>Non-current assets</b>			
Property, plant and equipment		980	1,050
Right-of-use assets	1(b)	1,841	-
<b>Total non-current assets</b>		<b>2,821</b>	1,050
<b>Total assets</b>		<b>46,666</b>	48,859
<b>Current liabilities</b>			
Trade and other payables		5,193	4,917
Lease liabilities	1(b)	593	26
Provision for employee benefits		1,036	1,056
Deferred income		428	427
<b>Total current liabilities</b>		<b>7,250</b>	6,426
<b>Non-current liabilities</b>			
Lease liabilities	1(b)	1,280	-
Provision for employee benefits		61	38
<b>Total non-current liabilities</b>		<b>1,341</b>	38
<b>Total liabilities</b>		<b>8,591</b>	6,464
<b>Net assets</b>		<b>38,075</b>	42,395
<b>Equity</b>			
Contributed capital	7	193,621	193,621
Reserves		18,314	16,775
Accumulated losses		(173,860)	(168,001)
<b>Total equity</b>		<b>38,075</b>	42,395

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 2019

	Notes	Half-year December 2019			
		Contributed equity \$'000	Reserves \$'000	Accumulated losses \$'000	Total equity \$'000
Balance at 1 July 2019		193,621	16,775	(168,001)	42,395
Application of AASB 16 <i>Leases</i>		-	-	4	4
<b>Restated total equity at the beginning of the financial year</b>		193,621	16,775	(167,997)	42,399
Loss for the period		-	-	(5,863)	(5,863)
Other comprehensive income (loss)		-	-	-	-
<b>Total comprehensive income (loss) for the half-year</b>		-	-	(5,863)	(5,863)
<b>Transactions with owners, recorded directly in equity</b>					
Employee performance rights plan		-	1,539	-	1,539
<b>Total transactions with owners</b>		-	1,539	-	1,539
<b>Balance at 31 December 2019</b>		193,621	18,314	(173,860)	38,075

For the half-year ended 31 December 2018

	Notes	Half-year December 2018			
		Contributed equity \$'000	Reserves \$'000	Accumulated losses \$'000	Total equity \$'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 (loss)		-	-	-	-
<b>Total comprehensive income (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>		193,583	15,332	(161,012)	47,903

## Consolidated statement of cash flows

For the half-year ended 31 December 2019

	Notes	Half-year	
		2019 \$'000	2018 \$'000
<b>Cash flow from operating activities</b>			
Receipts from trade and other debtors (inclusive of GST)		2,067	2,123
Grant income and R&D tax incentives (inclusive of GST)		4,898	-
Payments to suppliers and employees (inclusive of GST)		(12,418)	(9,964)
Interest received		336	563
Interest paid		(43)	(1)
<b>Net cash outflows from operating activities</b>		<b>(5,160)</b>	<b>(7,279)</b>
<b>Cash flow from investing activities</b>			
Payments for property, plant and equipment		(72)	(153)
Proceeds from sale of available-for-sale financial assets		-	8
<b>Net cash outflows from investing activities</b>		<b>(72)</b>	<b>(145)</b>
<b>Cash flow from financing activities</b>			
Lease repayments	1(b)	(286)	(13)
<b>Net cash inflows from financing activities</b>		<b>(286)</b>	<b>(13)</b>
<b>Net decrease in cash and cash equivalents held</b>		<b>(5,518)</b>	<b>(7,437)</b>
Cash and cash equivalents at the beginning of the half-year		41,251	51,319
Effects of exchange rate changes on cash and cash equivalents		143	519
<b>Cash and cash equivalents at the end of the half-year</b>		<b>35,876</b>	<b>44,401</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 2019

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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 2019 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 2019 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 16 Leases

AASB 16 results in 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 corresponding financial liability to pay rentals are recognised on the balance sheet. An exception applies for short-term and low-value leases under the standard.

The group has adopted AASB 16 from 1 July 2019 using the simplified (cumulative effect) approach and therefore has not restated comparative amounts for the 2019 interim reporting period.

On adoption of AASB 16, lease liabilities were measured at the present value of the remaining lease payments, discounted using either the interest rate implicit in the lease or the incremental borrowing rate as of 1 July 2019. The group's weighted average incremental borrowing rate applied to the lease liabilities on 1 July 2019 was 4.4%.

	1 July 2019 \$'000
Operating lease commitments as at 30 June 2019	2,315
Discounted using group's incremental borrowing rate at date of initial application	2,151
Add: finance lease recognised as at 30 June 2019	26
Less: low-value leases recognised on straight-line basis as expense	(16)
<b>Lease liability recognised as at 1 July 2019</b>	<b>2,160</b>

The associated right-of-use assets for leases were initially measured at the amount equal to the lease liability, and relate to the following types of assets:

	31 Dec 2019 \$'000	1 July 2019 \$'000
Premises	1,830	2,134
Plant and equipment	11	26
<b>Total right-of-use assets</b>	<b>1,841</b>	<b>2,160</b>

The net impact on retained earnings at 1 July 2019 on the adoption of AASB 16 was a decrease of \$4,000.

The adoption of AASB 16 removes the lease rental repayments from the income statement. Instead, the income statement reflects straight-line depreciation expense on the right-of-use asset, and an interest expense on the lease liability. The group expects that reported expenses will increase by approximately \$50,000 for the full 2020 financial year, due to the interest component calculated on the lease liability under the new standard. Also operating cash outflows will decrease, and financing cash outflows will increase by approximately \$585,000 for the 2020 financial year, (\$286,000 for the half-year) as repayment of the principal portion of the lease liabilities will be classified as cash flows from financing activities.

## 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.

Certain research and product development activities are eligible under an Australian Government tax incentive for eligible expenditure. 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 2019, the group has recorded a contra research and development expense of \$2,957,000 (December 2018: \$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>2019</b>	2018
	<b>\$'000</b>	\$'000
<b>Revenue and other income from continuing operations</b>		
Revenue from contracts with customers	<b>5,353</b>	83
Interest revenue	<b>318</b>	566
<b>Total revenue</b>	<b>5,671</b>	649
Other income	-	12
<b>Total revenue and other income from continuing operations</b>	<b>5,671</b>	661

Revenue from contracts with customers includes licensing revenue, royalties and products sales, and research revenue from commercial partners.

Total revenue from contracts with customers for the half-year was \$5,353,000 (December 2018: \$83,000) which includes \$4,125,000 on AstraZeneca triggering a milestone for the first dose of AZD0466 administered in the phase 1 trial of its first DEP® product. The remaining \$1,228,000 for the half-year is predominately product sales and royalties on VivaGel® BV and VivaGel® condom products.

### 5. Expenses

	<b>Half-year</b>	
	<b>2019</b>	2018
	<b>\$'000</b>	\$'000
<b>Loss from continuing operations before income tax expense includes the following items:</b>		
R&D tax incentive (contra expense) <sup>1</sup>	<b>(2,957)</b>	(2,418)
Employee benefits expenses (including share-based payments)	<b>5,222</b>	5,443
Depreciation of property, plant and equipment	<b>137</b>	155
Depreciation of right-of-use assets <sup>2</sup>	<b>319</b>	-
Rental expense on operating leases <sup>2</sup>	-	289

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

<sup>2</sup> The adoption of AASB 16 *Leases* eliminates the lease rental expense from the income statement, rather depreciation is expensed on the right-of-use asset, and an interest expense on the lease liability. Refer to Note 1(b) for further information.

### 6. Current Assets – Trade and other receivables

Trade and other receivables of \$7,694,000 (30 June 2019: \$6,159,000) primarily comprises of \$4,068,000 milestone receivable from AstraZeneca for the first dose of AZD0466 administered in the phase 1 trial of its first DEP® product and \$2,957,000 (30 June 2019: \$4,898,000) of expenditure reimbursable under the Australian Government's R&D tax incentive scheme.

## 7. Contributed equity

### (a) Share capital

	December 2019 Shares	June 2019 Shares	December 2019 \$'000	June 2019 \$'000
Share Capital				
Ordinary shares – fully paid	<b>372,483,768</b>	371,694,347	<b>193,621</b>	193,621

### (b) Ordinary shares

As at 31 December 2019 there were 372,483,768 issued ordinary shares. During the half-year to 31 December 2019, 789,421 ordinary shares were issued upon the exercising of vested 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 32,920 shares was issued to eligible staff on 24 January 2020, subsequent to the reporting date.

### (d) Employee Performance Rights Plan

At 31 December 2019, there are 14,919,644 (30 June 2019: 13,183,915) performance rights on issue, of which 5,890,836 have vested and are exercisable at the balance date and 9,028,808 unvested. There were 2,969,830 performance rights issued during the financial half-year, 789,421 performance rights converted into shares on the exercise of vested performance rights and 444,680 rights lapsing during the period.

## 8. Events occurring after the balance sheet date

There are no significant events occurring since 31 December 2019 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	
	2019	2018
<b>Basic earnings/(loss) per share / Diluted earnings/(loss) per share</b>		
Total earnings/(loss) per share attributable to the ordinary equity holders of the company (cents)	<b>(1.58)</b>	(1.96)
<b>Reconciliations of earnings/(loss) used in calculating earnings per share</b>		
Profit/(loss) attributable to the ordinary equity holders of the company used in calculating basic earnings/(loss) per share (\$'000):	<b>(5,863)</b>	(7,266)
Weighted average number of ordinary shares used as the denominator in calculating basic earnings/(loss) per share	<b>371,919,697</b>	370,920,956

The performance rights on issue at balance date 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 2019 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, 24 February 2020

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## 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) and the entities it controlled during the half-year (together the Group), which comprises the consolidated balance sheet as at 31 December 2019, the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated cash flow statement for the half-year ended on that date, selected other explanatory notes and the directors' declaration.

#### *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 gives a true and fair view and 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 Group's financial position as at 31 December 2019 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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### *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 Group's financial position as at 31 December 2019 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*

PricewaterhouseCoopers

*Brad Peake*

Brad Peake  
Partner

Melbourne  
24 February 2020

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