









#### Important notice and disclaimer

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#### FLEURSTAT BVGEL (VivaGel® BV) for the treatment of BV and relief of symptoms

Ask your pharmacist – they must decide if this product is right for you. Always read the label. Follow the directions for use. Do not use for more than 7 days unless a doctor has told you to. See your doctor if symptoms persist after 7 days or recuration within 2 weeks, and if you consider you may be at risk of an STI. See a doctor if you are diabetic or pregnant/breastfeeding (or plan to be).



1 Overview

2 DEP®

3 SPL7013 & VivaGel® Portfolio

4 Outlook



#### **Key Investment Data**

ASX code	SPL
OTCQX code	SPHRY
Share price	A\$1.605
Shares on issue	372.8M
Market capitalisation	~A\$600M
Daily average volume (shares)	~2.6M
Cash at 30-Jun	\$30.1M
Share register	Institutions ~55% Retail ~40% Staff & other ~5%

## Starpharma's dendrimer platform delivers significant optionality with multiple potential revenue streams, valuable products & clinical-stage assets

Through innovative research and development, Starpharma is creating therapies which have the potential to improve patient health worldwide.

- Unique polymer (dendrimer) platform creating patented high-value healthcare products (>150 patents)
- Deep portfolio of high-value products on-market and clinical stage assets,
   with near term potential commercial and clinical milestones
- Products address clear unmet medical need for large markets
- Established global supply chain and manufacturing
- Proven record of development & commercialisation including successful partnerships with leading global companies





**VivaGel® BV** – Licensed in >160 countries, on-market in the UK, Europe, Asia, Australia & NZ



SPL7013 COVID-19 nasal spray – expedited product development & regulatory pathway



**VivaGel® condom** – Approved in Japan, Europe, Australia & Canada



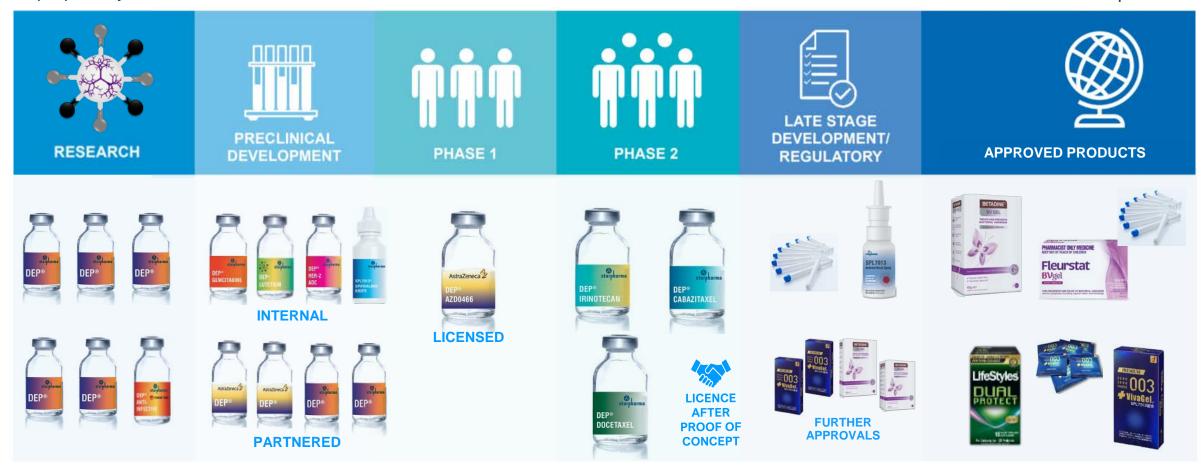
**DEP**<sup>®</sup> – a valuable proprietary nanoparticle drug delivery platform creating significant optionality, accelerates path to market and manages investment risk

### Starpharma's portfolio: High-value assets including VivaGel® products on market, SPL7013 antivirals and multiple DEP® clinical assets

Extensive & growing pipeline of proprietary assets

Multiple clinical stage assets

Multiple approved products





### SPL7013 COVID-19 nasal spray is virucidal, inactivating >99.9% of SARS-CoV-2 (coronavirus)

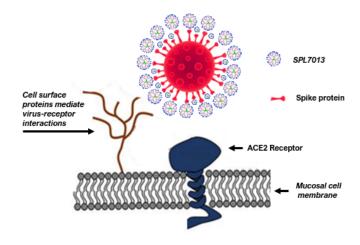
#### SPL7013 has antiviral activity when applied before, or after, exposure of cells to virus



### BROAD SPECTRUM ANTIVIRAL SPRAY

- SPL7013 COVID-19 nasal spray is virucidal inactivating >99.9% SARS-CoV-2
- Has the potential to prevent acquisition and transmission of SARS-CoV-2
- Complement vaccinebased prevention strategies
- Broad spectrum virucidal activity also creates potential in future pandemic preparedness

#### **ANTIVIRAL MECHANISM**



#### **SPL7013: POSITIVE FEATURES**

- SPL7013 has potent antiviral activity against
   SARS-CoV-2 if applied before, or after exposure of cells to virus
- SPL7013's high selectivity index (>2000) compares very favourably with remdesivir (279) and hydroxychloroquine (55)
- Based on previously established antiviral mechanism of action data, SPL7013 is thought to bind to the SARS-CoV-2 "spike" proteins, blocking the ability of the virus to attach to and enter nasal mucosal cells
- Other SPL7013 products inhaled, ophthalmic and injection also possible

Above: indicative packaging for the SPL7013 COVID-19 nasal spray



Testing conducted at The Scripps Research Institute (US) and 360biolabs; Selectivity Index is a measure of relative safety or therapeutic index

#### Starpharma is expediting the development of the SPL7013 COVID-19 nasal spray; expected to be ready for market 1H CY2021

SPL7013 is the active included in marketed VivaGel® products; In addition to coronavirus (SARS-CoV-2), SPL7013 has also demonstrated activity in HIV, HSV, HPV, Adenovirus, HBV, Zika and H1N1 (influenza)

#### EXISTING APPROVALS & SUPPLY CHAIN FOR SPL7013 ALLOW FAST-TRACK DEVELOPMENT & LAUNCH



**SPL7013** is the active included in marketed VivaGel<sup>®</sup> products



- Reformulation completed
- Pilot product manufacture undertaken
- Device & packaging components selected
- Manufacturer identified
- Regulatory documentation compiled in preparation for submission
- \$1M MRFF grant





SPL7013 active is already scaled up for commercial supply, and the availability of existing stocks of SPL7013 will further expedite development and commercialisation of the nasal spray product



Regulators have confirmed that minimal re-development is required, leading to an expedited program & regulatory documentation compiled in preparation for submission











**BROAD RANGE** OF POTENTIAL **USERS** 

- Front-line healthcare workers:
- Staff in other high-risk environments e.g. airlines, aged care, mining, abattoirs
- Broader population, including airlines, public transport, restaurants, bars



#### DEP® remdesivir: slow release (long-acting) & soluble version of Gilead's remdesivir

Gilead's antiviral drug, remdesivir, is being utilised for the treatment of COVID-19 under emergency use authorisation from the US Food and Drug Administration for patients with severe disease

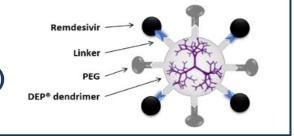


Remdesivir contains an excipient, cyclodextrin called SBECD

DEP® remdesivir: >100-fold higher solubility than remdesivir, no cyclodextrin

- Current remdesivir formulations are required to be administered IV, with each infusion taking up to 2 hours and requiring daily administration for 5 -10 days
- Remdesivir contains an excipient, cyclodextrin and is not recommended in patients with renal impairment<sup>1</sup>
- DEP® remdesivir expands the potential application of remdesivir, by creating a long-acting version which doesn't require IV infusion;
- DEP® remdesivir could be administered ~2-3mls subcutaneously cf. large volume IV infusion (in hospital)

DEP® remdesivir is a water-soluble nanoparticle incorporating remdesivir and PEG, providing a controlled release of remdesivir (longer half-life)





#### **Key highlights**

▶ AstraZeneca's first DEP<sup>®</sup> product, AZD0466, commenced phase 1, triggering US\$3M milestone

AstraZeneca

\$1M MRFF GRANT





**▶ DEP**<sup>®</sup> cabazitaxel trial advanced into phase 2 on positive results



► ► DEP® docetaxel + gemcitabine combination study commenced



▶► SPL7013 shown to be active against SARS-CoV-2 (coronavirus); and significant progress with product development





► ► VivaGel® BV approved in multiple countries in Asia, and multiple further regulatory submissions progressed



► ► Fleurstat **BVgel ranked** as #1 topical **BV** treatment in Australia

Okamoto added 11 more Asian countries to its VivaGel® condom licence & EU approval granted



▶ DEP® radiotherapeutic candidate, DEP® lutetium, showed significant anti-cancer activity and 100% survival in a human prostate cancer model

► ► DEP® irinotecan + immuno-oncology agent resulted in superior anti-tumour activity and significant survival benefit in two human colorectal cancer models



▶ ▶ DEP® irinotecan, alone and in combination with Lynparza<sup>®</sup>, showed significant anti-tumour efficacy and synergy in an irinotecan-refractory human colon cancer model

► New DEP® candidate. DEP® HER-2 ADC. **Demonstrated** significant tumour regression and 100% survival in a preclinical human ovarian cancer model



cancer model





#### **Financial summary**

Key Financial Data	FY20 A\$M	FY19 A\$M
Revenue and other income	7.1	2.7
Loss for the period	(14.7)	(14.3)
Net operating cash outflows	(10.8)	(10.3)
Net cash burn <sup>1</sup>	(11.2)	(10.1)
Cash as at 30 June	\$30.1M	\$41.3M

#### **FY20 Result:**

- Total revenue and other income of \$7.1M (pcp: \$2.7M), includes:
  - US\$3M AstraZeneca milestone payment
  - VivaGel® product sales and royalties of \$1.5M
- Reported loss for year of \$14.7M (pcp: \$14.3M), marginally higher by 3%
- Increased research and product development expenses on expanded clinical product portfolio of three phase 2 clinical programs
- Net cash burn<sup>1</sup> of \$11.2M for the year

pcp = prior corresponding period





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.



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#### Starpharma's DEP® platform strategy creates significant optionality and upside

DEP® platform strategy provides technical, IP and financial leverage, as well as increasing commercial opportunities, improving ROI and de-risking development

#### **INTERNAL DEP®**

- Application to established drugs reduces risk and expedites development
- Multiple therapeutic areas – e.g. oncology and antivirals
- Patent life extension
- Self-funded
- Potential returns through licensing, milestones and royalties



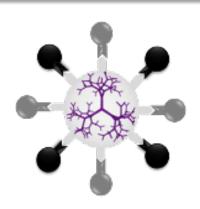
#### PARTNERED DEP®

- Application to partners' drugs, both novel (e.g. AZD0466) and existing drugs
- Patent life extension
- Largely partner-funded
- Returns through licensing, milestones and royalties

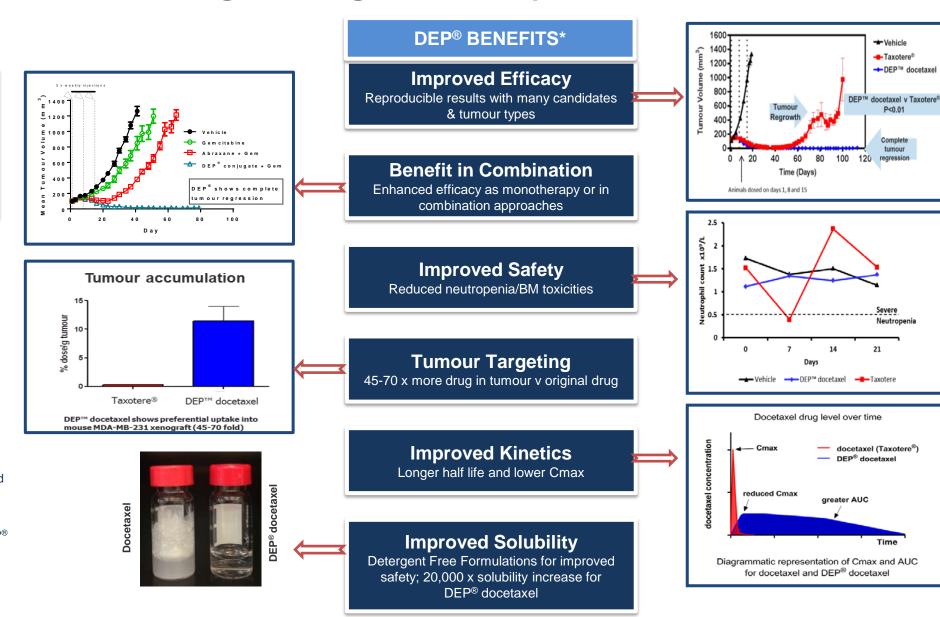


### Starpharma's DEP® platform conveys product benefits and enhances the commercial value of a wide range of drugs and therapeutic areas

DEP® platform: numerous reproducible benefits across multiple drugs



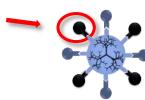
- \*Clinical studies have demonstrated reduction in important side effects with DEP® including bone marrow toxicity, anaphylaxis, oedema and hair-loss
- \*Multiple preclinical studies have established improved efficacy, survival and safety with DEP® with many different drugs



#### DEP® platform creates significant leverage through partnering

DEP® can be used by commercial partners to improve novel drugs or existing products for life-cycle management

Starpharma attaches the partner's drug to the dendrimer creating a nanoparticle with key benefits





DEP® nanoparticles can be used to enhance the features of novel drugs that may otherwise limit clinical use due to issues such as toxicity or insolubility



DEP® has utility as a lifecycle management tool to make existing drugs better and create new IP (patents)



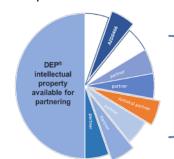
Partner funds development of their DEP® product(s)



Starpharma is eligible to receive milestone payments & royalties on DEP® products



Licences are structured to allow for multiple DEP® programs to run in parallel



DEP® platform optionality allows for multiple partnerships.

Starpharma has DEP® programs with large pharma companies incl. AstraZeneca, Chase Sun, and several undisclosed partnerships





DEP® case study: AstraZeneca's DEP® programs include clinical stage oncology agent AZD0466 Bcl2/xl inhibitor

#### **Multiproduct licence**

- US\$7M in milestones received thus far
- Total milestones of up to US\$124M + royalties for AZD0466
- AZ funds development of AZ DEP® products including AZD0466

#### 1<sup>st</sup> AZ DEP<sup>®</sup> candidate (AZD0466)

- Up to US\$124M milestones + escalating royalties
- Est. up to A\$2.4B revenue to SPL

#### 2<sup>nd</sup> AZ DEP<sup>®</sup> candidate (& subsequent candidates)

 Up to US\$93.3M in milestones plus escalating royalties on net sales



AZD0466 multi-centre phase 1 trial recruiting patients in the US with solid & haematological tumours (including MD Anderson Cancer Center)

AZD0466 a highly optimized DEP® nanoparticle formulation of AZ's novel Bcl2/xl inhibitor; Bcl2 is a validated oncology target - Venclexta<sup>TM</sup> - AbbVie) - est. sales projected to be US\$2-3B pa.

AstraZeneca describes AZD0466 as having the potential to be a "best-in-class" agent with a broad application in both solid and haematological tumours

#### **Development & Option Agreement**



additional AstraZeneca program separate to above multiproduct licence

- 3<sup>rd</sup> AstraZeneca DEP<sup>®</sup> candidate (major existing AZ oncology medicine)
- US\$5M on option exercise, industry standard milestones, plus escalating royalties



#### DEP® Internal: Multiple clinical-stage assets with high commercial value potential

COMMERCIAL OBJECTIVE



Create value through clinical proof-ofconcept in one or more cancer types – alone and/or in combination



License following proof-of-concept clinical data; platform validation



Utilise accelerated development / regulatory pathways (i.e. 505b2) for optimal ROI



DEP® DOCETAXEL: Enhanced version of docetaxel (Taxotere®) – widely used for breast, lung & prostate cancer

PHASE 2

Docetaxel (Taxotere®) is a blockbuster cancer drug with peak global sales
>US\$3B despite having multiple US FDA
"Black Box" warnings

Advantages of DEP® docetaxel#\*:

Reduction in neutropenia; detergent-free formulation; tumour-targeting (~70x more); improved efficacy; improved pharmacokinetics; patent filings to 2032 (plus up to an additional ~5 years).



DEP® CABAZITAXEL: Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana®)

PHASE 2

Cabazitaxel (Jevtana®) – global sales of ~US\$500M for 2019 despite having multiple US FDA "Black Box" warnings

Advantages of DEP® cabazitaxel\*:

Improved toxicity profile; detergent-free formulation; no steroid pretreatment; tumour-targeting, improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).



DEP® IRINOTECAN: Improved version of irinotecan (Camptosar®) predominantly used for colorectal cancer

PHASE 2

Camptosar® had peak global sales of US\$1.1B despite having multiple US FDA "Black Box" warnings.

#### Advantages of DEP® irinotecan\*:

Irinotecan is a pro-drug that is converted to the more active metabolite, SN38; This conversion leads to variability between patients and toxicity. DEP® solubilises SN38 and allows direct dosing avoiding the need for liver conversion; improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).



DEP® GEMCITABINE: Preclinical & phase 1 planned: Enhanced version of gemcitabine (Gemzar®). Lilly's Gemzar® is a wellestablished anti-cancer drug for pancreatic cancer, which had peak sales of US\$1.7B.





Starpharma's preclinical pipeline includes DEP® radiotherapeutic candidates & antibody drug conjugate (ADC) candidates & further therapeutic candidates



<sup>\*</sup> Multiple preclinical studies have established improved efficacy, survival and safety with DEP® with many different drugs

#### DEP® docetaxel phase 2 program – ongoing recruitment and positive interim results

#### **MONOTHERAPY ARM**



35 patients treated



Encouraging efficacy signals observed including prolonged stable disease (up to 40 weeks) & tumour shrinkage



Efficacy signals in variety of tumour types including prostate cancer, lung cancer and several hard-to-treat tumours including oesophageal, cholangiocarcinoma (2<sup>nd</sup> most common liver cancer), gastric and pancreatic



Efficacy signals observed in heavily pre-treated patients (treated with up to 40 cycles and 9 different anti-cancer regimens previously)



Based on efficacy signals observed & investigator interest, recruitment ongoing including patients with selected hard-to-treat tumour types



Notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects inc. hair-loss, mouth ulcers, anaphylaxis and oedema.



#### **DEP® DOCETAXEL**

Open-label, two-stage design to allow for exploration of efficacy of DEP® docetaxel as a monotherapy.

In parallel, combination of DEP® docetaxel & nintedanib (Vargatef®) in lung cancer.

Combination of DEP® docetaxel & gemcitabine in pancreatic cancer.



The Newcastle upon Tyne Hospitals NHS Foundation Trust









#### **COMBINATION ARM (+ VARGATEF)**



#### 13 patients treated



Encouraging efficacy signals observed - prolonged stable disease & tumour shrinkage in non-small cell lung cancer; heavily pre-treated patients



Based on positive interim results in the DEP® docetaxel + nintedanib combination arm, recruitment was expanded



Notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects including mouth ulcers, anaphylaxis and oedema





Based on compelling DEP® preclinical data & investigator interest, combination DEP® docetaxel with gemcitabine trial targeting pancreatic cancer commenced



Combinations with immunotherapy also being explored to create value

The phase 2 DEP® docetaxel trial continues to progress well, with further observations of encouraging efficacy signals, including prolonged stable disease and tumour shrinkage in patients with cancers including pancreatic and gastric cancer.



#### Case study: DEP® docetaxel in advanced oesophageal cancer



Stage IV metastatic oesophageal patient:

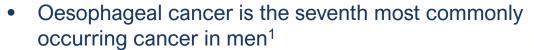


#### 66 year old man with stage IV oesophageal cancer with liver metastases:

 Had progressive disease after two different treatment regimens (approx. 9 cycles total) as well as radiotherapy

#### Response DEP® docetaxel:

- Reduction in size of tumour lesions of up to 48%
- Partial response maintained for >16 weeks





• Est. 5-year mortality for stage IV disease > 85% to 90%

<sup>1</sup> http://www.wcrf.org/dietandcancer/cancer-trends/oesophageal-cancer-statisticss

#### **DEP®** docetaxel



16 WEEKS POST Rx

48% reduction in size of tumour lesion



#### Case study: DEP® docetaxel in advanced lung cancer



Stage IV metastatic lung cancer (NSCLC) patient:



#### 46 year old man with stage IV lung cancer (NSCLC):

- Genetic profile limited treatment options (he didn't qualify for 1<sup>st</sup> line immunotherapy)
- Cancer had progressed after 7 cycles platinum-based chemo + immunotherapy & an investigational enzyme inhibitor
- Received x2 cycles of DEP® docetaxel + nintedanib

#### **Response DEP® docetaxel:**

- Reduction in size of tumour lesions of up to 45%
- Stable disease > 9 weeks
- Improvement in tumour-related pain



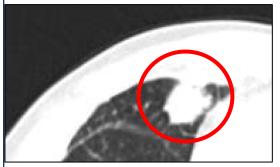
- Non-Small Cell Lung Cancer (NSCLC) accounting for 84% of all lung cancers
- Stage IV lung cancer patients have a 5 year survival rate of 4.7%<sup>1</sup>

#### **DEP®** docetaxel + nintedanib

CT scans of lung: right middle lobe

#### **BASELINE**

9 WEEKS POST Rx





41% reduction in size of tumour lesion



#### DEP® cabazitaxel – positive phase 1 results & phase 2 underway

#### **PHASE 1 RESULTS**

#### Positive phase 1 results (dose-escalation)

- 14 patients enrolled and received DEP<sup>®</sup> cabazitaxel at doses between 2 mg/m<sup>2</sup> to 25 mg/m<sup>2</sup>
- Up to 15 cycles of DEP® cabazitaxel; no steroid, antihistamine or anti-emetic pre-treatment
- Encouraging signs of efficacy were observed in 67% of patients evaluable for treatment response, including:
  - prolonged stable disease in multiple patients and in a variety of cancer types, including prostate, gastro-oesophageal, breast, ovarian, cholangiocarcinoma and pancreatic (& at doses several-fold lower than usually used for cabazitaxel).
    - One prostate cancer patient experienced >47 weeks stable disease & a reduction in PSA of 79%
    - One stage IV ovarian cancer patient achieved a reduction in tumour biomarker (CA-125) of 56%
    - One stage III cholangiocarcinoma cancer patient achieved a 82% decrease in a tumour biomarker after two cycles
- Significantly less toxicity than is usually associated with Jevtana®, including less bone marrow toxicity (neutropenia, anaemia, thrombocytopenia), anorexia and vomiting. No cases of hypersensitivity; no cases of hair-loss; no need for anti-nausea medications



Open-label trial, with the objective of establishing antitumour activity (efficacy) & safety at the RP2D of 20 mg/m2





University College London Hospitals
NHS Foundation Trust



Imperial College Healthcare
NHS Trust

#### PHASE 2



First stage will enrol ~20 patients with a variety of cancers, including prostate cancer; final numbers may be adjusted based on results in certain patient cohorts



Patient recruitment progressing well with 14 patients treated with up to 6 cycles of treatment



The phase 2 DEP® cabazitaxel trial continues to progress with encouraging efficacy signals, including stable disease, significant target tumour shrinkage and substantial tumour marker reductions (e.g. PSA), in cancers including prostate, ovarian, lung, gastroesophageal and others



Study will further explore efficacy in selected tumour types



Five sites: Guy's & St Thomas', University College London, Velindre Cancer Centre, Imperial College London and Kinghorn Cancer Centre.



#### Clinical case study: DEP® cabazitaxel in advanced prostate cancer

#### Prostate cancer is the second most commonly occurring cancer in men



#### **Stage III Prostate Cancer Patient:**

- Stable Disease >47 weeks
- 79% decrease in PSA levels



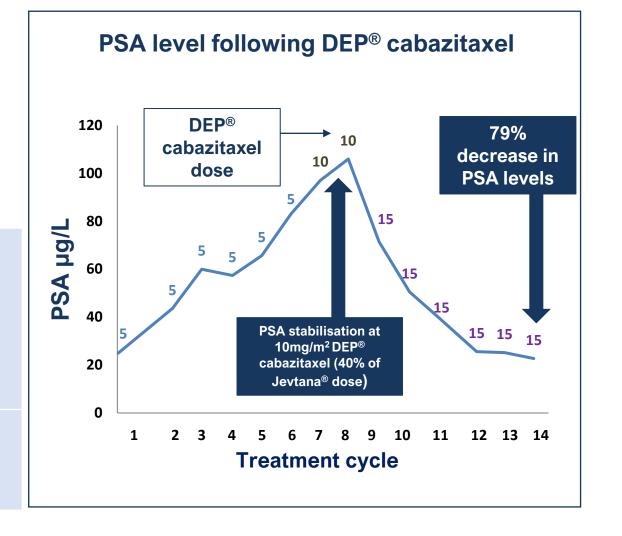
#### 70 year old man with stage III prostate cancer:

- Heavily pre-treated; cancer progressed on 4 other anti-cancer therapies
- Was unable to tolerate docetaxel due to toxicity (neutropenia)
- Received 15 cycles of DEP® cabazitaxel with no neutropenia
- Response to DEP® cabazitaxel began at 40% of the typical dose

#### Response to DEP® cabazitaxel:

- Prolonged stable disease >47 weeks
- PSA stabilised following a 79% decrease







#### Clinical case study: DEP® cabazitaxel in ovarian cancer



Advanced ovarian cancer patient with extensive metastases



#### 60 year old woman with advanced (metastatic) ovarian cancer:

- Heavily pre-treated; cancer progressed on 3 other anti-cancer therapies including paclitaxel (another taxane)
- Previously had 14 cycles of treatment and multiple surgeries
- Received 6 cycles of DEP® cabazitaxel

#### Response to DEP® cabazitaxel:

- Response seen after 3 cycles of treatment
  - 26% reduction in total tumour burden
- Further reduction in tumour size seen following end of treatment
  - 40% reduction in total tumour burden, 50% reduction in biomarkers



Ovarian cancer has the lowest survival rate of women's cancer\* and is the eighth most commonly occurring cancer in women

\* https://ovariancancer.net.au/wp-content/uploads/2019/01/Ovarian-Cancer-Facts-\_2019\_-FINAL.pdf

#### **DEP® CABAZITAXEL**

CT scans of ABDOMINAL TUMOUR



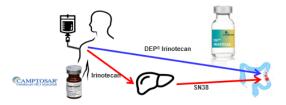


43% reduction in size of tumour



#### DEP® irinotecan - positive phase 1 results & phase 2 now underway

DEP® irinotecan incorporates the irinotecan active moiety (SN38) and is an improved version of Camptosar®



#### DEP®:

- provides the ability to solubilise the active metabolite, SN38
- removes the need for liver metabolism

DEP® irinotecan showed improved efficacy and survival benefit established in preclinical models

#### POSITIVE PHASE 1 RESULTS (DOSE-ESCALATION)

- 7 patients were enrolled and received DEP® irinotecan at a range of doses up to 12.5 mg/m² and up to 10 cycles of treatment each
- Encouraging efficacy signals observed in 50% of evaluable patients to date, and in all three tumour types enrolled, despite the fact conventional irinotecan is not approved for breast or pancreatic cancers & that enrolled patients were heavily pretreated. Efficacy signals observed included:
  - prolonged stable disease and substantial tumour shrinkage in a range of tumour types including CRC, pancreatic and breast cancer.
- Patients generally experienced less severe side effects than typically associated with Camptosar<sup>®</sup>, with no cases of the severe high-grade diarrhoea which is experienced by 20-40% of patients with conventional irinotecan and often requires hospitalisation.
- Conventional irinotecan (Camptosar®) has two FDA black box warnings (severe diarrhoea and neutropenia) and is associated with a high frequency of adverse events (AEs), including nausea, vomiting, alopecia and neutropenia.
  - AEs observed with DEP® irinotecan treatment were consistent with those seen in Camptosar® and generally less severe and mostly mild (grade 1).
  - AEs observed with DEP® irinotecan included nausea, vomiting, alopecia and neutropenia.



#### PHASE 2 UNDERWAY









Dose expansion: open-label trial, with the objective of establishing anti-tumour activity (efficacy) and safety at the RP2D



 ~ 20-30 patients with colorectal cancer and other cancers (likely to expand due to strong investigator interest)



• 22 patients already enrolled



 Combinations with immunotherapy being explored with partners to create value



#### Clinical case study: DEP® irinotecan in advanced breast cancer



Stage IV breast cancer patient with extensive liver metastases



#### 45-year old woman with stage IV breast cancer:

- Extensive metastases including in the liver
- Very heavily pre-treated >100 cycles of 11 different treatment regimens
- Received 17 cycles of DEP® irinotecan to date

#### **Response to DEP® irinotecan:**

- Response seen after 3 cycles of treatment
- Prolonged stable disease >45 weeks
- Overall up to 18% reduction in target tumours
- Well tolerated

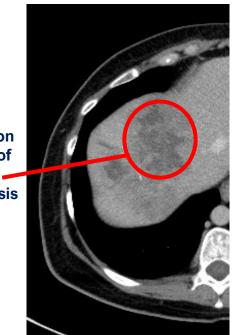


Breast cancer is the most common cancer affecting women and is the second leading cause of cancer-related death in Australian women, accounting for 14.9% of all female cancer deaths

Scan showing a 30% reduction in liver metastases size (18 weeks post treatment)

# BASELINE 30% reduct in size

30% reduction in size of liver — metastasis



**18 WEEKS POST TREATMENT** 



### DEP® irinotecan in combination with immuno-oncology agent (anti PD-1 antibody) boosts efficacy and survival in multiple colon cancer models



DEP® irinotecan + anti PD-1 Ab in combination showed significant enhancement of anti PD-1 antibody activity by DEP® irinotecan in both CT-26 and MC-38 colon cancer models

Figure 1: Mean Tumour Volume Over Time MC-38

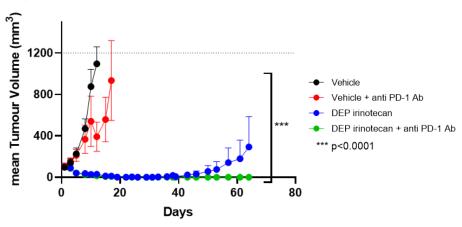
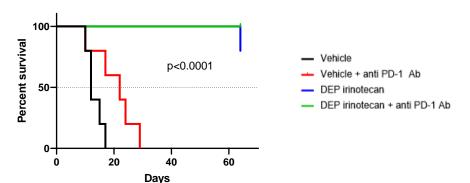


Figure 2: Kaplan-Meier survival curve MC-38



These results indicate that DEP® irinotecan in combination with an anti PD-1 antibody could boost the efficacy over anti PD-1 antibody alone, or immuno-oncology (IO) combinations with standard chemotherapeutic agents.

 DEP® irinotecan in combination with an IO therapy (anti PD-1 antibody) resulted in superior anti-tumour activity and significant survival benefit compared to the IO therapy alone in two colorectal cancer (CRC) models



IO agents are now important treatments in several major cancers and the market for these agents is expected to exceed US\$55 billion by 2025, and include Merck's Keytruda®, BMS' Yervoy® and AstraZeneca's Imfinzi®



These results provide important information which will assist with the identification of value-adding clinical combinations and partnering opportunities



Anti PD-1 antibodies have been a major breakthrough in cancer treatment, but substantial unmet need remains, and non-responders make up more than 75% of all incident cancers, highlighting the need for more effective agents and combinations (August 2019 IO presentation by Peter F Lebowitz (M.D. PhD), Global Therapeutic Area Head, Oncology, Janssen Oncology, with data sourced from Cancer Incidence from Globocan 2018)

#### DEP® ADCs further build the value of the DEP® platform

Interest in clinical and late stage ADC therapeutics heating up

Starpharma's DEP® technology provides enhanced therapeutic **benefits** to ADCs including:

- greater homogeneity
- site specific attachment
- Higher drug antibody ratio (DAR)

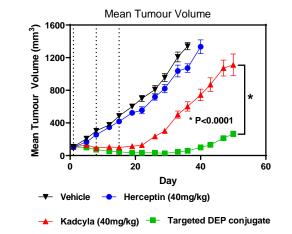
than conventional ADC approaches.

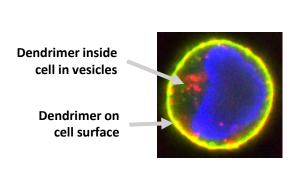
#### Novel DEP® HER-2 ADC conjugate:

- resulted in tumour regression and 100% survival, and
- significantly outperformed both Kadcyla® (T-DM1), a HER-2 targeted antibody-drug conjugate (ADC), and Herceptin® (Trastuzumab) itself.

in a human ovarian cancer model.

This experiment was conducted in a human ovarian cancer (SKOV-3) xenograft model in NOD SCID mice by an internationally recognised translational Cancer group. Groups of animals (6/group) were dosed once per week for 3 weeks with the novel HER-2 Targeted DEP® conjugate, Kadcyla®, or a saline control. Another group of animals was treated with Herceptin® twice a week for 3 weeks. The tumour volume data represent the mean  $\pm$  standard error of the mean (SEM) and significance values determined using a Two-Way ANOVA (Tukey's post hoc). Survival analysis was carried out using Kaplan-Meier survival curves and the Log-rank test. (Note: If error bars do not display on the graphs, they are shorter than the height of the symbol and not visible.





binds to tumour cells and

then is internalised where drug release can be triggered

**Targeted DEP conjugate** 



2019 sales of Roche's Kadcyla® US\$1.62B and Adcetris >US\$1B











Strong corporate activity in ADCs is as illustrated by the recent licensing deal between AstraZeneca & Daiichi Sankyo, with an announced value of up to US\$6.9 billion for rights to a HER-2 targeted ADC.

July 2020



Gilead acquired Immunomedics in a transaction valued at approximately **US\$21 billion** – a deal that includes the Trodelvy that was granted accelerated approval by the U.S. FDA

Sep 2020





Seattle Genetics and Merck signed an agreement for a phase 2 ADC - Seattle Genetics will receive \$600 million upfront payment, eligible for up to \$2.6 billion in milestone payments. Merck will also make a **\$1.0 billion** equity investment.

Sep 2020



### First DEP® radiotherapeutics candidate, DEP® lutetium, shows impressive efficacy in human prostate cancer model

in the DU-145 human prostate

cancer model.

- Starpharma has developed multiple novel radiotherapeutic and radiodiagnostic candidates
- DEP® radiopharmaceutical conjugates have the potential to minimise off target toxicity and enhance efficacy when used alone or in combination with other therapeutic approaches
- DEP® radiotherapeutics incorporate radioisotopes on to the DEP® scaffold and patent applications have been filed for DEP® radiotherapeutic candidates

#### Rapidly growing radiopharmaceuticals market



The radiopharmaceuticals area is a rapidly developing area of cancer treatment and diagnosis, and this area has recently generated several high-value deals and sales in this category are estimated to grow to \$12–15 billion by 2030<sup>1</sup>







Recent deals including Sirtex acquisition ~A\$1.9B by CDH Genetech





#### **DEP®** lutetium Starpharma's first DEP® radiotherapy Lutetium-177 candidate showed highly statistically significant anticancer activity, tumour regression and 100% survival<sup>1</sup> in a DEP® dendrimer human prostate cancer model (DU-145) % Change Tumour Volume Change in Volun Figure 1: DEP lutetium 2 x 9MBq \*\*\* p<0.0001 Percentage change in tumour volume over time as measured in the DU-145 human prostate cancer model. **Days Post Injection** 100% Survival - Kaplan-Meier curve Figure 2: DEP lutetium 2 x 9MBq Kaplan-Meier survival curve 1000.00a \*\*\*

15

45

**Days Post Injection** 

OF QUEENSLAND



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### VivaGel® BV - a breakthrough product for the management of BV - the most common vaginal infection worldwide



50-60% experience recurrent

BV

Large market opportunity

BV Treatment: US\$750M (est) Prevention of recurrent BV: US\$1B (est)

#### Management of BV is an area of significant unmet need:

- Very Current therapies are inadequate and do not prevent BV recurring:
- Current BV treatment is typically with antibiotics (e.g. metronidazole)
- × Antibiotic resistance is a problem and antibiotics have unpleasant side effects and other issues that limit usage
- No US approved therapies for prevention of recurrent BV



#### "This product represents a true innovation in the management of BV".

Raman Singh, CEO, Mundipharma













#### VivaGel® BV licensed in >160 countries around the world



Global market for BV treatment est. to be US\$750M and prevention est. to be US\$1B annually



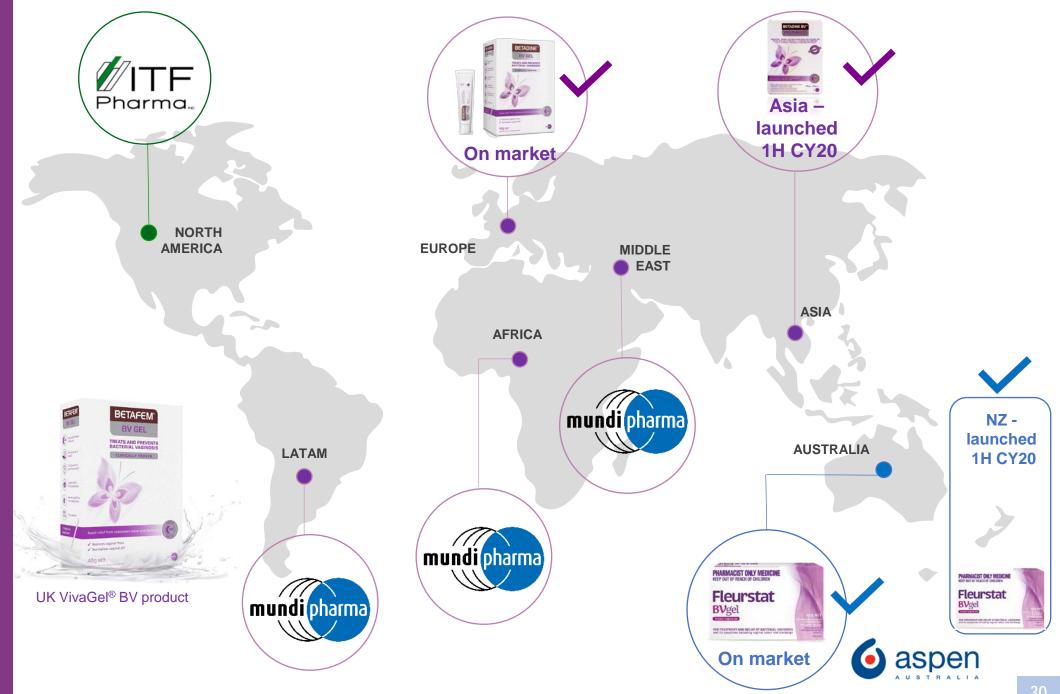
Launched in the UK, Europe, Asia, Australia & NZ



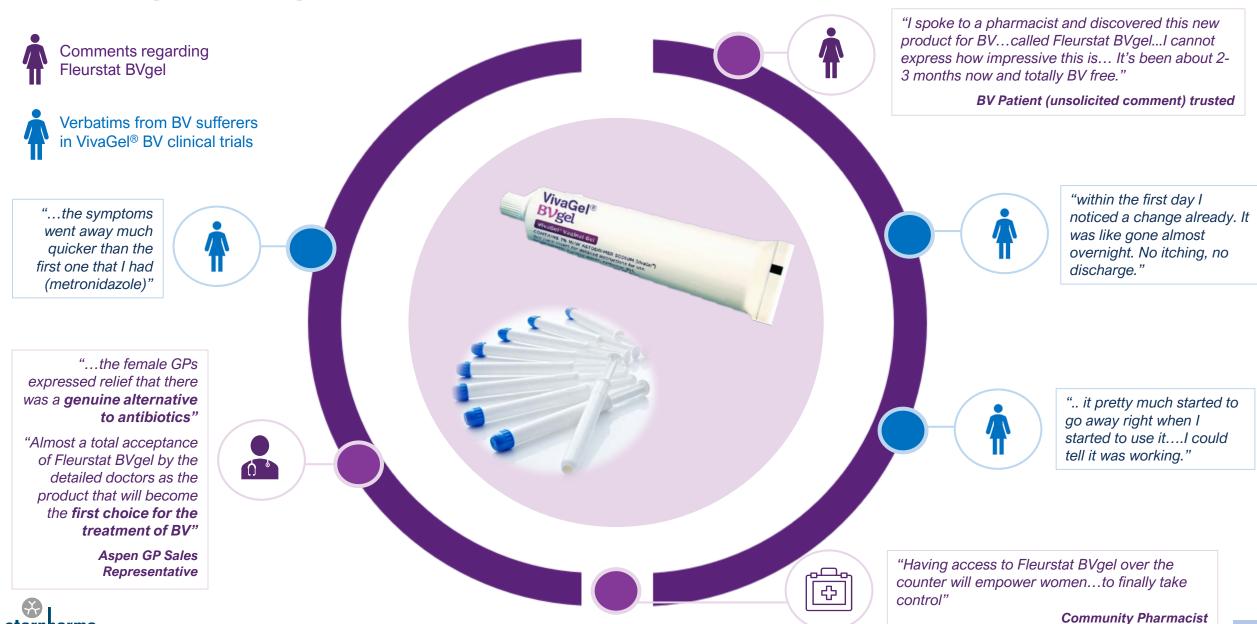
**Further launches** and regulatory submissions progressing in multiple regions



3 further territories to license (Canada, India, Israel)



#### Positive patient experiences about VivaGel® BV benefits







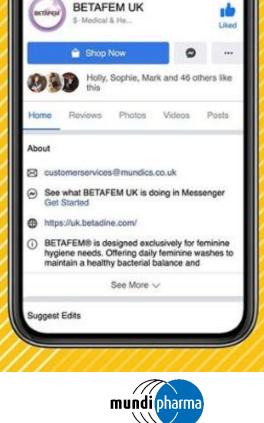


Fleurstat BVgel ranks as #1 topical **BV** treatment in Australia





Your Location				
Search radius	50 km	٧	FIND STORE	



Its Time To Talk About The #sixletterword



FLEURSTAT BYGEL (VivaGel® BV) for the treatment of BV and relief of symptoms: Ask your pharmacist – they must decide if this product is right for you. Always read the label. Follow the directions for use. Do not use for more than 7 days unless a doctor has told you to. See your doctor if symptoms persist after 7 days or recur within 2 weeks, and if you consider you may be at risk of an STI. See a doctor if you are diabetic or pregnant/breastfeeding (or plan to be).





Marketing campaigns for VivaGel® BV in multiple regions

### VivaGel® BV regulatory: approved in 40 countries with further submissions underway

Licensed region	Approved	Submitted / submissions underway
UK	✓	
Europe	✓	
Asian countries	✓	✓
Australia & New Zealand	✓	
African & Middle Eastern countries	✓	✓
Latin American countries		✓
US		✓







#### **Progress with US regulatory strategy**

- Regulatory options thoroughly explored; ongoing input from a team of expert FDA consultants (regulatory, statistical, clinical, legal - including senior ex-FDA staffers)
- Formal FDA review is ongoing. COVID-19 impact on timing. Due to the significant disruption to the US healthcare system associated with COVID-19, activities relating to a potential BV treatment trial in the US are on hold
- FDA consistently acknowledges potential benefits (e.g. mechanistic and safety) of VivaGel® BV vs. antibiotics
- VivaGel® BV's Fast Track status & QIDP (qualified infectious disease status) remain on foot based on potential for VivaGel® BV to address a serious infection and significant unmet need in BV



### VivaGel® antiviral condom launched in Japan and recently approved in Europe





Japan's leading marketer of condoms & holds strong market positions in several other Asian markets  VivaGel<sup>®</sup> antiviral condom (HIV, Herpes, HPV) is being marketed under Okamoto's leading and highly successful Zero Zero Three (003) brand



 Starpharma receives royalties based on sales of the VivaGel<sup>®</sup> condom and also revenue on supply of SPL7013 active







Okamoto & Japanese
Ministry of Health, Labour &
Welfare have developed a
joint STI prevention
campaign using VivaGel®
condoms



Okamoto have manufactured VivaGel® condom samples for Japan Foundation for AIDS Prevention (JFAP) – to increase awareness for health centres nationwide and the LGBT community





Starpharma was recently granted marketing approval for the VivaGel® antiviral condom in Europe.

Starpharma's marketing partner in Europe, LifeStyles, is undertaking marketing preparations ahead of the launch of the VivaGel<sup>®</sup> condom under the brand name Absolute<sup>™</sup> DUAL PROTECTION. LifeStyles also has the marketing rights to the VivaGel<sup>®</sup> condom in other markets, including Australia and Canada.





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#### Outlook





**SPL7013 for Coronavirus** • Expedite development and launch of SPL7013 nasal spray

LEVERAGE EXISTING APPROVALS

#### **VIVAGEL®**









- Commercial roll-out of VivaGel® BV in Europe, Asia & other markets
- Further regulatory approvals and launches for VivaGel® BV; building revenues milestones and sales/royalties
- Ongoing formal FDA review process
- Further VivaGel® BV licences for India, Canada & Israel
- VivaGel® condom approvals/launch in additional regions, such as China/Europe
- Further development / co-development of SPL7013 antiviral ophthalmic drops

#### **COMMERCIAL OUTCOMES**



**Products on market** milestones, product sales, royalties, revenue share

#### **DEP**®



- Progress and completion of DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan trials; valueadding combination studies;
- AZD0466 clinical progress, and receipts from milestones
- AstraZeneca: Exercise of Option Agreement and/or deals for further compounds
- Partnered DEP® deals & program developments, including DEP® ADCs
- Advance DEP® radiopharmaceuticals, DEP® ADCs and DEP® antivirals e.g. DEP® remdesivir
- Advance value-adding DEP® combinations in clinic and other DEP® products



**Leveraging the DEP®** platform to build value



**Advancing** internal DEP® assets builds value for future licensing



**Partnered** DEP® upfront fees, milestones. royalties







#### FOR INVESTOR RELATIONS **ENQUIRIES CONTACT:**

Dr Jackie Fairley, CEO Nigel Baade, CFO & Company Secretary +61 3 8532 2704



4-6 Southampton Crescent Abbotsford Vic 3067

#### **WWW.STARPHARMA.COM**

ASX:SPL OTC:SPHRY

#### Disclosure:

This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.









### **Appendix: Key Risks**

#### **Key risks**

This section discusses some of the key risks which may affect the value of Starpharma shares. These risks ought not to be taken as exhaustive of the risks faced by Starpharma or by investors in Starpharma. The group operates in the biotechnology and pharmaceutical sectors and is in the development and early commercialisation phase. Any investment in these sectors is considered high risk. The group is subject to normal business risks, including but not limited to interest rate movements, labour conditions, government policies, securities market conditions, exchange rate fluctuations, inflation and a range of other factors outside the control of the Board and management. More specific key risks include, but are not limited to:

Investment in shares: There are general risks associated with investments in equity securities such as Starpharma shares. The trading price and liquidity of Starpharma shares may fluctuate with movements in equity capital markets in Australia and overseas which can be impacted by many factors. This may result in the market price for the New Shares being less or more than the Offer Price. None of Starpharma, its directors nor any other person guarantees the performance of the New Shares. Equity markets have in the past been, and may in the future be, subject to significant volatility.

Dilution risk: Existing shareholders who do not participate in the equity raising will have their percentage shareholding in Starpharma diluted. Depending on the size of a shareholder's existing holding, a participating shareholder may still be diluted even though they participate in the Placement or SPP depending on the number of shares allocated to them.

Equity raising: The Placement and SPP are not underwritten. There is therefore a risk that less than the amount sought could be raised.

Scientific, technical and clinical: Product development requires a high level of scientific rigour, the outcomes of which cannot be known beforehand. Activities are experimental in nature, so the risk of failure or delay is material. Key development activities, including clinical trials, are undertaken by specialist contract research organisations and there are risks in managing the quality and timelines of these activities.

Regulatory and Legal regimes: Products and their testing may not be approved, or may be delayed or withdrawn, by regulatory bodies (e.g. US Food and Drug Administration) whose approvals are necessary for products to be sold in market. In addition, changes in laws, regulations, and government policy, or more vigorous enforcement thereof or other unanticipated events could require extensive changes to Starpharma's operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, results of operations and financial condition of the Company.

Financial: The group currently, and since inception, does not receive sufficient recurrent income to cover operating expenses. There is no certainty that additional capital funding may not be required in the future, and no assurance can be given that such funding will be available, if required. Credit risk may arise for the non-performance of partners or customers of their contractual financial obligations to Starpharma.

Intellectual Property (IP): Commercial success requires the ability to develop, obtain and maintain commercially valuable patents, trade secrets and confidential information. Gaining and maintaining IP across multiple countries and preventing the infringement of the group's exclusive rights involves management of complex legal, scientific and factual issues. The company must also operate without infringing upon the IP of others.

Commercialisation: Starpharma relies upon corporate partners to market, and in some cases finalise development and registration of its products, on its behalf. There are risks in establishing and maintaining these relationships, and with the manner in which partners execute on these licensing and collaborative agreements.

*Product Supply*: Starpharma is required to manufacture and supply product under certain licencing agreements. The manufacture of product is undertaken by specialist, regulatory approved, third party contract manufacturing organisations experienced in the sector. However, there are quality and supply delay/failure risks associated with the supply of product.



#### **Key risks (Continued)**

Product acceptance and competitiveness: A developed product may not be considered by key opinion leaders (e.g. doctors), reimbursement authorities (e.g. Pharmaceutical Benefits Scheme listing) or the end customer to be an effective alternative to products already on market, or other products may be preferred. This may reduce product sales, volume, pricing and/or reimbursement of any product.

Product liability: A claim or product recall may significantly impact the company. Insurance, at an acceptable cost, may not be available or be adequate to cover liability claims or any product recall costs (if any) if a product is found to be unsafe.

Key personnel: Starpharma's success and achievements against timelines depend on key members of its highly qualified, specialised and experienced management and scientific teams. The ability to retain and attract such personnel is important.

Taxation & grants: Future changes in taxation laws, including changes in interpretation or application of the law by taxation authorities or the courts, may impact the future tax liabilities of Starpharma or affect the taxation treatment of an investment in securities of Starpharma. Such changes maybe in Australia or in the various jurisdictions in which Starpharma operates. Starpharma may undertake R&D activities part-funded by incentive programs (e.g. R&D tax credits) and under other competitive grants. There is no certainty that grants or incentive programs will continue to be available to the company, and changes in government policy may reduce their applicability.

Litigation: Starpharma is subject to the usual business risk that litigation or disputes may arise from time to time in the ordinary course of its business activities. These may include claims and disputes involving competitors, customers, consumers, suppliers, employees, governmental agencies/authorities, regulators or other third parties. Claims may be made in relation to intellectual property, product safety, unfair competition, employment, and other matters typical for Starpharma's industry. Amongst other things, Starpharma is subject to legal obligations in multiple jurisdictions related to privacy, information security, and data protection, which may form the basis of claims against it. There can be no assurance that any claims will not be made against Starpharma, or that insurance will continue to be available or adequate to cover liabilities resulting from any such claims. Any successful claim against Starpharma may adversely impact its future financial performance or position as well as its reputation and brand.

COVID-19 pandemic: Events related to the ongoing COVID-19 pandemic have resulted in significant health and economic impacts in Australia and overseas. There is continued uncertainty as to government responses and the likelihood of economic impacts of unknowable duration and severity. While Starpharma has been monitoring the ongoing impact of the COVID-19 pandemic on its operations, the full impact is not currently ascertainable due to the unknown length of time that the economy, businesses and people will be required to adhere to certain government responses, or regulatory requirements related to COVID-19. COVID-19 and its longer-term impact could potentially impact suppliers, clinical trial participants, customers, employees and the Company's operations, in Australia and overseas.

Data security / IT: Starpharma and its contract research organisations maintain sensitive personal information, such as clinical/health data. Starpharma may be subject to a cyber security attack or data breaches by employees or external parties with either permitted or unauthorised access. A cyber security attack or data breach may also have implications for Starpharma under relevant data protection or privacy legislation, and failure to comply can result in penalties and damage to its reputation. Starpharma is dependent on the performance, reliability and availability of IT systems. There is a risk that these systems may be adversely affected by disruption, failure, service outages or data corruption that could occur as a result of computer viruses, malware, internal or external misuse by websites, cyber-attacks or other disruptions including natural disasters, power outages or other similar events.

Reputation: Starpharma's reputation may be impacted by a future event that creates adverse perception of the Group for the public, investors, regulators, or rating agencies that directly or indirectly impacts earnings and value.





# **Appendix: Foreign Selling Restrictions**

#### **Foreign Selling Restrictions**

This document does not constitute an offer of new ordinary shares ("New Shares") of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

#### **Hong Kong**

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the "SFO"). No action has been taken in Hong Kong to authorise or register this document or to permit the distribution of this document or any documents issued in connection with it. Accordingly, the New Shares have not been and will not be offered or sold in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

#### **Singapore**

This document and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part XIII of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), or as otherwise pursuant to, and in accordance with the conditions of any other applicable provisions of the SFA.

This document has been given to you on the basis that you are (i) an existing holder of the Company's shares, (ii) an "institutional investor" (as defined in the SFA) or (iii) an "accredited investor" (as defined in the SFA). In the event that you are not an investor falling within any of the categories set out above, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party. There are on-sale restrictions in Singapore that may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

#### **European Union**

This document has not been, and will not be, registered with or approved by any securities regulator in the European Union. Accordingly, this document may not be made available, nor may the New Shares be offered for sale, in the European Union except in circumstances that do not require a prospectus under Article 1(4) of Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union (the "Prospectus Regulation").

In accordance with Article 1(4)(a) of the Prospectus Regulation, an offer of New Shares in the European Union is limited to persons who are "qualified investors" (as defined in Article 2(e) of the Prospectus Regulation).



#### **Foreign Selling Restrictions**

#### **United Kingdom**

Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the New Shares.

The New Shares may not be offered or sold in the United Kingdom by means of this document or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This document is issued on a confidential basis in the United Kingdom to "qualified investors" (within the meaning of Article 2(e) of the Prospectus Regulation (2017/1129/EU), replacing section 86(7) of the FSMA). This document may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the New Shares has only been communicated or caused to be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investment to which this document relates is available only to relevant persons who is not a relevant person should not act or rely on this document.

#### **Switzerland**

The New Shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange or on any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the New Shares constitutes a prospectus or a similar notice, as such terms are understood under art. 35 of the Swiss Financial Services Act or the listing rules of any stock exchange or regulated trading facility in Switzerland.

Neither this document nor any other offering or marketing material relating to the New Shares may be publicly distributed or otherwise made publicly available in Switzerland. The New Shares will only be offered to investors who qualify as "professional clients" (as defined in the Swiss Financial Services Act). This document is personal to the recipient and not for general circulation in Switzerland.

No offering or marketing material relating to the New Shares has been, nor will be, filed with or approved by any Swiss regulatory authority or authorised review body. In particular, this document will not be filed with, and the offer of New Shares will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

#### **United States**

This document does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The New Shares have not been, and will not be, registered under the US Securities Act of 1933 or the securities laws of any state or other jurisdiction of the United States. Accordingly, the New Shares may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws.

The New Shares will only be offered and sold in the United States to:

- institutional accredited investors (as defined in Rule 501(a)(1), (2), (3) and (7) under the US Securities Act); and
- dealers or other professional fiduciaries organized or incorporated in the United States that are acting for a discretionary or similar account (other than an estate or trust) held for the benefit or account of persons that are not US persons and for which they exercise investment discretion, within the meaning of Rule 902(k)(2)(i) of Regulation S under the US Securities Act.



#### **Foreign Selling Restrictions**

#### Canada (British Columbia, Ontario and Quebec provinces)

This document constitutes an offering of New Shares only in the Provinces of British Columbia, Ontario and Quebec (the "Provinces"), only to persons to whom New Shares may be lawfully distributed in the Provinces, and only by persons permitted to sell such securities. This document is not a prospectus, an advertisement or a public offering of securities in the Provinces. This document may only be distributed in the Provinces to persons who are "accredited investors" within the meaning of National Instrument 45-106 – *Prospectus Exemptions*, of the Canadian Securities Administrators.

No securities commission or authority in the Provinces has reviewed or in any way passed upon this document, the merits of the New Shares or the offering of the New Shares and any representation to the contrary is an offence.

No prospectus has been, or will be, filed in the Provinces with respect to the offering of New Shares or the resale of such securities. Any person in the Provinces lawfully participating in the offer will not receive the information, legal rights or protections that would be afforded had a prospectus been filed and receipted by the securities regulator in the applicable Province. Furthermore, any resale of the New Shares in the Provinces must be made in accordance with applicable Canadian securities laws. While such resale restrictions generally do not apply to a first trade in a security of a foreign, non-Canadian reporting issuer that is made through an exchange or market outside Canada, Canadian purchasers should seek legal advice prior to any resale of the New Shares.

The Company as well as its directors and officers may be located outside Canada and, as a result, it may not be possible for purchasers to effect service of process within Canada upon the Company or its directors or officers. All or a substantial portion of the assets of the Company and such persons may be located outside Canada and, as a result, it may not be possible to satisfy a judgment against the Company or such persons in Canada or to enforce a judgment obtained in Canadian courts against the Company or such persons outside Canada.

Any financial information contained in this document has been prepared in accordance with Australian Accounting Standards and also comply with International Financial Reporting Standards and interpretations issued by the International Accounting Standards Board. Unless stated otherwise, all dollar amounts contained in this document are in Australian dollars.

Statutory rights of action for damages and rescission. Securities legislation in certain Provinces may provide a purchaser with remedies for rescission or damages if an offering memorandum contains a misrepresentation, provided the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's Province. A purchaser may refer to any applicable provision of the securities legislation of the purchaser's Province for particulars of these rights or consult with a legal adviser.

Certain Canadian income tax considerations. Prospective purchasers of the New Shares should consult their own tax adviser with respect to any taxes payable in connection with the acquisition, holding or disposition of the New Shares as there are Canadian tax implications for investors in the Provinces.

Language of documents in Canada. Upon receipt of this document, each investor in Canada hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the New Shares (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.

#### Israel

The New Shares have not been registered, and no prospectus will be issued, under the Israeli Securities Law, 1968 (the "Securities Law"). Accordingly, the New Shares will only be offered and sold in Israel pursuant to private placement exemptions, namely (i) to no more than 35 offerees or (ii) to "Sophisticated Investors" as described in the First Addendum of the Securities Law, subject to certain conditions.

Neither this document nor any activities related to the Offer shall be deemed to be the provision of investment advice. If any recipient of this document is not the intended recipient, such recipient should promptly return this document to the Company. This document has not been reviewed or approved by the Israeli Securities Authority in any way.

