

#### AGM Chairman's address and CEO's presentation

**Melbourne, Australia; 20 November 2020:** Attached is the Chairman's address together with the CEO's presentation to the Annual General Meeting (AGM) of Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY), to be held at 11am (Melbourne time) today.

The AGM will be held online. Shareholders and proxyholders will be able to listen, view presentations, vote and ask questions during the meeting in real-time through the Lumi virtual platform, for which details are available via https://starpharma.com/2020agm.

#### About Starpharma

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

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

VivaGel<sup>®</sup>: Starpharma's women's health product - VivaGel<sup>®</sup> BV is based on SPL7013, astodrimer sodium, a proprietary dendrimer. VivaGel<sup>®</sup> BV for bacterial vaginosis (BV), is available for sale under the brand names Betafem<sup>®</sup> BV Gel (UK), Betadine BV<sup>™</sup> (Europe), Betadine<sup>™</sup> BV Gel (Asia) and Fleurstat BVgel (Australia and New Zealand) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel<sup>®</sup> BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel<sup>®</sup> condom (an antiviral condom which includes VivaGel<sup>®</sup> in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel<sup>®</sup> condom has been launched in Japan under Okamoto's 003 brand, and in Australia and Canada under the LifeStyles Dual Protect<sup>®</sup> brand. The VivaGel<sup>®</sup> 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.

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#### Starpharma Holdings Limited

Dr Jackie Fairley, Chief Executive Officer Nigel Baade, CFO and Company Secretary +61 3 8532 2704 investor.relations@starpharma.com 4-6 Southampton Crescent Abbotsford Vic 3067 Disclosure This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.

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 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. St



#### <u>Chairman's Address</u> Starpharma Holdings Limited Annual General Meeting 20 November 2020

On behalf of your Board of Directors, I welcome you to Starpharma's 2020 Annual General Meeting, which is our first virtual AGM.

The COVID-19 pandemic has had such a disruptive impact on our lives and the economy. I sincerely hope that you and your loved ones have remained safe and healthy throughout the year. During this time, Starpharma's Senior Executives and Board have responded proactively, employing a comprehensive set of measures to ensure the safety of our staff and trial participants, while also minimising disruption to our business, including the continued operations of our laboratories in Melbourne. It has taken a significant coordinated commitment from management and all of our staff to achieve this, especially in Victoria, and we commend our staff for their diligence and professional response in a rapidly evolving and uncertain environment. I am pleased to say that we have been able to achieve this, whilst still maintaining our focus on our strategic priorities despite the extraordinary challenges presented by the pandemic.

The strategic focus of Starpharma over many years has been to leverage our proprietary dendrimer technology to build a stable of high-value products and partnerships that address significant unmet patient need for the betterment of the community and our shareholders.

This year, in a year like no other, we did exactly that.

Those of you familiar with our business will know that our proprietary dendrimer SPL7013, which is the active component in our VivaGel<sup>®</sup> products, is a broad spectrum antiviral and has significant antiviral activity against a range of viruses. With the advent of the coronavirus pandemic, we quickly moved to test SPL7013 and found it to be virucidal, inactivating more than 99.99% of the coronavirus that causes COVID-19.

With this data in hand, Starpharma's team worked rapidly to identify a highly novel and valuable product opportunity and since then has worked tirelessly to expedite the development and commercialisation of our product VIRALEZE, a preventative COVID nasal spray which incorporates our broad spectrum antiviral SPL7013. SPL7013 is the active in other Starpharma products which are already approved in 40 countries and on market in the UK, Europe, Asia, Australia and New Zealand. VIRALEZE is designed to be an additional line of defence against COVID-19, alongside PPE and any potential vaccine, for use by the general population, and workplaces including those in the frontline of this crisis. As we have learnt in 2020, there is still some uncertainty around the availability of an effective vaccine that can minimise the human and economic impact of this pandemic.

I think VIRALEZE and its evolution and fast-tracked development is a perfect illustration of the Company's ability to rapidly innovate and leverage its dendrimer technology to create additional valuable opportunities for the health of people globally, as well as our shareholders.

Notwithstanding the challenges of the pandemic and the rapid development of our nasal spray, Starpharma continued to expand the global footprint for VivaGel BV<sup>®</sup> with further launches in additional countries in Europe and Asia and further approvals in new regions

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such as Africa and the Middle East. While the pandemic has caused some disruption to launches, and lockdowns have had some impact on consumer demand, our global expansion for VivaGel<sup>®</sup> BV continues, and it has been very pleasing to receive so many positive product reviews by new customers and healthcare professionals.

Given the typical development timeframes for new medical products, it has been a privilege to see an Australian innovation, VivaGel® BV, fully commercialised during my tenure, and now with another novel product expected to be in market next year.

Starpharma has also built strong and lasting partnerships, which are a critical feature to bringing medical innovations and breakthroughs to patients in need.

It has been really exciting to see AstraZeneca advance its novel anti-cancer drug AZD0466 into human trials in the US this year. This product is of high priority for AstraZeneca and continues to attract significant interest from clinicians. We look forward further updates as the trial progresses.

The partnerships we have executed with our DEP<sup>®</sup> platform have the potential to create life changing products for patients, and long-term revenues for Starpharma by way of milestones and royalties. Because the DEP<sup>®</sup> platform can be licensed to multiple partners, and be applied to multiple products in parallel, it creates exceptional optionality. While a number of our partnerships must remain confidential at this stage, we were able to share the signing of a new partnership this year, with Chase Sun, for a novel anti-infective DEP<sup>®</sup> program. Partnering in this new therapeutic area illustrates the versatility and broad applicability of DEP<sup>®</sup>.

Our DEP<sup>®</sup> technology has been used to improve the performance of, and reduce the side effects of many oncology drugs, and this year we also expanded its use to create DEP<sup>®</sup> versions of other non-oncology drugs, including anti-infectives, and most recently the antiviral drug, remdesivir. Gilead's remdesivir is proving to be a critically important antiviral drug which was recently approved by the FDA for the treatment of COVID-19 patients. In its current form, this drug needs to be administered as an intravenous infusion in hospital, which can take more than 2 hours. Starpharma has developed a long-acting DEP<sup>®</sup> version of remdesivir, which potentially could be administered subcutaneously, in 2-3mls. This potentially expands the usage of this product into non-hospital settings, such as aged care.

This program illustrates the Company's capacity to rapidly turnaround new DEP<sup>®</sup> candidates with compelling benefits for patients and commercial partners.

Alongside our partnered DEP<sup>®</sup> programs, we have made significant progress with our internally developed DEP<sup>®</sup> products. We now have three clinical stage DEP<sup>®</sup> assets in phase 2, for which we have reported positive patient outcomes across a range of tumours. We are thrilled that multiple patients have also experienced benefits such as tumour shrinkage and prolonged periods of stable disease. In addition to AZD0466, the results from Starpharma's three phase 2 trials will be important milestones for the Company and will support new DEP<sup>®</sup> licences.

To ensure that we are in the best position to accelerate the development of these important DEP<sup>®</sup> products, their commercialisation and others, Starpharma recently completed an oversubscribed capital raising and is now in an extremely strong financial position. These funds will also enable the Company to accelerate the development and commercialisation activities for the launch of the VIRALEZE, as well as expedite the pipeline development of new DEP<sup>®</sup> candidates. On behalf of the Board, I thank all the investors and shareholders who participated in the Share Purchase Plan and placement.

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When I reflect on Starpharma's recent progress, for such a small company, it is truly remarkable what has been achieved. We licensed VivaGel<sup>®</sup> BV in more than 160 countries around the world and then launched this important women's health product in the UK, Europe, Asia, Australia and New Zealand. We partnered with

AstraZeneca to develop a DEP<sup>®</sup> improved version of one of their major drugs and progressed a novel AstraZeneca DEP<sup>®</sup> product into the clinic. We also advanced two further DEP<sup>®</sup> products within our own portfolio, whereby we now have three clinical stage DEP<sup>®</sup> assets, and a deep pipeline which includes exciting programs in Antibody Drug Conjugates and radiotherapeutics. And most recently, we developed the SPL7013 COVID-19 nasal spray, which could prove to be a hugely important product, as COVID numbers continue to surge in the Northern hemisphere.

I think this quantum of achievement of our team of around 45 staff speaks to the innovation and drive embedded in the culture at Starpharma. On behalf of the Board I thank all our staff for their hard work and determination over this period and Jackie and her management team for their strong and clear leadership.

I also thank my fellow board members. This year we welcome David McIntyre to his first AGM for Starpharma. David has been a fantastic addition to the Board. We also say farewell to Dick Hazleton, who retires at the end of this meeting. Dick has made an invaluable contribution to the Company during his tenure and we sincerely thank him for his commitment and wise counsel.

As we look to the future, I am enormously proud to be part of Starpharma and am excited for the key inflection points in the period ahead. In 2021 we expect to have the nasal spray ready for market in the first half of calendar year, and will see further approvals and launches of VivaGel<sup>®</sup> BV, as well as the expansion and completion of some of our phase 2 DEP<sup>®</sup> trials, and we expect to sign further DEP<sup>®</sup> partnerships with leading pharmaceutical companies.

With each passing quarter, the progression of our strategy reinforces our long term growth prospects and our potential to deliver excellent returns to shareholders. We are really well funded, we have globally leading platform technology and potentially our strategies can deliver very substantial future royalty flows.

I thank shareholders for their support, and look forward to the year ahead.

Thank you

Rob Thomas AO Chairman



# **Annual General Meeting**

20 NOVEMBER 2020

ASX:SPL OTC:SPHRY

DR JACKIE FAIRLEY CEO



# Important notice and disclaimer

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 health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health 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 clinical trial results, including additional analysis of existing clinical data, and new clinical 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 presentation 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. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product. 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 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).



#### **Key Investment Data**

ASX code	SPL
OTCQX code	SPHRY
Share price	A\$1.34
Shares on issue	403.4M
Market capitalisation	~A\$550M
Daily average volume (shares)	~1.3M
Cash on hand - as at 30/10/20	>\$70M

	Institutions ~55%
register	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 valuable patented 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 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



**VivaGel<sup>®</sup> condom** – Approved in Japan, Europe, Australia & Canada





VIRALEZE<sup>™</sup> COVID-19 preventative nasal spray – expedited product development & regulatory pathway; expected on market H1 2021





Share

# Starpharma's portfolio High-value assets including VivaGel<sup>®</sup> products on market, SPL7013 antivirals and

# multiple DEP<sup>®</sup> clinical assets

Extensive & growing pipeline Multiple approved Multiple clinical stage assets of proprietary assets products LATE STAGE PRECLINICAL **DEVELOPMENT**/ RESEARCH PHASE 2 PHASE 1 **APPROVED PRODUCTS** DEVELOPMENT REGULATORY VACIST ONLY MEDI Fleurstat **DEP**<sup>®</sup> AstraZeneca BVgel DEP<sup>®</sup> CABAZITAXI **INTERNAL INTERNAL & PARTNERED** LICENSED 003 AstraZeneca EF" Ormer o LICENCE **AFTER** PARTNERED DOCETAX **PROOF OF** FURTHER CONCEPT **APPROVALS** s. 红日药业集团 CHASE SUN starpharma

# **Starpharma's strategy**

Utilise proprietary dendrimer technology to build a portfolio of high-value products and partnerships that address important unmet patient need and create significant commercial value





#### **EXPAND DEP® ASSETS** (INTERNAL FOR LICENSING)

- Strategic investment in high-value DEP<sup>®</sup> products & add additional value via combinations
- Explore other therapeutic opportunities for dendrimers (e.g. radiopharmaceuticals)



#### LEVERAGE DEP® PLATFORM (PARTNER LICENCES)

- Add to Starpharma's deep portfolio of global products
- Secure valuable DEP<sup>®</sup> partnerships for high-value returns



#### LEVERAGE SPL7013 ACTIVE (INTERNAL & LICENSING)

Leverage existing regulatory and clinical data for new antiviral/antimicrobial products, including for COVID-19 and pandemic preparedness



# Starpharma responded rapidly and proactively to minimise COVID-19 impact

Starpharma implemented a broad program of measures to protect the health and safety of our staff and clinical trial patients, and to ensure product supply to customers.

- Melbourne-based laboratory and in-house GMP manufacturing facilities continued to operate throughout with COVID-19 Safe Plan in place
- In Starpharma's clinical trials, there was some disruption to new patient recruitment associated with the initial UK lockdown. Recruitment has resumed in all DEP<sup>®</sup> clinical trials and several new sites have been opened.
- AstraZeneca continues to recruit for its phase 1 DEP<sup>®</sup> trial for AZD0466.
- As experienced by companies around the world, Starpharma's partners for VivaGel<sup>®</sup> BV have encountered some disruption to their sales and marketing activities, and COVID-19 lockdowns delayed some launches and may impact consumer demand.
- There continues to be significant disruption to the US healthcare industry and infrastructure due to COVID-19, including at the FDA - impacts on timing of the ongoing formal FDA review.
- Starpharma identified attractive new product opportunities to assist in the fight against COVID-19, and expedited the development of VIRALEZE<sup>™</sup> nasal spray





New product opportunities identified & developed



# VIRALEZE<sup>™</sup>- preventative COVID nasal spray is virucidal, inactivating >99.9% of SARS-CoV-2 (coronavirus)

Broad spectrum antiviral activity against *multiple* important respiratory viruses including influenza and RSV



- The broad antiviral activity of VIRALEZE<sup>™</sup> creates potential in future pandemics
- To be available OTC (no prescription); Convenient room temperature storage

## 

**MECHANISM OF ACTION** 

SPL7013 acts by binding to "**spike**" proteins" blocking the ability of the virus to attach to ACE2 and enter nasal mucosal cells\*

SPL7013 has also demonstrated activity in HIV, HSV, HPV, Adenovirus, HBV, Zika, H1N1 (influenza) **and RSV** 



**^Testing conducted at The Scripps Research Institute (US)** and 360biolabs; \* Based on data for SARS-C \*\*Selectivity Index is a measure of relative safety or therapeutic index

# Starpharma is expediting the development of the VIRALEZE<sup>™</sup> preventative COVID nasal spray

EXPECTED TO BE READY FOR MARKET 1H CY2021

#### **Broad range of potential customers**

- Front-line healthcare workers; staff in high-risk environments e.g. airlines, aged care, mining, abattoirs
- Broader population, including for use on airlines, public transport, in restaurants, bars, shopping etc

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



- ✓ Reformulation completed
- ✓ Virucidal activity

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



completed
 ✓ Labels developed; device
 components selected;

Pilot manufacture

- components selected; building inventories
- Regulatory documentation compiled in preparation for submission
- Commercial preparations advancing well

Starpharma is currently developing and implementing its market entry strategy for VIRALEZE<sup>™</sup> with input from Boston Consulting Group Channels include:



Direct to consumer (online)

**Business to Business** 

HE BOSTON CONSULTING GROUP

Pharmacy (in-store and online) SPL7013 is the active included in other VivaGel<sup>®</sup> products approved in 40 countries and is **already scaled up for commercial supply** 

Existing stocks of SPL7013 will expedite launch of the VIRALEZE<sup>™</sup>, and Starpharma is building inventories in preparation.

Regulators have confirmed that **minimal re-development is required**, leading to an expedited program

# VIRALEZE<sup>™</sup>- preventative nasal spray for coronavirus & other respiratory viruses VIRALEZE<sup>™</sup> market research shows a high level of consumer interest

"Of course I would (be interested in a spray available for prevention), yeah!"

Consumer research, November 2020

"...You can use this and feel better about going to work. Not so anxious all the time."

Consumer research, November 2020

"...shopping malls, public transport; you use it because you're going to at risk areas.... then yes, why not."

Consumer research, November 2020

"It looks really, really useful. It really does. It would reduce the risk of developing Covid-19. Straightaway, that captures you."

Consumer research, November 2020



"So I think wearing gloves and a mask reduces the risk, but not enough... this would reduce it even more just an additional barrier"

Consumer research, November 2020

#### "Wow. I would take that... I'll take it before I go to work"

Consumer research, November 2020

"Yeah, I would use it definitely. It does make sense"

Consumer research, November 2020

"Buying online is not a problem for me. I buy virtually everything online"

Consumer research, November 2020



The Boston Consulting Group (BCG) is providing management consulting services, including market analysis, in connection with Starpharma's development of its go-to-market strategy for Starpharma's Viraleze Nasal Spray.



## VIRALEZE<sup>™</sup> EU consumer research: High likeability and high purchase intent

## What is the likelihood of you buying VIRALEZE™?



- ~60% of respondents liked
  VIRALEZE<sup>™</sup>
- Likeability translated to high purchase intent
- >60% likeability and purchase intent for VIRALEZE<sup>™</sup> in both millennials and Gen-X



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#### Top 4 features of VIRALEZE™ driving strong purchase intent

- 1. Activity against multiple viruses (coronavirus, RSV, influenza)
- 2. Inactivates >99.9% coronavirus
- 3. Preventative spray
- 4. Handy & convenient solution

# **COVID-19: Experts agree that preventative measures will be critical even after an effective vaccine is widely adopted**



A successful vaccine against COVID-19 would be a great lifesaving advance. But vaccines alone won't be enough to bring the crisis under control.



"...likely that Covid-19 would remain endemic — native and widespread — for <u>years to come</u>".

FINANCIAL TIMES

THE LANCET

narma

*"I don't think it's going to be one and done .... people may be re-susceptible to infection from the virus".* The Financial Times, Dr Fauci

"It will be important to communicate to policy makers and the general public that first-generation vaccines are only one tool in the overall public health response to COVID-19 and are unlikely to be the ultimate solution that many expect"

November 2020, Malik Peiris, Gabriel M Leung

# Significant risk of future pandemics



"It is highly likely that after SARS-CoV-2 there will be another pandemic. It might be another coronavirus, an influenza virus, a paramyxovirus, or a completely new disease.

We believe that learning from this experience is crucial so that we can meet a future pandemic threat..."

September 2020, Prof Eskild Petersen, MD et al

THE LANCET



https://www.ft.com/content/c6c6b704-964a-4df6-8330-8e3290ea65fa

https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30484-9/fulltext

# **Starpharma's DEP<sup>®</sup> platform strategy: multiple partnerships + new products**

DEP<sup>®</sup> platform can be licensed to multiple partners, and be applied to multiple products in parallel, which creates exceptional optionality

**INTERNAL**: Starpharma uses its DEP<sup>®</sup> platform to create improved versions of already marketed drugs, to licence to partners following proof-of-concept



# 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



**PARTNERED**: Starpharma's partners use the DEP®

platform to improve their novel or existing drugs - for

which Starpharma is paid milestones & royalties





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

**DEP® PLATFORM:** 

LEVERAGES IP

& CREATES

**SYNERGIES** 

# **DEP<sup>®</sup> remdesivir** Slow release (long-acting) & soluble version of Gilead's remdesivir

Gilead's antiviral drug, remdesivir, is an antiviral drug recently approved by the FDA for the treatment of COVID-19 patients with severe disease DEP<sup>®</sup> remdesivir is a water-soluble nanoparticle incorporating remdesivir and PEG, providing a controlled release of remdesivir (longer half-life)

- 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 (Veklury) contains an excipient (a cyclodextrin, SBEDC) and is not recommended in patients with renal impairment<sup>1</sup>
- DEP<sup>®</sup> remdesivir expands the potential application of remdesivir, by creating a long-acting version which doesn't require IV infusion;
- DEP<sup>®</sup> remdesivir could be administered ~2-3mls subcutaneously (out-patient setting) compared to large volume IV infusion (in hospital)





DEP® remdesivir has >100-fold higher solubility than remdesivir and needs no cyclodextrin

🚺 GILEAD



<sup>1</sup> FDA Emergency Use Authorisation Fact Sheet for Veklury (remdesivir)

# **DEP<sup>®</sup> partnering creates significant value and optionality**

Starpharma's DEP<sup>®</sup> platform enhances the commercial and therapeutic value of a wide range of drugs, creating multiple potential revenue streams and significant IP leverage

#### DEP<sup>®</sup> can be used by partners to improve novel drugs





DEP<sup>®</sup> nanoparticles can be used to enhance novel drugs addressing issues such as toxicity or insolubility, which may limit their clinical use

R	R
AstraZeneca 2 DEP®	AstraZeneca
100	DEP* AZD0466

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

#### AstraZeneca's novel DEP<sup>®</sup> nanoparticle AZD0466

- Dual Bcl2/xL inhibitor with DEP<sup>®</sup> significantly improving its therapeutic index
- Phase 1 trial recruiting at MD Anderson and other US sites
- US\$7M in milestones received to date; total AZD0466 deal up to US\$124M + royalties (est. up to A\$2.4B revenue to SPL)
- AZD0466 is the first candidate in Starpharma's multiproduct licence with AZ

#### DEP<sup>®</sup> can also be used to improve existing products for life-cycle management & create new IP

Starpharma has DEP<sup>®</sup> programs with large pharma companies incl. AstraZeneca, Chase Sun, and several undisclosed partnerships, including for ADCs

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红日药业集团 CHASE SUN



For example, AstraZeneca's third DEP<sup>®</sup> program (separate to the above multiproduct licence):

- AstraZeneca DEP<sup>®</sup> candidate is a major existing AZ oncology medicine
- US\$5M on option exercise (Development & Option Agreement), industry standard milestones, plus escalating royalties



AstraZeneca

# AZD0466 – AstraZeneca's highly optimized DEP<sup>®</sup> nanoparticle formulation of a novel dual Bcl2/xL inhibitor - outperforms in multiple cancer models

#### AZD0466

- a highly optimized patented nanoparticle formulation of a novel anticancer utilising Starpharma's DEP® technology
- In Phase 1 clinical program in multiple sites in the US
- Granted US patent provides US exclusivity until 2038 (+up to 5 years' extension)
- Expected to be "best in class"; comparator is Abbvie/Genentech's Venclexta<sup>®</sup> forecast peak sales of US\$2-3 billion

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DEP® Bcl2/xL conjugates in a human acute lymphoblastic leukemia model

AstraZeneca DEP® Bcl2/xL inhibitor conjugates were significantly more efficacious than the Bcl2/xL inhibitor alone, resulting in complete tumour regression in most animals



## AstraZeneca's AZD0466 AZD0466 significantly outperformed marketed Bcl2 inhibitor venetoclax (AACR Meeting 2020)





AZ is currently running a multi-centre phase 1 trial of AZD0466

in the US

AZD0466 has been described as having **the potential to be a** *'best-in-class' agent* in this field with a broad opportunity in solid and haematological tumours (blood cancers) **due to its ability to target both Bcl2 and Bcl/xL**<sup>1</sup>.

These posters highlight:

- the **significant improvement in therapeutic index** afforded to AZD0466 through the application of the DEP<sup>®</sup> technology, and
- the potent and broad ranging anti-cancer activity of AZD0466 which results from the dual Bcl2 and Bcl/xL activity.
- AZD0466 demonstrated impressive and consistently superior anti-cancer activity in a wide range of tumour types including Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), Non-Hodgkin's Lymphoma and Non-Small Cell Lung Cancer (NSCLC) in preclinical models.
- MD Anderson poster illustrates consistent out performance of venetoclax in ALL





# **DEP<sup>®</sup> 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

DEP

CABAZITAXE

warnings

years).



DEP<sup>®</sup> DOCETAXEL: Enhanced version of docetaxel (Taxotere<sup>®</sup>) – 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<sup>®</sup> docetaxel<sup>#\*</sup>:

Reduction in neutropenia; detergent-free formulation; no steroid pre-treatment; 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<sup>®</sup>)

PHASE 2

Cabazitaxel (Jevtana®) – global

sales of ~US\$500M for 2019 despite

having multiple US FDA "Black Box"

Advantages of DEP<sup>®</sup> cabazitaxel\*:

Improved toxicity profile; detergent-

free formulation; no steroid pre-

improved efficacy; patent filings to

2039 (plus up to an additional ~5

treatment; tumour-targeting,

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



DEP<sup>®</sup> IRINOTECAN: Improved version of irinotecan (Camptosar<sup>®</sup>) 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<sup>®</sup> 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).



Utilise accelerated development / regulatory

pathways (i.e. 505b2) for optimal ROI

Starpharma's deep preclinical pipeline includes DEP<sup>®</sup> chemotherapeutic candidates including DEP<sup>®</sup> gemcitabine, DEP<sup>®</sup> radiotherapeutic candidates & DEP<sup>®</sup> antibody drug conjugate (ADC) candidates & further therapeutic candidates



#Clinical studies have demonstrated reduction in important side effects with DEP<sup>®</sup> including bone marrow toxicity, anaphylaxis, oedema and hair-loss

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

# **DEP<sup>®</sup> docetaxel** Phase 2 ongoing recruitment and positive interim results



#### Monotherapy

Open-label trial, with the objective of establishing anti-tumour activity (efficacy) & safety



37 patients treated



Phase 2 DEP<sup>®</sup> docetaxel trial continues to progress well, with further observations of encouraging efficacy signals, including prolonged stable disease and tumour shrinkage in patients with tumours including pancreatic, oesophageal and gastric cancer



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



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

The same **tumour targeting** observed with DEP<sup>®</sup> in animal studies has been **replicated in patients** treated with DEP<sup>®</sup> docetaxel, delivering **substantially higher levels of drug to the tumour (> 63x) than in blood** 





Guy's and St Thomas' NHS Foundation Trust



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

Combination DEP<sup>®</sup> docetaxel + gemcitabine trial commenced



Combinations

Other DEP<sup>®</sup> docetaxel combinations being explored to create value

#### $\label{eq:combination} \textbf{DEP}^{\texttt{®}} \mbox{ docetaxel + nintedanib (Vargatef^{\texttt{®}}) in lung \mbox{ cancer}}$



13 patients treated

Encouraging efficacy signals observed

- prolonged stable disease & tumour shrinkage in non-small cell lung cancer; heavily pre-treated patients
- Notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects including mouth ulcers, anaphylaxis and oedema



The Newcastle upon Tyne Hospitals NHS Foundation Trust

**NHS** The Leeds

Teaching Hospitals

# **DEP<sup>®</sup> docetaxel case studies**





72-year-old woman: extensive intrahepatic cholangiocarcinoma, an often-fatal cancer that affects the bile ducts

Cholangiocarcinoma is a rare but aggressive form of cancer. The 5-year survival rate for intrahepatic cholangiocarcinoma is very low (8%).

- Patient was heavily pre-treated having progressed following 8 cycles of prior anti-cancer therapy
- Patient received 4 cycles of DEP<sup>®</sup> docetaxel and achieved >28 weeks stable disease



A tumour biopsy from the patient after dosing with DEP® docetaxel showed 63x more DEP® docetaxel in the tumour tissue than in blood



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

Oesophageal cancer is the seventh most commonly occurring cancer in men. The estimated 5-year survival rate for stage IV disease is only 10% to 15%.

- Patient had progressive disease after radiotherapy and 9 cycles of two different treatment regimens
- Response to DEP<sup>®</sup> docetaxel: Reduction in size of tumour lesions of up to 48%; maintained for >16 weeks



# **DEP® cabazitaxel** Phase 2 ongoing recruitment with positive interim results

### PHASE 2

Open-label trial, with the objective of establishing antitumour activity (efficacy) & safety



First stage will enrol 30 patients with a variety of cancers, including prostate cancer; final numbers will be adjusted based on results in certain patient cohorts



Patient recruitment progressing well - 17 patients treated with up to 8 cycles of treatment



Encouraging efficacy signals, including stable disease, significant 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



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NHS

University College London Hospitals

NHS Found

Guy's and St Thomas'

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

Canolfan Ganser Felindre



# PSA level following DEP® cabazitaxel

Prostate cancer patient experienced >47 weeks stable disease & 79% reduction in PSA (Prostate Specific Antigen)

#### PHASE 1 RESULTS SUMMARY

- 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<sup>®</sup> cabazitaxel; no steroid, antihistamine or anti-emetic pre-treatment
- Encouraging signs of efficacy were observed in 67% of patients evaluable for treatment response
- Significantly less toxicity than is usually associated with Jevtana<sup>®</sup>

# **DEP<sup>®</sup> cabazitaxel case studies**





65-year-old man with late-stage (metastatic) gastro-oesophageal cancer

Oesophageal cancer is the seventh most commonly occurring cancer in men. The estimated 5-year survival rate for stage IV disease is only 10% to 15%.

- Heavily pre-treated patient with >15 cycles & three different kinds of anti-cancer treatment and cancer progressed
- Response to DEP<sup>®</sup> cabazitaxel: Patient received 6 cycles of DEP<sup>®</sup> cabazitaxel and achieved a 50% reduction in total tumour size maintained for >27 weeks





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

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

- Heavily pre-treated; cancer progressed on 3 other anticancer therapies including paclitaxel (another taxane);
   Previously had 14 cycles of treatment and multiple surgeries
- Response to DEP<sup>®</sup> cabazitaxel: Patient received 6 cycles of DEP<sup>®</sup> cabazitaxel - response seen after 3 cycles of treatment with overall response:
  - 40% reduction in total tumour burden
  - 50% reduction in biomarkers



43% reduction in size of abdominal tumour lesion

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

# **DEP<sup>®</sup> 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<sup>®</sup>:

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

DEP<sup>®</sup> irinotecan showed improved efficacy and survival benefit established in preclinical models

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

- 7 patients were enrolled and received DEP<sup>®</sup> irinotecan at a range of doses up to 12.5 mg/m<sup>2</sup> 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<sup>®</sup>) 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<sup>®</sup> irinotecan treatment were consistent with those seen in Camptosar<sup>®</sup> but generally less severe and mostly mild (grade 1)
  - AEs observed with DEP<sup>®</sup> irinotecan included nausea, vomiting, alopecia and neutropenia

Evaluable patients are those patients who have received ≥1 dose DEP<sup>®</sup> irinotecan and have had a tumour assessment conducted post treatment

#### **PHASE 2 UNDERWAY**

- Dose expansion: open-label trial, with the objective of establishing antitumour activity (efficacy) and safety at the RP2D
- Rapidly recruiting patients, with 27 patients already dosed and a high level of interest in the study
- Encouraging efficacy signals have been observed for multiple tumour types, including colorectal, ovarian, breast, pancreatic, lung and oesophageal cancer
- Combinations based on investigator interest and preclinical studies being explored with partners to create value, including with immunotherapy





# **DEP<sup>®</sup>** irinotecan case studies





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60-year old male with stage IV oesophageal adenocarcinoma (metastatic)

Oesophageal cancer is the seventh most commonly occurring cancer in men. The estimated 5-year survival rate for stage IV disease is only 10% to 15%.

- Previously with 6 cycles with 3 different agents
- Response to DEP<sup>®</sup> irinotecan seen after 3 cycles of treatment;
  4 cycles of DEP<sup>®</sup> irinotecan treatment to date
- Stable disease >9 weeks; 71% reduction in tumour biomarkers (CA 19-9); well tolerated, minimal side effects





# 45-year old woman with stage IV breast cancer with extensive liver metastases

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

- Extensive metastases including in the liver
- Very heavily pre-treated with >100 cycles of 11 different treatment regimens
- Response to DEP<sup>®</sup> irinotecan seen after 3 cycles of treatment
- 20 cycles of DEP<sup>®</sup> irinotecan treatment to date; well tolerated
- Prolonged stable disease >54 weeks; 21% reduction in target tumours

#### BASELINE

#### **18 WEEKS POST TREATMENT**



CT Scan showing 30% reduction in size of liver metastasis



# **DEP**<sup>®</sup> irinotecan

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

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



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

• DEP<sup>®</sup> 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<sup>®</sup>, BMS' Yervoy<sup>®</sup> and AstraZeneca's Imfinzi<sup>®</sup>



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 nonresponders 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<sup>®</sup> is a technology platform with multiple commercial opportunities in oncology and beyond





https://www.rootsanalysis.com/reports/view\_document/antibody-drug-conjugates-market-5th-edition-2019-2030/270.html

# **DEP<sup>®</sup> Antibody Drug Conjugates (ADC)** DEP<sup>®</sup> ADCs further build the value of the DEP<sup>®</sup> platform

Starpharma's DEP<sup>®</sup> technology provides enhanced therapeutic benefits to ADCs including greater homogeneity, site specific attachment, and higher drug antibody ratio (DAR), than conventional ADC approaches



#### Green -**Blood Vessel** Red dots -**Targeted DEP** conjugate

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Targeted DEP® penetrates deep into the tumour (left) and then binds and is internalised into tumour cells (right) for antitumour effect

**Dendrimer** inside cell in vesicles **Dendrimer** on cell surface

#### **Recent deals – growing interest in ADC** therapeutics

Strong corporate activity in ADCs is 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

Daiichi-Sankyo AstraZeneca



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





# **DEP<sup>®</sup> radiotherapeutics** DEP<sup>®</sup> is a valuable tool for radiotherapeutics and radio-diagnostics

- 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

#### **Rapidly growing** radiopharmaceuticals market



The radiopharmaceuticals area is a rapidly developing area of cancer treatment and diagnosis, which has recently generated several high-value deals. Sales in this category are estimated to grow to US\$12-15 billion by 20301



### **DEP<sup>®</sup> radio-dendrimers**

**DEP<sup>®</sup>** lutetium

Starpharma's first DEP®

radiotherapy candidate

1000

750-

500.

250

Change in Volurr

survival<sup>1</sup>

showed highly statistically

- Provide opportunities in targeted and passive approaches
- Applications in therapeutics and diagnostics

Davs Post Injection

human prostate cancer model (DU-145)

• Utility in the delivery of different radioisotopes e.g. Lutetium, Zirconium, Copper etc



## **DEP<sup>®</sup> zirconium**

DEP<sup>®</sup> radiodiagnostic candidate, DEP® zirconium, showed significant tumour accumulation: >100x in tumour v blood





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



# BV is caused by an imbalance of naturally occurring normal bacterial flora

BV can lead to a range of medical problems including pelvic inflammatory disease, infertility, premature delivery and miscarriage, low birth weights and uterine infection.

#### **Current BV 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







#### Large market opportunity

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



VivaGel<sup>®</sup> BV licensed in >160 countries around the world

Global market

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



# VivaGel<sup>®</sup> BV Positive patient experiences about VivaGel<sup>®</sup> BV benefits

"Amazing, amazing, amazing...within two days I noticed the BV clearing up." UK customer review

"Great news re Fleurstat and use in prevention of BV, I had many doctors ask about this" Aspen GP Team feedback

"One of my female GP's ... calls Fleurstat her 'Genie in a bottle'" Aspen Medical Rep feedback

"I used it 12 months ago and BV hasn't come anywhere nearby me ever since! The med is called Fleurstat."

Aspen consumer feedback



#### XXXXX

"Simple and effective, This pack contains enough treatments to provide 7 days of applications to treat existing BV, or when used every other day to prevent the occurrence of BV. This could happen if you are on antibiotics and are prone to developing it when so" *iron Maiden 1 Mar 2020* 

#### XXXXX

"It's really easy to use, my itchiness was gone after the first two applications making my life so much more comfortable" C Foley 3 Jan 2020

BETAFEM

BV GEL

TREATS AND PREVENTS BACTERIAL VAGINOSIS

"Much better for you than taking repeated courses of antibiotics" Rochycoo 12 Dec 2019

"I was a bit weary at first if it would work but within 24 hours I saw my symptoms improve especially the fishy smell and the funny colour discharge" Mummy 30 Dec 2019 AMAZON CUSTOMER REVIEWS "The pharmacist and the girls absolutely love the new symptom checker!! They all think that it will make life much easier when it comes to having this conversation. Left one pad with the pharmacist in the dispensary and another on the shelf"

Feedback from Pharmacy Rep

How does Fleurstat BVgel treat bacterial vaginosis?

Fleurstat BVgel is a product for the treatment of bacterial vaginosis and relief of its symptoms. It works to treat BV by disrupting the attachment of BV-causing bacteria to the vaginal lining. It is not an antibiotic.

( READ MORE



"I'm gobsmacked by the response to Fleurstat. It seems some GP's actually start to remember the name; some has prescribed it and has seen good results... a GP said he has seen good results and kept praising the product."

Aspen GP Team feedback



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 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).

# BETAFEM<sup>®</sup> Is Part Of The Trusted BETADINE<sup>®</sup> Brand .



Get back to yourself: Treat Bacterial Vaginosis PLUS relieve its symptoms\*



🧕 aspen

Marketing campaigns for VivaGel<sup>®</sup> BV in multiple regions

Could it be bacterial vaginosis?

READ MORE

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 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).

FLEURSTAT BVGEL RANKS AS #1 TOPICAL BV TREATMENT IN AUSTRALIA

Award winning

campaign

DIAMOND

# **VivaGel<sup>®</sup> BV regulatory progress**

## Approved in 40 countries with multiple other submissions underway

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





#### US regulatory

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

# VivaGel<sup>®</sup> condom VivaGel<sup>®</sup> antiviral condom launched in Japan; next launch is Europe

✓ Approved for sale in Japan, Europe, Australia & Canada

✓ World's first antiviral condom



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
- Okamoto expanded its licence to acquire marketing rights for a further 11 countries in Asia (incl. Sth Korea, Indonesia, Malaysia, Thailand, Singapore and the non-government China market)
- 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<sup>®</sup> condoms
- Okamoto have manufactured VivaGel<sup>®</sup> condom samples for Japan Foundation for AIDS Prevention (JFAP) – to increase awareness for health centres nationwide and the LGBT community





 Partners include Okamoto, LifeStyles, Sky & Land (China)

#### Starpharma was recently granted marketing approval for the VivaGel<sup>®</sup> 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™ DUAL PROTECTION. LifeStyles also has the marketing rights to the VivaGel<sup>®</sup> condom in other markets, including Australia and Canada





# **Financial summary** Strong balance sheet with >\$70M cash on hand\*

Key Financial Data	FY20 A\$M	FY19 A\$M
Revenue and other income	7.1 162%	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)

#### FY20 Result:

- Total revenue and other income of \$7.1M (FY19: \$2.7M), includes:
  - US\$3M AstraZeneca milestone payment
  - VivaGel<sup>®</sup> product sales and royalties of \$1.5M
- Reported loss for year of \$14.7M (FY19: \$14.3M)
- Increased research and product development expenses on expanded clinical product portfolio for three phase 2 clinical programs

#### Post FY20:

- Placement and Share Purchase Plan raising \$48.9M
- Use of funds focused on:
  - ➢ commercialisation & launch of VIRALEZE™
  - expedite and advance DEP<sup>®</sup> clinical programs to support licensing
  - > DEP<sup>®</sup> pipeline development
- Receipt of \$5.7M R&D tax incentive received in October
- Awarded \$1M MRFF funding for VIRALEZE™
- Quarterly customer receipts for VivaGel<sup>®</sup> BV reflect timing of batch supply and vary according to launch schedule and timing



<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.

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Fleurstat

# Outlook



#### VIRALEZE™

• Expedited development and launch of VIRALEZE™ nasal spray

#### **VIVAGEL**®

- Commercial roll-out of VivaGel<sup>®</sup> BV in Europe, Asia & other markets
- Further regulatory approvals and launches for VivaGel<sup>®</sup> BV; building revenues milestones and sales/royalties



- Ongoing formal FDA review process
- Further VivaGel<sup>®</sup> BV licences e.g. India, Canada & Israel
- VivaGel<sup>®</sup> condom approvals/launch in additional regions, such as China/Europe
- Further development / co-development of SPL7013 antiviral ophthalmic drops

#### DEP®

- Progress and completion of DEP<sup>®</sup> docetaxel, DEP<sup>®</sup> cabazitaxel & DEP<sup>®</sup> irinotecan phase 2 trials; value-adding combination studies;
  - AZD0466 clinical progress, trial expansions and receipts from milestones
  - AstraZeneca: Exercise of Option Agreement and/or deals for further compounds
  - Partnered DEP<sup>®</sup> deals & program developments, including DEP<sup>®</sup> ADCs
  - Advance DEP<sup>®</sup> radiopharmaceuticals, DEP<sup>®</sup> ADCs and DEP<sup>®</sup> antivirals e.g. DEP<sup>®</sup> remdesivir
  - Advance value-adding DEP<sup>®</sup> combinations in clinic and other DEP<sup>®</sup> products



#### LEVERAGE EXISTING APPROVALS

#### **COMMERCIAL OUTCOMES**



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









Advancing internal DEP<sup>®</sup> assets builds value for future licensing Partnered DEP<sup>®</sup> - upfront fees, milestones, royalties





# starpharma

# FOR INVESTOR RELATIONS ENQUIRIES CONTACT:

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ASX:SPL OTC:SPHRY



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