



## **Business Update**

CEO, Cheryl Maley 22 May 2024

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### Our Mission

"To help patients with significant illness, such as cancer, achieve improved health outcomes and quality of life through the application of our unique dendrimer technology."



### Starpharma Today

#### **Corporate Overview**

MASX OTE QX	Ticker Symbol	ASX:SPL OTCQX: SPHRY
(\$)	Cash Balance (31 March 2024)	A\$26.6 M
	Market Capitalisation	~A\$47 M
(\$)	Share Price	~A\$0.12
S	Total ordinary shares on issue	412 M
(\$)	Expected R&DTI refund (~Sept 2024)	~\$5 M

### **Starpharma Value Proposition**



### **Clinically validated technology**

More than 350 patients treated with DEP® across multiple clinical programs.



#### Strong intellectual property position

21 active patent families with over 200 granted patents and more than 100 patent applications pending.



#### Uniquely experienced team

Expertise in dendrimer science. Staff of ~40 people.



#### Pipeline of products and partnerships

Portfolio includes clinical-stage assets, early-stage research, partnerships, and commercial products.



# DEP® Dendrimers: Versatile, Multifunctional Delivery Platform for Therapies and Diagnostics

#### Clinically validated platform

More than 350 patients treated across multiple clinical programs and multiple drug classes

#### Targets tumours

Delivers 40-70x more drug in tumour compared to the original drug

#### Improves performance

Favourable tolerability, safety and efficacy profile leading to positive outcomes and Quality of Life benefits



#### **Commercial Products**

Starpharma is the only company to have commercialised dendrimer-based products

### Improves pharmacokinetics (PK) and half-life

Tuning of drug release and plasma half-life

#### **Broad applicability**

Applicable to a wide range of therapeutic areas, treatment modalities and applications, including radiotheranostics, antibody-drug conjugates (ADCs) and drug rescue



# Clinician Perspectives on the DEP® Platform and Related Clinical Trials





### Key Insights from the Business Review

Portfolio	Shareholders	Operations	Partners	Capability
<ul> <li>Broad portfolio and optionality - previous strengths, but may have led to some confusion in SPL's value proposition</li> <li>High interest in the</li> </ul>	Strong belief in the value of the dendrimer technology with an increasing sense of urgency to return shareholder value	<ul> <li>Opportunity to strengthen plan execution through new processes and governance</li> <li>Many competing priorities requires a</li> </ul>	<ul> <li>Extremely positive feedback – SPL is proactive, strong collaborator, novel approaches</li> <li>Large corporations: longer time frames,</li> </ul>	<ul> <li>Unique strength and very broad experience in developing dendrimer drug conjugates</li> <li>Commercial capability will</li> </ul>
market and with potential partners for the application of dendrimers in Radio and ADCs	<ul> <li>Request for improved communications in market updates</li> <li>The composition of the Shareholder</li> </ul>	further refined focus, and appropriate resource allocation	part of a large portfolio  • SPL is agile and can advance assets faster	enhance new asset identification and improve ROI for commercial assets  • Recognised as the
DEP® Assets – partner feedback, clinician experience, and external expert input points to prioritisation	Register has shifted in the past few years - retail % increase		Learnings from 15+     years of multiple     engagements     captured	only dendrimer technology to be commercialised; strong CMC experience



### **Our Strategy**

Starpharma, refocused

Drive growth and shareholder value through clear prioritisation and a clear focus on delivery and execution.





### Starpharma, Refocused

Three key focus areas to optimise shareholder returns

01

Maximise DEP® asset value

02

Accelerate early asset development

03

Build long-term sustainability



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### Maximise DEP® Asset Value

### **Key objective:**

Successfully convert priority opportunities to license deals

### **Key priorities:**

- 1. Signing partnership deals for priority assets, DEP® irinotecan and DEP® cabazitaxel
- 2. Advance Radio and ADC assets



- DEP® asset and indication prioritisation
- Enhanced BD capability (internal and external)



- License deals
- Revenue generated

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### Current DEP® Portfolio and Next Steps

Product	Target indication	Research	Pre-clinical	Phase 1	Phase 2	Goal / Next Steps
DEP° cabazitaxel	Prostate and other cancers	Phase 2 complete & results reported			License – Prostate, Ovarian	
DEP° irinotecan	Colorectal and other cancers	Phase 2 recruitment complete & results to be reported ahead of ASCO			License/co-develop – Ovarian, Colorectal	
DEP° docetaxel	Pancreatic and other cancers	Phase 2 complete & results reported			Active outreach paused	
DEP® HER2 radiodiagnostic	Diagnostic				Optimise and accelerate to pre-clinical	
DEP® HER2 radiotherapeutic	Solid cancers				Continue pre-clinical	
DEP® HER2 ADC	Solid cancers					Advance to pre-clinical



## DEP® Clinical Assets Offer a De-risked Development Program with an Established Market Opportunity



Chemotherapies remain standard-ofcare and form the backbone of many cancer treatments



DEP® delivery improved tolerability and anticancer efficacy in multiple cancers in Phase 2 studies



Demonstrated ability to overcome anticancer treatment resistance / failure in patients previously treated with the originator drug



Translation of preclinical findings (pharmacokinetics, efficacy and safety) to the clinic; GMP manufacture



Potential for a partner to leverage accelerated development/regulatory pathways (e.g., Fast Track, 505(b)(2))



Patent filings up to 2039, plus potential for up to an additional ~5 years

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### Partner for DEP® Clinical Assets

### Potential deal structures

	Big Pharma or Mid-Tier or Specialty Pharma					
Global		Regional e.g. EU/North America	Country e.g. China, Japan			
Benefits	<ul> <li>Single partner -         one commercialisation plan</li> <li>Well resourced</li> </ul>	<ul> <li>Core expertise in regional regulatory guidelines</li> <li>Adapt to regional and country market dynamics</li> <li>Greater interest in partnering earlier</li> </ul>	<ul> <li>Country-centric development and commercialisation plan</li> <li>Focus on large single markets e.g. US, Japan, China</li> </ul>			
Risks	<ul><li>Lower priority in broad portfolio</li><li>Prefer to wait for Phase 3 data</li></ul>	<ul> <li>Resource intensive to find the right partners</li> </ul>	Third party support required			

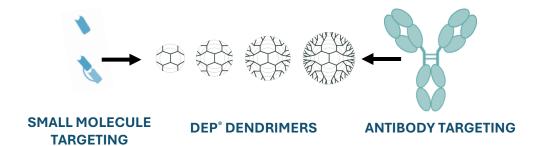


# DEP® Dendrimers: Bridging the Gap for Precision Cancer Radiopharmaceuticals

Radiopharmaceuticals help realise the potential of personalised medicine through achieving selective and targeted precision tailored to a patient's specific disease or biological target



DEP® dendrimers bridge the gap between small molecule and antibody targeting for tunable, precision radiopharmaceutical delivery



### Why we're targeting HER2+ cancers

- HER2 is a validated and important marker in many cancers, including breast and gastric
- Current diagnostic approaches have limitations
- Unmet need matched by HER2 targeted radio-diagnostic
- Current ADC-directed therapies are associated with significant toxicities

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Commercial opportunity



# Radiopharmaceuticals and ADC Development Update

### **DEP® Radiopharmaceuticals**

#### **DEP® HER2-radiodiagnostic**

For whole-body localisation of HER2+ tumours, to aid in diagnosis, staging and monitoring therapy

**DEP® HER2-radiotherapy** 

For targeted treatment of HER2+ tumours

- ✓ Rapid and significant tumour accumulation
- ✓ Rapid clearance from blood
- ✓ High tumour-to-blood and tumour-to-organ ratios, excellent imaging contrast achieved in vivo
- Can achieve limited exposure to radio-sensitive organs (e.g., kidney, bone marrow) for therapeutic applications

#### What's next:

- Candidate optimisation
- Implementation of required preclinical studies
- ☐ Clinical trial preparations for first-in-human radiodiagnostic study in CY25

### **DEP® Antibody-drug Conjugates**

#### **DEP® HER2-ADC**

For targeted treatment of HER2+ tumours

- Higher drug-to-antibody ratio (DAR) than standard ADC
- ✓ Highly water-soluble despite higher DAR for an insoluble drug payload
- ✓ Flexible linker strategies to achieve precisely controlled drug release

#### What's next:

- Candidate optimisation
- ☐ Implementation of required preclinical studies to demonstrate proof-of-concept



### Starpharma, Refocused

### Three key focus areas to optimise shareholder returns

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Build long-term sustainability



### Accelerate Early Asset Development

### **Key objectives:**

- Increase # assets in early development
- Increase efficiency of early development

### **Key priorities:**

- Advance Genentech and MSD
- Establish innovation / collaboration hub
- Petalion milestones



- Approach to asset candidate identification
- Models for partner engagement
- Pace of development

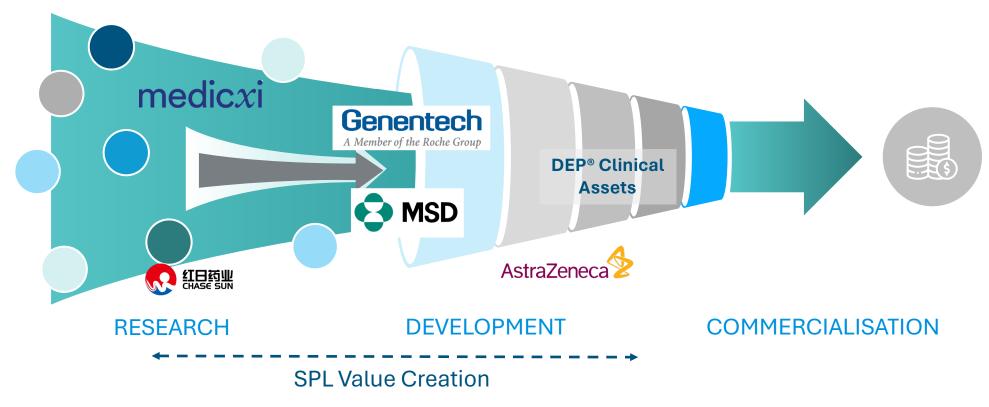
#### **KPIs**

- Partnerships and license conversion
- Asset progression and milestone achievement



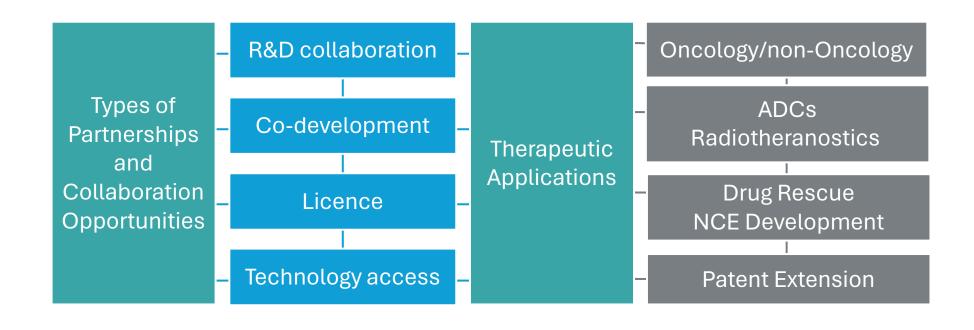
### **Accelerate Early Asset Development**

Increasing collaboration opportunities with the aim of successfully progressing through to partnering for value creation (e.g., development, commercialisation or asset sale)





### Early-Stage Partnerships / Collaborations



Current Active Partnerships









### Our Strategic Partnership with medicxi

Medicxi is a leading healthcare investment firm with a track record of success, and a partner of choice for the development and commercialisation of novel therapies using Starpharma's dendrimer technology

#### **Recap of the partnership**

- Medicxi and Starpharma have co-created a new company called Petalion Therapeutics to develop a single asset
- SPL receives 22.5% equity in Petalion in exchange for licensing specific IP
- SPL maintains background IP
- SPL Board member appointed
- Target and investment milestones commercial in confidence

#### Why this is important for SPL now

- Asset-centric approach with financial and R&D resources and a highly experienced team to support
- SPL revenue stream from fee-for-service development work
- Ability to learn and demonstrate accelerated research and development



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### **Build Long-term Sustainability**

### **Key objectives:**

- Build revenue and manage costs
- Create a self-sustaining organisation

### **Key priorities:**

- License revenue
- Digital marketing capability to deliver Viraleze™ strategy
- VivaGel® partner(s) for EU and Asia
- IP prosecution



### What is changing?

- Digital consumer strategy for Viraleze<sup>™</sup> in the UK and Europe
- Address capability gaps

#### **KPIs**

- Marketed product sales
- Total Shareholder Return (TSR)
- New IP created



### Increase VivaGel® BV and Viraleze™ Revenue

#### VivaGel® BV

- Registered in more than 40 jurisdictions, including in the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.
- Partnered with Aspen (Australia and New Zealand) and ITROM Pharmaceutical Group (Middle East and North Africa) for sales and marketing.

#### Viraleze™

- Registered in more than 35 jurisdictions\*, including in Europe, the UK, and Asia.
  - Awaiting TGA outcome.
- Primarily sold online, with local supply and distribution partners in Vietnam, Hong Kong and Macau.



### **Priorities going forward**

- Maximise asset value by:
  - Securing new partners in regions where there is a clear opportunity and business case.

**Fleurstat** 

- Focusing marketing and regulatory efforts on countries/regions with high potential growth only.
- Aligning and building brand positioning with partners.



### **Build Long-term Sustainability**

### Financials

- Increase revenue: licensing, Viraleze™ and VivaGel® sales
- Effectively manage fixed and variable costs

### People

- Enhance performance culture
- Address capability gaps to deliver strategy

### Intellectual Property

- Protect background IP for DEP®
- Continue to generate new IP in novel areas

### **ESG**

- Environmental impact
- Society / patient impact

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### Short- and Medium-Term Priorities

Our Approach	Immediate 0 – 9 months	Short 9 – 18 months	Medium 18 – 24 months
Maximise DEP® asset value	<ul><li>License DEP® asset/s</li></ul>	<ul> <li>Radio and ADC Development</li> </ul>	Radiotheranostic collaboration
Accelerate early asset development	<ul> <li>Advance radiodiagnostic</li> <li>Partner Milestones – MSD, Genentech and Petalion</li> </ul>	<ul><li>New collaborations</li><li>New target assets</li></ul>	<ul><li>New collaborations</li><li>New asset development</li></ul>
Build long-term sustainability	<ul><li>Viraleze UK &amp; EU webstore digital marketing</li><li>Increase Viraleze webstore sales</li></ul>	<ul><li>VivaGel® BV license partnership</li><li>Sustainable income streams</li></ul>	<ul><li>IP strategy review</li><li>Considered investment in new candidates</li></ul>



### Leadership Team For Q&A Session



Cheryl Maley, BSc, DipEd, MBA, GAICD

### **Chief Executive Officer and Managing Director**

- >25 years experience in the pharmaceutical industry, including at Novartis and AbbVie.
- Extensive experience in leading pharmaceutical innovation, marketing, commercialisation, and delivering business growth across Australia, Asia, and international markets.
- Strong commercial background with a proven record in successful product launches and patient access and reimbursement to innovative medicines.



Justin Cahill, BBus, MPA, CPA
Chief Financial Officer and Company
Secretary

- >15 years of experience in corporate finance and leadership roles in the biopharmaceutical, food, and agricultural sectors for both ASX-listed and private companies including CSL.
- Justin has managed financial performance, planning and reporting, compliance, and capital control for global companies, including CSL and Costa Group.



Jeremy Paull, BSc (Hons), PhD Vice President, Development and Regulatory Affairs

- >20 years of experience in pharmaceutical and MedTech product development, regulatory affairs, and commercialisation.
- Jeremy has managed all aspects of development and commercialisation projects for multiple products in areas including HIV/STIs, COVID-19, women's health, dermatology, and oncology, and has achieved market approval and commercialisation of products in multiple global markets.



Tony Eglezos, BSc (Hons), PhD, MBA Vice President, Business Development

- >30 years in the pharmaceutical industry in Australia, the US and Europe for companies including CSL, Amgen and Abbott.
- Extensive experience in global business development, commercialisation and management, including licensing and partnerships, acquisitions and due diligence, product and IP commercialisation.



## Q&A



Presented By: CEO, Cheryl Maley

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ASX: SPL

OTCQX: SPHRY

## Thank you.

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