



**ASX:SPL; OTCQX:SPHRY** 

ASX Spotlight New York March 2015



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.

# **Starpharma Holdings – Snapshot**

- starpharma

- ASX listed company (ASX:SPL, OTCQX:SPHRY )located in Melbourne,

  Australia
- Market Cap ~ A\$ 165M
- Deep product portfolio of commercial and late stage products based on novel polymer (dendrimer) platform:
  - Highly versatile drug delivery platform in the clinic (DEP™ docetaxel)
  - VivaGel® portfolio : 2 late-stage women's health (BV) products &
     World's first antiviral condom (marketed)
- Strong cash position (31 Dec 2014 \$39.3M)
- Strong share register ~30% international institutions

### **Analyst Coverage**









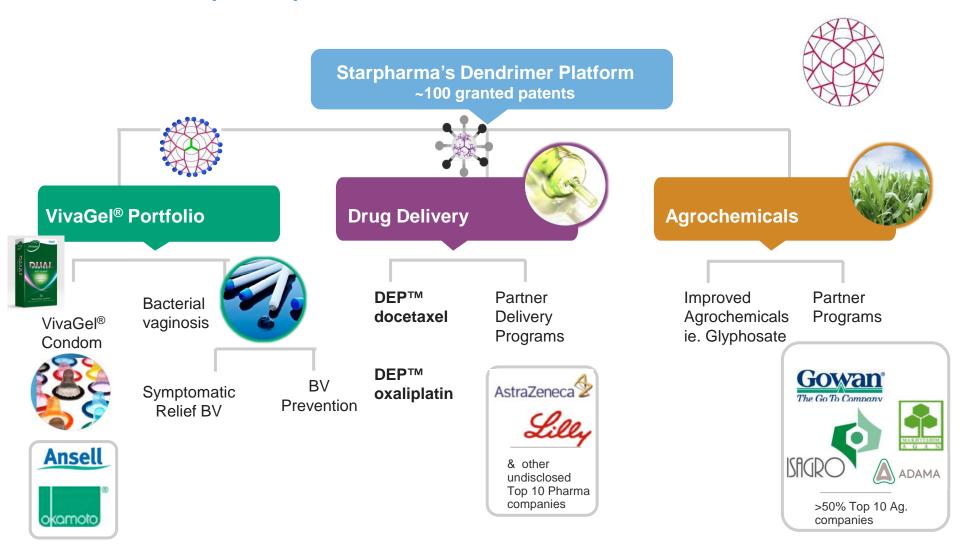






Starpharma is a global leader in products utilising nanoscale polymers (dendrimers)

Potential for multiple and parallel revenue streams





### Pharmaceutical Development Portfolio – Recent Progress and Plans

			Res	PC	Phl	Phll	PhIII	Reg.	Mkt
	VivaGel <sup>®</sup>	BV Symptomatic Relief					(		
Antimicrobial / Antiviral	VivaGel <sup>®</sup>	BV Prevention of Recurrence				(			
(SPL7013)*	VivaGel <sup>®</sup>	VivaGel <sup>®</sup> Coated Condom						-(	
	Drug Delivery	DEP™ Docetaxel (various cancers)							
Oncology	Drug Delivery	DEP™ Oxaliplatin							
(Internal)	Drug Delivery	Various oncology DEP™							
Undisclosed	Partnered programmes	Drug Delivery - Various							





- 1. SPA Granted for Phase 3 BV Prevention; Trial underway
- 2. TGA certification for VivaGel® Condom; Launch
- 3. Positive early data in DEP™ docetaxel trial
- 4. BV Symptomatic Relief Submissions planned H1 2015







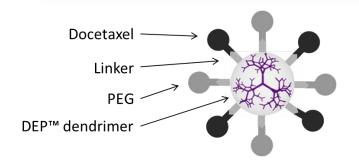
### Starpharma's DEP™ docetaxel: Multiple benefits

- Docetaxel (Taxotere®) is a blockbuster chemotherapeutic
- Docetaxel sales US\$3.1B(2012)
- Docetaxel is used in major cancer types including breast, prostate and lung cancer
- Docetaxel is insoluble so Taxotere® incorporates a detergent (polysorbate 80) to solubilize, which is associated with significant toxicity
- Starpharma's patented DEP<sup>™</sup> docetaxel is a nanoparticle formulation with multiple advantages compared to Taxotere<sup>®</sup>
- Patents filed will offer coverage to 2032
- DEP<sup>™</sup> docetaxel Phase 1 Trial underway



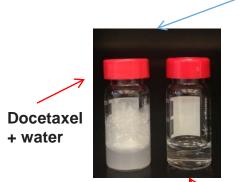
### **DEP™** docetaxel vs. Taxotere®

- Elimination of major dose-limiting toxicity (neutropenia)
- Improved water solubility allowing removal of toxic components
- 3. Tumour-targeting
- 4. Extended half-life
- Improved efficacy (breast, ovarian, prostate)





# DEP<sup>™</sup> docetaxel preclinical: Multiple Benefits Better efficacy <u>and</u> less toxicity

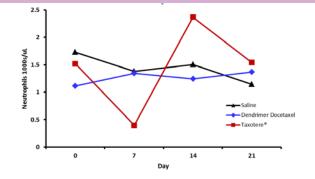


DEP™ docetaxel:
solubility
enhancement
>↑ 20,000x
polysorbate 80-free

# Enhanced Safety & Less toxicity

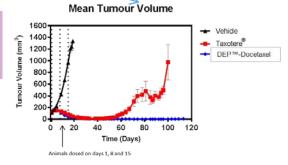
### **Enhanced Efficacy**

Complete lack of neutropenia with DEP™ docetaxel cf. severe neutropenia for Taxotere®

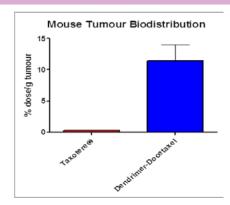


DEP<sup>TM</sup> Docetaxel formulation and Taxotere® at equivalent doses (based on docetaxel; 9mg/kg); n=6 rats/group

DEP™ docetaxel: improved pharmacokinetics vs. Taxotere®



Tumour Targeting:
DEP™ docetaxel > 40 fold greater
accumulation in tumour
vs. Taxotere®



# DEP™ docetaxel: Phase 1 Clinical Trial - Encouraging clinical data



- Underway at 3 Australian sites\*; Open label study allowing progressive results
- Estimated sample: 25-30 cancer patients (various solid tumours)
- DEP™ docetaxel administered every 3 weeks; no steroid pre-treatment

### **Primary Objectives:**

Establish the maximum tolerated dose (MTD) and dose limiting toxicities (DLT) for DEP™ docetaxel

### **Secondary Objectives:**

- Characterise safety and tolerability
- Characterise pharmacokinetics and define dose for Phase 2; Explore preliminary anti-tumour efficacy with CT scans, bone scans, tumour markers etc.

### **Current Status and Preliminary Findings**

- Patients currently being enrolled in dose escalation phase; several dosed with multiple cycles
- Approaching 50% recruitment
- DEP™ docetaxel well tolerated; No neutropenia (docetaxel DLT), nor hair loss observed so far
- Not yet at the MTD but a number of patients have exhibited potential anticancer activity (one with stable disease over > 20 weeks)
- Expansion phase to follow at MTD

# DEP docetaxel® Pharmacokinetics (PK) in humans cf. Taxotere®^



### 1. Extended duration of exposure with DEP™ docetaxel

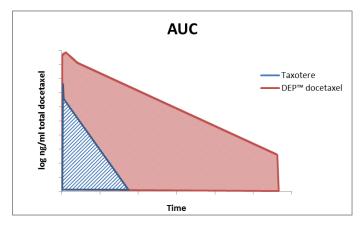
 DEP<sup>™</sup> docetaxel plasma half-life substantially longer (~8 x) than Taxotere<sup>®</sup> (~150x longer in the initial, rapid phases of plasma clearance)

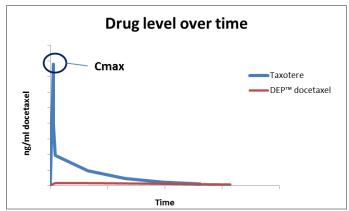
### 2. Increased extent of exposure with DEP™ docetaxel

- DEP<sup>™</sup> docetaxel drug exposure (Area Under the Curve /AUC) for total docetaxel, is ~500-800x times greater than an equivalent dose of docetaxel administered as Taxotere<sup>®</sup>
- reflects the gradual release of docetaxel (DEP™ docetaxel acts as a 'depot' of docetaxel )

### 3. Reduced peak drug levels with DEP™ docetaxel

 Cmax (peak blood level) of docetaxel is substantially (~50-100 times) lower than the Cmax of an equivalent dose of docetaxel administered as Taxotere<sup>®</sup>





Example plasma drug levels over time DEP™ docetaxel vs.Taxotere®)

^ Taxotere® parameters based on published data (Bruno et al, 1996)

# DEP<sup>™</sup> docetaxel compared with BIND's docetaxel Compelling product benefits for DEP<sup>™</sup>

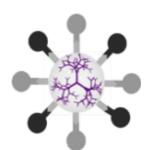


Aspect	BIND	DEP™ docetaxel	Starpharma Benefit
Manufacture	complex, self assembled particles; potential inconsistency b/w batches; Untested with FDA	Standard chemistry	SPL dendrimer manufacture is readily scalable and validated through extensive FDA input
Stability	self loading particle; inherently unstable	Excellent stability	Important for drug approval, storage and subsequent shelf life
Drug loading w/w	10%	25%	SPL delivers higher dose per mg of drug
Particle Size	60-120nm	10-15nm	Smaller particles enter tissues more easily
Tumour concentration of active	10-20x	30-60x	Higher level of docetaxel delivery to tumour SPL - better efficacy & reduced toxicity
Plasma Half life	6-20 hours	>50 hours	Longer duration of effect, less frequent dosing and greater anti cancer effect
Enhanced Solubility?	No	water soluble; ~ 20,000 fold increase	Water soluble; safer formulation (see "polysorbate 80" below)
Neutropenia prevented	No	Yes	Avoids risks & need for expensive rescue therapies / GCSF and hospitalisation
Polysorbate used	Yes - cortisone pre-treatment required	No - cortisone pre-treatment is not required	Avoids potentially fatal toxicities with polysorbate-containing formulations



# Starpharma's DEP™ oxaliplatin: Multiple benefits

- Dendrimer Enhanced (DEP™) oxaliplatin is a proprietary dendrimer version of blockbuster cancer drug, oxaliplatin (ELOXATIN®, Sanofi)
- Oxaliplatin sales ~ US\$2B (2012)
- Neuropathy is reported in ~90% patients and Neutropenia in > 70% receiving ELOXATIN<sup>®</sup> (standard oxaliplatin)



### **SPL's DEP™ oxaliplatin**:

- Several important benefits vs. Eloxatin®
- Granted patents to 2028; additional filings to 2034
- Preclinical development underway

#### DEP™ oxaliplatin vs. Eloxatin®

- 1. Improved efficacy (colon cancer model)
- 2. Extended half life (> 50x oxaliplatin)
- 3. Protection against primary dose–limiting toxicity, neurotoxicity
- 4. Protection against neutropenia



# Starpharma's DEP™ - a true platform Multiple, reproducible benefits in major oncology drugs

Attribute	DEP™ docetaxel	DEP™ oxaliplatin	DEP™ doxorubicin
Elimination or Reduction of major dose-limiting toxicity	√	✓	✓
	(neutropenia)	(neurotoxicity)	(cardiotoxicity)
Water soluble – Polysorbate 80 free	√ (x20,000)	NA	NA
Tumour-targeting (passive)	√	√	√
	(>40-fold)	(>40-fold)	(>40-fold)
Extended half-life	✓	✓	✓
	(x60)	(x60)	(x60)
Efficacy	√ (various cancer models)	√ (colon cancer model)	✓ (MTD twice that of originator)

# Additional DEP™ candidates



SPL's dendrimer enhanced product (DEP™) nanoparticle technology

- -broad applicability, especially in oncology
- -allows for new patent filings creating proprietary products
- Proof of DEP™ concept for docetaxel, doxorubicin, oxaliplatin, methotrexate, gemcitabine and paclitaxel, proteins (insulin), peptides and Targeted agents (ADCs)
- A number of additional DEP™ candidates from the list below are currently in preclinical testing

				Sales (US\$ M)	
Brand	Generic Name	Type of Drug	Innovator Company	2013 Sales	Peak Sales (prior to loss of exclusivity)
Alimta	Pemetrexed	Anti-metabolite	Eli Lilly	2,703	
Eloxatin	Oxaliplatin	Cytotoxic	Sanofi Aventis		2,293
Gemzar	Gemcitabine	Anti-metabolite	Eli Lilly		1,720
Camptosar	Irinotecan	Cytotoxic	Pfizer		1,100
Herceptin	Trastuzumab	Antibody	Roche	6,562	
Kadcyla	ado-trastuzumab emtansine	ADC	Roche	253*	
Adcetris	brentuximab vedotin	ADC	Takeda	285*	

<sup>\*</sup> Adcetris launched 2011; Kadcyla launched 2013



# **DEP™** insulin – Improved pharmacokinetics (long acting)



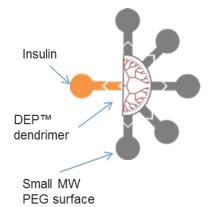
# Efficacy and Duration of action^ 500 400 300 DEP™ insulin 1 day DEP™ insulin 1 week

84

Time (hours)

96

DEP™ insulin –



12

24

36

0

0

^Glucose Time Course study in the STZ induced diabetic SD rat model after a single subcutaneous injection.

108 120 132 144 156 168



# **VivaGel® Condom – World's first antiviral condom star Lifestyles® DUAL PROTECT ™ - Available in Australian retail outlets**







THE WALL STREET JOURNAL

# FINANCIAL REVIEW



ELITE DAILY
The Voice of Generation-Y

The GIZMOD Washington

Times N

**GLAMOUR** 

ABC

Daily **Mail** 



IFL Science posted a story on Dual Protect™->83,000 Likes; shared > 18,000 times

>2,000 Tweets; including Perez Hilton to

~5.9m followers



DUAL PROTECT™ with VivaGel®:

Iubricated with **VivaGel®** which has been shown to **inactivate up to 99.9% HIV, HPV and HSV (Herpes)** in laboratory studies

# VivaGel® condom: A compelling and differentiated product



### Extensive consumer research of the VivaGel® condom^:

- Confirms strong interest and purchase intent (~90%)
- Strong consumer interest across genders, ages and relationship status

Percentages shown are the 'top-2-box' scores	TOTAL		i	18-30 years	31-40 years	41-50 years
Level of interest	85%	88%	82%	87%	86%	82%

"I would buy this product right now if I could....."

"I like the idea of a condom doing more for us than just being a barrier....seems more reassuring to know it's doing extra"

"I would definitely buy this product without a shadow of a doubt...." VivaGel® Condom Consumer Research "I think that this product is amazing...... This product is very special and interesting."
"I have rated this product a 5/5 as this is a major breakthrough in the condom market and for World health..."

VivaGel® Condom Consumer Research

Ansell

"Our partnership with Starpharma is a great example of two highly innovative companies working together to bring to market a groundbreaking new sexual health product.

New product development is central to Ansell's business strategy and this highly innovative product is exciting for both companies."

Vice President, Asia Pacific – Sexual Wellness Division

marie claire WINNETS



If it's on, it's not completely foolproof: condoms aren't 100 per cent effective at preventing pregnancy or STIs. But that could be a thing of a past, if Australian biotech firm Starpharma has its way. The company has teamed up with Ansell to incorporate an antiviral gel into condoms that tests show can kill up to 99.9 per cent of HIV, herpes and some other STIs – effectively doubling up on your protection.

AUSTRALIADECEMBER 2014 AUSTRALIA



# **VivaGel® condom: A compelling and differentiated product**

- Condom coated with SPL's patented antiviral lubricant (VivaGel®)
- VivaGel® shown in laboratory studies to inactivate up to 99.9% HIV, HPV & Herpes
- Licensed to Ansell and Okamoto (SPL receives royalties on sales)
- Regulatory Certification received in Japan and Australia, NZ other filings in progress
- Product selling in Australia under Lifestyles Dual Protect<sup>™</sup> brand
- Extensive international consumer research indicates strong consumer interest
- Branded global condom market: \$1.1B

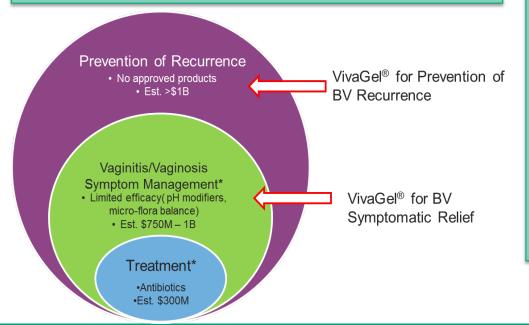
Partner	Market Position/Share	Major Brands	
Okamoto Industries (listed on TSE)	<ul> <li>No. 1 in Japan with ~60% Japanese market (the 2nd largest condom mkt. Est. ~US\$500M)</li> <li>Total revenues &gt;US\$760M</li> </ul>	Skinless®	© 003
Ansell Limited ASX:ANN	<ul> <li>No. 2 globally for condom sales ~ 20% global share of</li> </ul>	Lifestyles® SKYN®	LifeStyles.
Ansell	branded condom market (~\$1.1B)	ZERO® Manix®	Zero skyn

# VivaGel®- Bacterial Vaginosis (BV) Two attractive commercial opportunities

### **Bacterial Vaginosis:**

the most common vaginal infection worldwide

- ~29% women infected in US; up to 51% in some groups
- Recurrent BV an issue in 50-60% of BV sufferers
- Current therapies have low cure rates and nasty side effects
- No approved products for Recurrent BV (R-BV)







- "It was like gone almost overnight"
- "I would definitely use it again."
- "The next day I noticed a huge difference."
- "I would use it....I will use it indefinitely..."

VivaGel® Trial Participants

#### **Product Proposition:**

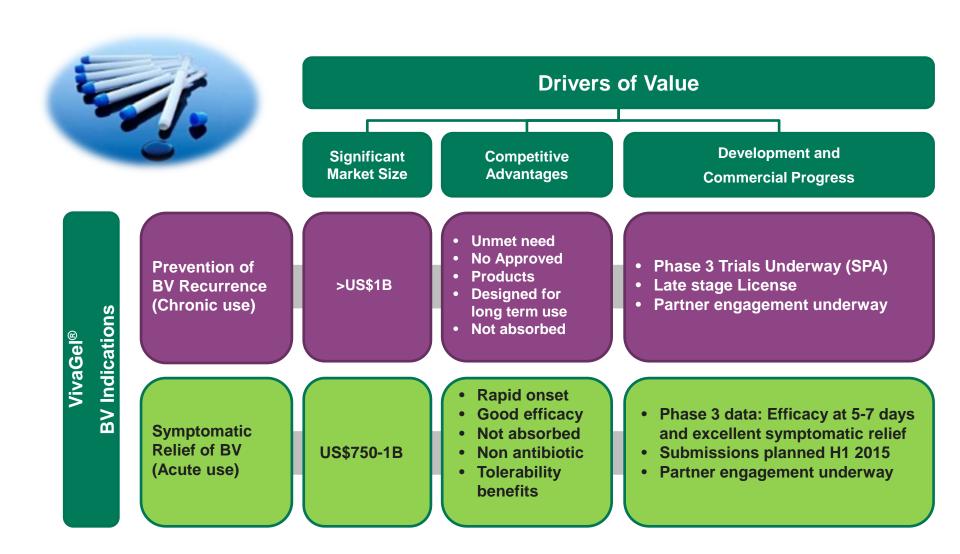
#### VivaGel®:

- a <u>non-antibiotic therapy</u>
- management of BV symptoms and
- prevention of Recurrent BV
  - a selective antimicrobial effect for pathogens that cause BV
  - a local effect and is not systemically absorbed
  - Large market opportunity for both prevention of recurrent BV and BV Symptomatic Relief

\* Global Data, IMS, various Industry reports,



# VivaGel® for Bacterial Vaginosis: Two product opportunities





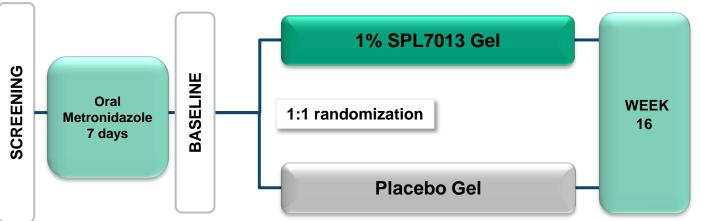
# **BV Prevention of Recurrence Phase 3 Program Two double-blind, multi-centre, randomised trials**

SPA granted by



#### **PERIODIC STUDY VISITS**

Primary Endpoint: Recurrence of BV at or by week 16 visit



12-weeks follow-up

16-WEEK TREATMENT PERIOD
(DURING WHICH PRIMARY ENDPOINT IS MEASURED)

Dosing regimen: 5g gel every second day at bedtime

SPA granted by FDA on trial design (EMA agreement also gained)

Phase 3 Trials underway with Quintiles



# VivaGel®: Symptomatic Relief of BV

### VivaGel® (once a day for 7 days):

- Two double-blind trials under IND (250p/trial) demonstrated statistically significant Clinical Cure at the end of treatment (EOT)
- VivaGel® resulted in rapid and sustained relief from symptoms
- Very positive Patient acceptability, excellent safety profile including very low rates of candidiasis
- FDA Treatment endpoint (Cure 2-3 wks following treatment cessation)
   not met

# Given the excellent symptomatic relief shown for VivaGel® and positive consumer feedback:

- Symptomatic Relief product submissions planned H1 2015
- Symptomatic Relief Product under active discussion with a number of interested commercial partners

Prevention of Recurrence

No approved products
Est. >\$1B

Vaginitis/Vaginosis
Symptom Management\*
• Limited efficacy(pH modifiers, micro-flora balance)
• Est. \$750M – 1B

"It was like gone almost overnight"

"I would definitely use it again."

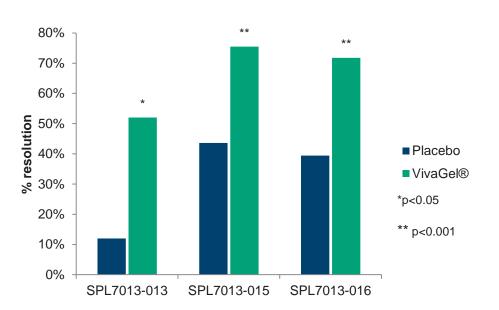
"The next day I noticed a huge difference."

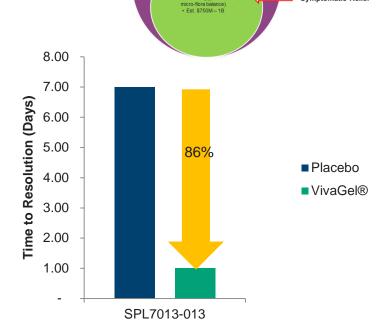
VivaGel® Trial
 Participants



Symptomatic Relief

**VivaGel® - Symptomatic Relief Odour Resolution – % resolved and time to resolution** 





Prevention of Recurrence

Symptom Management<sup>a</sup>

### **VivaGel® - 3 Clinical trials**

In 3 separate randomised, placebocontrolled trials VivaGel® consistently provided a statistically significantly greater improvement in odour resolution as compared to placebo Time to resolution of odour, as reported by patients, showed that VivaGel® resolved odour in 1 day, compared to 7 days for placebo





# The Opportunity for Starpharma's Priostar® Dendrimers in Agrochemicals

### The Challenge for Agrochemical Companies

- The cost and risk of registering new agrochemical actives to market is rising.
  - → fewer new actives being developed (~70 → 30 between 2000 and 2012)
- Agrochemical companies have more focus on creating new products with <u>existing actives</u>
- However most formulation components are available to all formulators



Challenge for agrochemical companies...

How to create defendably differentiated products without new actives?

# Priostar® benefits for innovative crop protection formulations

### Better in the can:

- Solubility enhancement
- Increased loading
- Formulation stability
- Reduction/removal of solvents – "greener" formulations

#### Better in the field:

- Increased efficacy
- Modification of soil penetration
- Protection of Actives



Starpharma's Patented Priostar® offers...

Improved formulations with high barrier to entry for competitors, with or without new actives

# **Starpharma's Agrochemical Programs**



### **Partnered Programs**

 During 2013/2014 seven new agreements have been signed with leading agrochemical companies in Europe, Japan and USA



- Several have now progressed to field trials, with positive interim results
- Anticipate move towards product registration subject to continued positive results
- Priostar® exclusivity offered in a region on a per active basis
  - → multiple potential opportunities for revenue streams
- Estimated value of partners" share of market for actives under development: >US\$5B

### **Internal Programs**

- SPL is also developing a small number of complete formulations of selected generic actives with enhanced characteristics
- Several programs, including glyphosate, are underway with numerous field trials conducted through the year
- Field trials conducted both domestically and internationally to address different regional weed populations for global coverage
- Internal development candidates include (USD sales 2012):

Glyphosate	(\$4-5B)	Improve efficacy
Metolachlor	(\$605M)	Improve efficacy
Deltamethrin	(\$340M)	Improve efficacy/ remove solvent
Propiconazole	(\$350M)	Improve efficacy / Loading
Imidacloprid	(>\$1B)	Improve efficacy / Loading





Key Financial Data (Financial Year to 30 June)	FY 2014 AUD \$M	FY 2013 AUD \$M	FY 2012 AUD \$M
Total revenue and income	1.3	2.4	2.9
<b>R&amp;D Tax Incentive</b> # incl. \$4.1M from FY2012 expenditure	4.2	8.7#	1.3
Net loss after tax	(14.6)	(5.2)	(13.7)
Cash outflow from operations	(9.8)	(9.8)	(9.8)
Cash at 30 June	24.0^	33.8	42.8

^Cash at 31 Dec 2014 \$39.3M

**Analyst Coverage** 



CANACCORD Genuity

**BELL POTTER** 







### **Expected Short-Medium Term News Flow**

#### VivaGel® Portfolio:

- Regulatory filings for BV Symptomatic Relief product
- Commercialisation agreements for BV Symptomatic Relief product
- Progress VivaGel® Phase 3 BV Prevention of Recurrence trials
- Launches of VivaGel® condom, further approvals/geographic roll-out

### **DEP™** Delivery technology:

- Further data from DEP<sup>™</sup> docetaxel clinical trial
- Complete DEP<sup>TM</sup> docetaxel clinical trial
- Partnered program announcements and new deals
- Advance additional DEP<sup>TM</sup> candidates through preclinical and into clinic

### **Dendrimers in Agrochemicals:**

- Advance internal candidates eg. glyphosate (Roundup®) including regulatory-compliant field trials
- Pre-registration activities to support commercialisation
- Partnered program announcements eg. Licences from existing and new deals



# **VivaGel®**

# **Drug Delivery**







Dr. Jackie Fairley CEO ph: +61385322704



e: <u>investor.relations@starpharma.com</u> <u>jackie.fairley@starpharma.com</u>

