

#### Starpharma presenting at Bell Potter LifeScience Conference

**Melbourne Australia**; **1 November 2012**: Starpharma Holdings Ltd (ASX:SPL;OTCQX: SPHRY) will today present at the Bell Potter LifeScience Conference for professional and sophisticated investors.

The conference is expected to be attended by more than 150 people including the leading institutional investors, high net-worth investors, and other influential industry players.

It follows Starpharma's success in winning the *Company of the Year Award* presented last night as part of the Janssen 2012 Industry Excellence Awards at the AusBiotech 2012 Conference.

Starpharma chief executive officer Jackie Fairley will be presenting.

Highlights of the presentation include:

**VivaGel® Bacterial Vaginosis:** This program is nearing completion with the completion of recruitment in the two Phase 3 studies for VivaGel® as a treatment for BV. Results are expected to be available by early December 2012.

A Phase 2 clinical trial to investigate the ability of VivaGel<sup>®</sup> to prevent the recurrence of BV is now also fully recruited, and completion of this trial is on track for Q4 2012 with results expected early in 2013.

**Drug delivery program:** New data demonstrates Starpharma's dendrimer-docetaxel formulation has significant tumour-targeting results. Starpharma's partnered program is also progressing with a partnership allowing global pharmaceutical giant AstraZeneca to test whether Starpharma dendrimer molecules could enhance the effectiveness of existing cancer drugs.

**Agrochemical program:** A new dendrimer-glyphosate (the active ingredient in Roundup<sup>®</sup>) formulation demonstrated improved efficacy and rain-fastness in Starpharma's internal agrochemical program. Starpharma also has a collaboration that will see its dendrimer technology used to develop innovative crop protection formulations for Nufarm's product portfolio.

The presentation is attached.

#### 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 uses. Starpharma has three core development programs: VivaGel® portfolio, drug delivery, and agrochemicals with the Company developing a number of products internally and others via commercial partnerships.

Starpharma's lead product is VivaGel® (SPL7013 Gel), a gel-based formulation of a proprietary dendrimer. VivaGel® is under clinical development for the treatment and prevention of bacterial vaginosis (BV) and also as a vaginal microbicide to prevent the transmission of sexually transmitted infections including HIV and genital herpes. Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries Inc (Tokyo Stock Exchange) to market a value-added, VivaGel®-coated condom. Ansell manufactures and sells leading condom brands worldwide, including Lifestyles®, ZERO® and SKYN®. Okamoto is the market leader for condoms sold in Japan, the world's second largest condom market.

In the wider pharmaceutical and life science fields, Starpharma has both partnered and internal programs in Drug Delivery. Partners include GSK, Lilly and AstraZeneca. In its internal program Starpharma recently announced significant tumour-targeting results in its docetaxel (Taxotere®) program, with animal studies resulting in levels of the cancer drug in tumour tissue more than 40 times greater than seen with the convention formulation. The company is also exploring dendrimer opportunities in agrochemicals in a series of industry partnerships with leading industry players including Nufarm (ASX:NUF) as well as with internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®).

#### FOR FURTHER INFORMATION

#### Media:

**Buchan Consulting** 

Rebecca Wilson Mob: +61 417 382 391 rwilson@buchanwe.com.au

Haley Price

Mob: +61 423 139 163 hprice@buchanwe.com.au

#### Starpharma:

Dr Jackie Fairley, Chief Executive Officer +61 3 8532 2704

Ben Rogers, Company Secretary ben.rogers@starpharma.com

www.starpharma.com

#### **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 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 document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.



# Starpharma Holdings Limited ASX:SPL

# Bell Potter Life Sciences Conference

1 November 2012

Dr. Jackie Fairley CEO







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### Starpharma Holdings Limited – ASX: SPL

A Global Leader in synthetic, nanoscale polymers called dendrimers



## Starpharma has a versatile platform technology with a portfolio of advanced programs and commercial assets

#### 1. VivaGel® Portfolio:

- ➤ VivaGel® for Bacterial Vaginosis (BV): Late stage Clinical Asset
  - BV Treatment Pivotal Phase 3 Trials complete (under SPA)
  - BV Recurrence prevention Phase 2 underway
- ➤ Two attractive commercial partnerships for VivaGel®-coated condom: Ansell (#2 globally) and Okamoto, market leader in Japan
- ➤ VivaGel® Microbicide Gel for HIV/HSV2/HPV prevention (STIs) in Phase 2

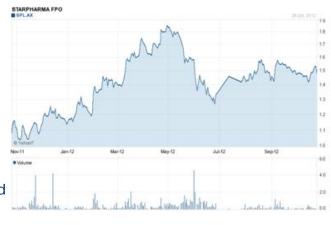
#### 2. Dendrimer Drug Delivery technology:

- Multiple Pharma. partnerships incl. Lilly, AstraZeneca, GSK plus multiple undisclosed
- Dendrimer-docetaxel demonstrated significant advantages vs. Taxotere®

#### 3. Dendrimers in Agrochemicals:

- ➤ Internal candidates in generic Agrochemicals incl. glyphosate (Roundup®)
- ➤ Multiple Agrochemical partnerships incl. Nufarm (NUF), Multibillion \$ US based Coy.

#### 29 October 2012 **Share Price SPL** A\$1.63 52 Week Range A\$1.025-1.88 **Shares on Issue** ~282.8 M Mkt. Cap. ~A\$460 M Cash 30/09/12 A\$37.6M Major Acorn, M&G, **Shareholders** Orbis, Dow 3 Year CAGR 40%









### Performance 2008 - 2012



- SPL has shown capital growth year-on-year
- •Market cap, ~\$450M ranks SPL 4<sup>th</sup> in Biotechs (excluding devices); joined ASX 300 2011
- •Strong and diversified portfolio for optionality in returns (VivaGel, Condom-coating, Delivery and Agrochemical)
- Major near-term milestones
- Strong cash position \$37.6M
- Shareholding increasing global: ~1/3 EU, 1/3 US and 1/3 Aust. & Asia

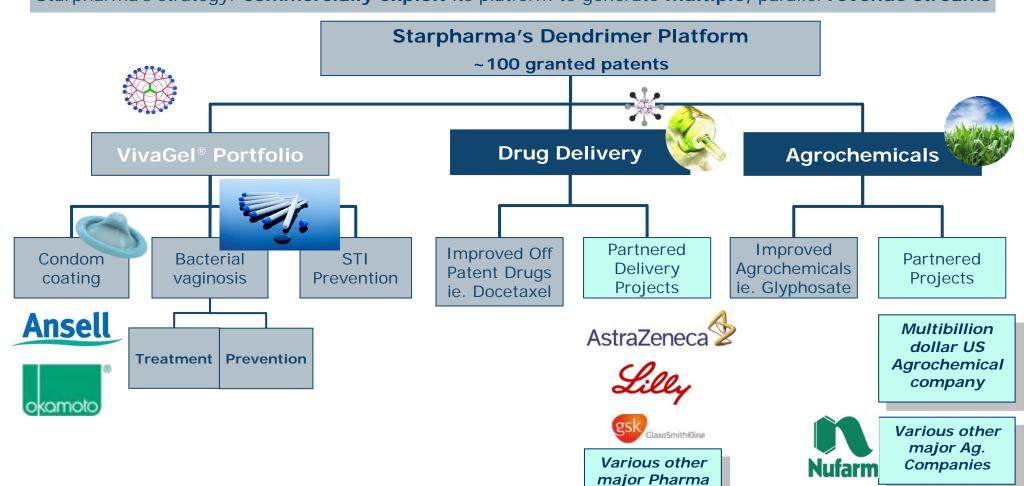






### SPL's Dendrimer technology platform

Starpharma's strategy: commercially exploit its platform to generate multiple, parallel revenue streams



companies

Other: **SIEMENS** 







### Starpharma's Major Commercial Partnerships

Starpharma's aim is to partner its dendrimers with market-leading companies





#### VivaGel® Condom coating

Commercial partnerships with Ansell and Okamoto (in Japan)







#### **Dendrimers for Drug Delivery**

Lilly (multiple), AstraZeneca, GSK; Drug delivery collaborations

- plus several undisclosed partnerships with Major Pharma. partners

Partnerships with leading global Ag. Companies



#### **Dendrimers for Agrochemicals**

Nufarm (NUF), Major US Ag. Company - plus various undisclosed partnerships

#### SIEMENS





#### **Stratus CS®**

Various diagnostics licensed to Siemens Healthcare (Dade Behring)

#### SuperFect®

Gene transfection technology licensed to Qiagen

#### Starburst®

Dendrimers commercially available via Sigma Aldrich

**Priofect®**: siRNA & DNA transfection reagents







#### VivaGel® Portfolio

VivaGel® active (SPL7013) is a potent antiviral and antibacterial

#### VivaGel®-Coated Condom





#### **VivaGel®**





Condom coated with patented antiviral

VivaGel® Kills ≥99.99% viral STIs 

( HIV & Herpes)

**Product** 

1. Bacterial Vaginosis (BV) Gel

2. Topical Microbicide Gel: for viral STIs (HIV, Herpes, HPV)

Ansell & Okamoto (Japan)

Commercialization Strategy

Late stage license

Branded Condom Market: \$1.1Bi

003

**Market Size** 

BV(treatment): \$350M BV(Prevention): >\$1 Bi

Combination Product (Device Branch review)

Regulatory path

Pharmaceutical; FDA Fast Track

7







### VivaGel® Coated Condom Partnerships

Ansell Limited (ASX: ANN) and Okamoto Industries

Partner	Market Position/Share	Major	r Brands
Okamoto Industries (listed on TSE)	<ul> <li>No. 1 in Japan with ~60% Japanese market         (the 2nd largest condom mkt. Est. ~U\$500M)</li> <li>No. 4 globally; strong positions in Korea,         Taiwan, Malaysia, Singapore, China</li> <li>Total company revenues &gt;USD 760M</li> </ul>	Skinless®  003®	003
Ansell Limited ASX: ANN Ansell	<ul> <li>No. 2 globally for condom sales ~ 20% global share of branded market ~\$1.1Bi</li> <li>No. 1 in Australia; Strong growth in USA, China, Brazil, India and Eastern Europe.</li> <li>Condom business growing ~18%</li> </ul>	Lifestyles®  SKYN®  ZERO®  Manix®	SKYN SS S SKYN

source: "^Condoms - a global strategic business report 2006", Annual Reports and industry data.



### VivaGel® - Bacterial Vaginosis (BV)

#### An Attractive Commercial Opportunity and Unmet Need



- ~29% women infected in US<sup>^</sup>; up to 51% in certain demographics
- Caused by overgrowth of pathogenic bacteria\* & reduction of normal flora (lactobacilli spp.)
- BV causes unpleasant discharge, irritation; PID/infertility, preterm birth, increased risk STIs eg. HIV

#### BUT <u>current antibiotic treatments have significant shortcomings</u>:

- High rate of recurrence (50-60%), low cure rates
- Adverse features: GI toxicity, 2° candida common, incompatibility with alcohol and condoms
- Are not suitable for long term use
- Antibiotic resistance is a significant issue
- Current global market for topical BV treatments : approx. US\$300-350M
- No products approved to prevent Recurrence (market est. >\$1 B)









### VivaGel® - Bacterial Vaginosis (BV) - An attractive Commercial Opportunity

2 separate product opportunities: Treatment and Prevention of BV Recurrence

Indication	Current Market/est.	Existing therapies	Stage of Development	Commercial Strategy
1. Bacterial Vaginosis Treatment	US \$300-350M (topical agents)	Metronidazole Clindamycin (antibiotics)	FDA Granted SPA*  Pivotal Phase 3 trials Complete; results Q4 ( 2 trials n~250 each)	Late stage License
2. Prevention of BV recurrence	Significantly larger vs. treatment:  Est. > US\$1 Bi.	None approved	Phase 2 Trial fully recruited; results Q1 2013 (n~200)	Late stage License

#### Benefits of VivaGel®:

\*SPA: FDA's Special Protocol Assessment

Comparable efficacy but Not systemically absorbed, lack toxicities associated with antibiotics, compatible with condoms, selective antimicrobial effect







### VivaGel® - Bacterial Vaginosis (BV) Treatment Phase 2 Trial Results

### VivaGel® demonstrates significant efficacy

- VivaGel® efficacy met study endpoints (n=132); P=0.006
- Comparable efficacy with conventional antibiotics (35-65%)
- VivaGel rapidly resolved symptoms of BV (1-4d): discharge (89%) and odour (78%)
- VivaGel® well tolerated, Patient satisfaction very high: 83% extremely satisfied/very/satisfied
- Trial results support new patent filing; will extend VivaGel® protection to 2032

Assessment	Time Point	1% SPL7013 Gel	Placebo Gel
Clinical	<b>EOT</b> (2-5d post Rx)	<b>74%</b> ** (P=0.0002)	22%
Cure^	TOC (2-3 wks post Rx)	<b>46%</b> ** (P=0.006)	12%

VivaGel® for BV Treatment	
Effective against the bacteria which cause BV	✓
Not absorbed into the blood stream	✓
Lacks common antibiotic side-effects	✓
Can be used with alcohol	✓
Compatible with condoms	✓
Designed to have minimal effect on 'good' bacteria	✓
Can be used long term	✓

<sup>\*\*</sup> Statistically significant result compared with placebo;

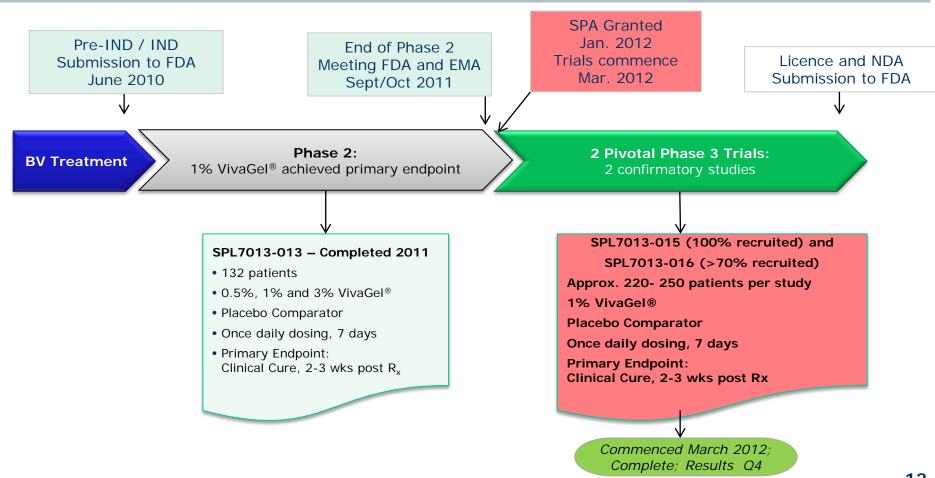






### VivaGel® - Bacterial Vaginosis (BV)

### Clinical Development Program



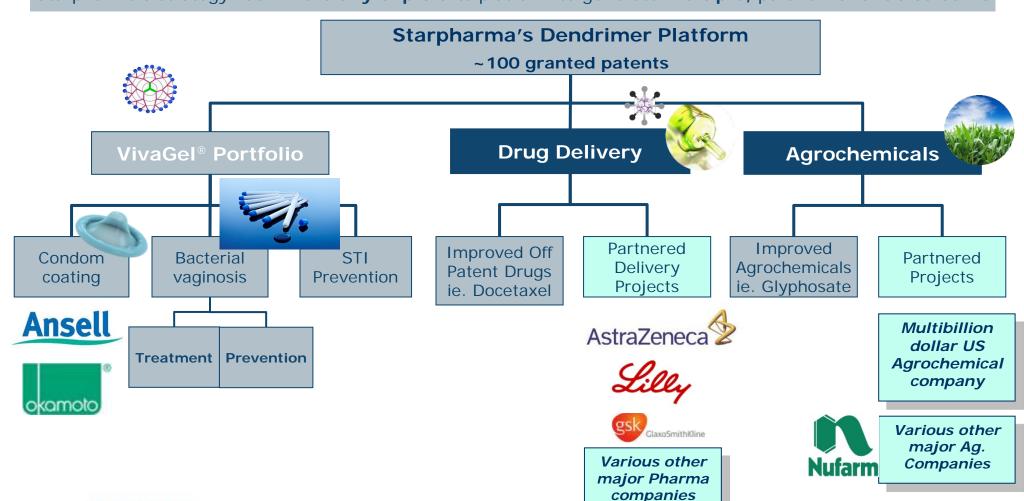






### SPL's Dendrimer technology platform

Starpharma's strategy: commercially exploit its platform to generate multiple, parallel revenue streams



Other: **SIEMENS** 

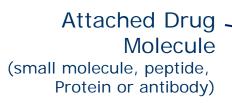


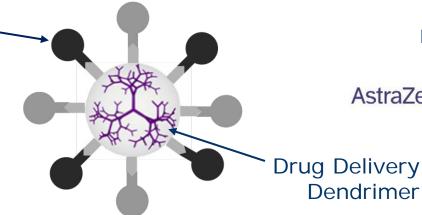




### Dendrimers for Drug Delivery

Key Advantages include: improved efficacy, reduced toxicity, less frequent dosing and new patents





Partners including:



gsk GlaxoSmithKline

Feature	Potential Benefits for Patients and/or Manufacturers
Improved Drug Efficacy	More effective treatments or lower doses
Reduced Toxicity of Actives	Reduced side-effects
Improved Drug Solubilisation	Less toxic formulations (allowing removal of toxic excipients)  Less painful injection formulations
Improved Pharmacokinetics	Less frequent dosing and less severe side effects
Targeted Drug Delivery	More effective treatments with reduced side effects
Product lifecycle management	Extension of patent life means lessened market risk for parties involved





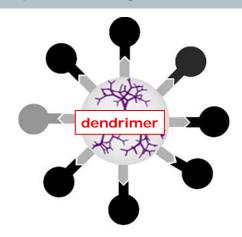


### Dendrimers for Drug Delivery - Proteins and Peptide Drugs

Longer half life – less frequent dosing







**Approach** 

Conjugate protein or peptide to functionalised dendrimer

Benefit

**Control half life** of protein or peptide therapeutics

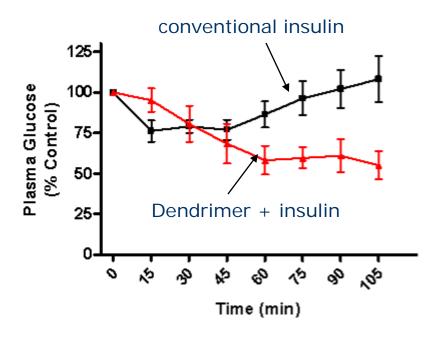
Improve dosing regimen Reduce protein metabolism

*in vivo* using insulin for proof of concept **achieved** 

#### **Status**

Co-development program with undisclosed partner

#### In vivo mouse model



Dendrimer insulin shows prolonged suppression of blood glucose *in vivo* 







### Starpharma's Dendrimer-Docetaxel formulation: significant improvement in solubility

Improved Docetaxel (Taxotere ®) Formulation

- Anti-cancer drug Docetaxel (Taxotere® Sanofi Aventis) Sales: US\$1.2Bi pa. (2011)
- Docetaxel is insoluble; Taxotere® incorporates a detergent which is associated with significant toxicity
- Starpharma's aim: to develop a reformulation of docetaxel with benefits: longer half-life in the body, enhanced efficacy and lower toxicity



### Efficacy: Breast Cancer Model\*

PBS (Vehicle control) 19d



SPL's Dendrimer-Docetaxel 19d



Taxotere® requires detergent to formulate



Starpharma's detergent-free Dendrimer-docetaxel (solubility ↑ 2000-8000x)







#### Starpharma's Dendrimer-Docetaxel- Pharmacokinetics and Distribution

Significant Tumour targeting and extended half-life

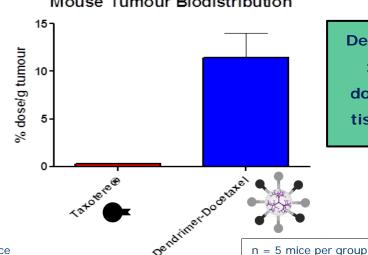
- Pharmacokinetic studies with radiolabelled drug demonstrate that the **Dendrimer**-Docetaxel formulation extends the docetaxel plasma half life by at least 60 fold vs. Taxotere®
- Greater half life will enable sustained and greater delivery of docetaxel to the tumour
- **Dendrimer-Docetaxel formulation** provides > 40 fold greater docetaxel accumulation in the tumour tissue compared to Taxotere® 3 days after administration

#### Dendrimer- Docetaxel plasma half life >60 fold longer than Taxotere®

	Plasma Half Life (hours) ^
Dendrimer - Docetaxel	39
Docetaxel (Taxotere)	0.5

 $^n = 4 \text{ rats}$ per group

#### Mouse Tumour Biodistribution



**Dendrimer-docetaxel** >40 fold greater docetaxel in tumour tissue v's Taxotere®







#### Starpharma's Dendrimer-Docetaxel formulation

## Starpharma's Dendrimer-Docetaxel formulation has significantly\* better efficacy than Taxotere®

- At 94 days 60% dendrimer-docetaxel mice no evidence of tumour
- At 94 days Taxotere® 100% mice tumour re-growth
- Follow up studies including other tumour types underway
- Patents filed will offer protection to 2032

PBS (Vehicle control) 19d

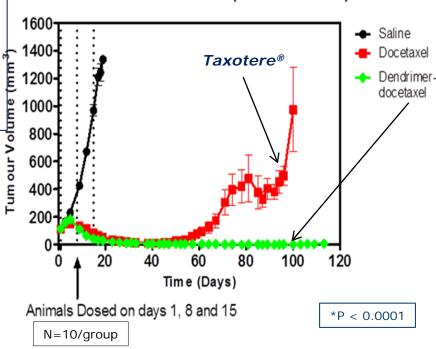


SPL's
Dendrimer-Docetaxel
19d



### **Efficacy: Breast Cancer Model\***

#### Mean Tumour Volume (MDA-MB-231)









### Starpharma's improved docetaxel formulation

#### Multiple Advantages shown with Starpharma's dendrimer formulation

- Taxotere® (docetaxel) is a blockbuster chemotherapeutic with 2011 sales of US\$1.2 billion
- Docetaxel is used in major cancer types including breast, prostate and lung cancer
- Significant potential for improved (patented) formulation using SPL's dendrimers
- Starpharma's Dendrimer-Docetaxel has demonstrated several significant advances which address undesirable characteristics of the original formulation of docetaxel:

## Improvements demonstrated for SPL's Dendrimer-Docetaxel over conventional formulations ie. Taxotere®

- 1. Improved solubility allowing removal of toxic components
- 2. Tumour-targeting or preferential delivery to cancer tissue
- 3. Extended half-life
- 4. Improved efficacy in breast cancer model







### Broad potential for dendrimers to improve major drugs, especially anti-cancers

Analysis shows dendrimers applicable to > 50% of leading pharmaceuticals

Brand	Molecule	Innovator Company	2009 Sales (\$ M USD)
Taxotere	Docetaxel	Sanofi Aventis	2,140
Eloxatin	Oxaliplatin	Sanofi Aventis	1,484
Alimta	Pemetrexed	Eli Lilly	1,306
Gemzar	Gemcitabine	Eli Lilly	1,107
Doxil/ caelyx	Pegylated doxorubicin	JnJ / Merck	384
Camptosar	Irinotecan	Pfizer	329
Abraxane	Albumin bound paclitaxel	Celgene	310
Vidaza	Azacitidine	Celgene	299
Taxol	Paclitaxel	BMS	292
Treanda	Bendamustine	Cephalon/ Astellas	241

- Starpharma's proprietary dendrimer nanoparticle technology has broad applicability
- Dendrimers have significant potential in cancer treatments due to targeted delivery and increased circulation times
- Starpharma has demonstrated significant benefits with its Docetaxel formulation and a number of other cancer drugs including gemcitabine, platinums, paclitaxel, doxorubicin
- Combination of chemotherapy loaded dendrimers and antibodies may enable further targeting to specific cancer cell populations in organs and metastases







Dendrimers in Agrochemicals: Apply SPL dendrimers to achieve significant product enhancement

Commercial Partnerships with Major Ag. Coys for product enhancement via dendrimers

# <u>Dendrimers can enhance the performance of existing agrochemicals and create proprietary (patentable) formulations</u>

- Extension/enhancement of effect
- Solublility enhancement
- Reduction/removal solvents "greener" formulations
- Modification of soil penetration
- Adhesion to difficult surfaces
- Protection of Actives/Sequestration



Partnerships with leading global Ag. Companies



#### **Reduced Hydrocarbon Formulations**

- Solvent-based pesticides make up ~US\$10BN of the global US\$40BN agrochemical market
- Dendrimers can increase water solubility of these active ingredients reducing the need for hydrocarbons
- Starpharma's aim is to develop formulations which offer:
  - Improved environmental profile due to a reduction in those hydrocarbon solvents that are considered harmful, including xylene, naphthalene and benzene.
  - Improved user and operator safety due to the lowered solvent loading
  - Lower transport costs and improved safety due to reduced flammability

Source: Various AgGrow Generic Pesticides Reports







#### Starpharma's internal Agrochemical programs: Growing Breadth and Depth

Dendrimers: Significant Commercial Opportunities for Improvement of Off-patent Actives

Significant opportunity, for both proprietary & generic actives

>\$5B

...the value of products coming off patent 2011-16 Phillips McDougall. 2010 Sales Value, US\$

Herbicides \$2,237M Insecticides \$1,858M Fungicides \$1,151M

Active Ingredient	Activity	Market Value (\$M USD)
Glyphosate	Herbicide	5000
Imidacloprid	Insecticide	1000
Acephate	Insecticide	350
Pendimethalin	Herbicide	350
Acetochlor	Herbicide	300
Chlorpyrifos	Insecticide	300
Trifluralin	Herbicide	300







### Dendrimers in Agrochemicals

Internal Program: Improvement of Glyphosate and other off-patent actives



#### Starpharma's initial results -

- Glyphosate (e.g. Roundup®) effectiveness measured using "brownout" (rate of vegetation dying off)
- Starpharma's dendrimers improved performance of glyphosate by ~160-320% compared to glyphosate alone
- Glyphosate market is US\$5BN globally

### 

Additional work also undertaken on key generic actives including:

- Imidacloprid (e.g. Confidor®) globally US\$1 Bi
- Trifluralin (e.g. Treflan<sup>™</sup>) globally US\$300 M





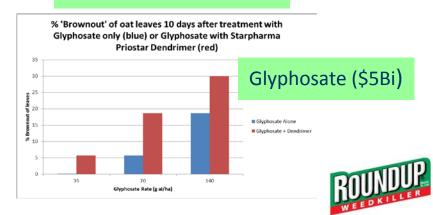




#### Starpharma's programs in Agrochemicals: Multiple Applications in Leading Products

Starpharma's Dendrimer formulations show significant advantages

### **Enhanced Efficacy**



### **Improved Rain-fastness**

### Retention of Effect: rain at 4 hours



### **Improved Soil Penetration**



#### Loading (g/L)









### **Investment Summary and Financials**

Starpharma's strategy: commercially exploit its platform to generate multiple, parallel revenue streams

#### Starpharma has:

- A highly versatile, proprietary technology platform
- An impressive and growing list of commercial partnerships and an active BD focus
- Several well advanced potential revenue streams
- Near term commercial and clinical milestones
- A sound financial position and industryexperienced Management Team and Board

	FY 2011 AUD \$M	FY 2012 AUD \$M
Total revenue and income	3.3	2.9
Net loss after tax	8.9	13.7
Cash outflow from operations	(6.5)	(9.8)
Net cash inflow from financing	3.5	33.7
Cash at period end	18.9	42.8





SIEMENS







"Dendrimers have numerous potential applications.... We see the possibility of lucrative licensing deals from dendrimer projects focused on drug delivery, animal health, agro-chemicals and many more" .... Bell Potter Securities

