



## ASX ANNOUNCEMENT

### Starpharma to present to US institutional investors

**Melbourne, Australia; 27 February 2014:** Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) will participate later today in the *ASX Spotlight New York* event.

Starpharma is one of 15 ASX listed companies to be featured at the event, which is held annually to showcase emerging Australian companies before US institutional investors.

CEO Dr Jackie Fairley will present at the event, which is in its seventh year and is attended by more than 240 investors.

“Starpharma welcomes this opportunity to speak to the Company’s recent achievements and to build on an already strong and international institutional investor base,” said CEO Dr Jackie Fairley.

There is an opportunity for one-on-one meetings in addition to the Company’s formal presentation, which will provide an overview of Starpharma’s business and portfolio including:

- Starpharma’s lead product, VivaGel® for the management and prevention of bacterial vaginosis, as a late-stage clinical asset.
- Two attractive commercial licenses for VivaGel®-coated condom: Ansell and Okamoto.
- Commencement of a Phase 1 clinical trial of DEP™ docetaxel and latest preclinical results for DEP™ oxaliplatin.
- An update on the agrochemical program, including internal development of a dendrimer-enhanced version of glyphosate (Roundup®).

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). 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. Drug Delivery partners include GSK, Lilly and AstraZeneca. A number of dendrimer-enhanced, or DEP™ versions of existing drugs are under development. The most advanced of these is DEP™ docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere®) which is in clinical development. In preclinical studies DEP™ docetaxel has shown significant tumour-targeting and superior anti-cancer effects across a range of important cancer types including breast, prostate, lung and ovarian tumour, when compared to Taxotere® (docetaxel).

In agrochemicals Starpharma has a series of partnerships with leading industry players including Nufarm (ASX:NUF) and Makhteshim Agan as well as 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](mailto:rwilson@buchanwe.com.au)

##### Starpharma:

Dr Jackie Fairley, Chief Executive Officer  
Nigel Baade, CFO and Company Secretary

+61 3 8532 2704

[investor.relations@starpharma.com](mailto:investor.relations@starpharma.com)

[www.starpharma.com](http://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 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 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.



February 2014  
Dr. Jackie Fairley CEO

**STARPHARMA HOLDINGS LIMITED**

ASX:SPL; OTCQX:SPHY

**ASX Spotlight Event – New York**  
27 February 2014

*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: A global leader in nanoscale polymers called dendrimers - A versatile technology platform & portfolio of commercial assets

### VivaGel® Portfolio:

- VivaGel® for Bacterial Vaginosis (BV): Late stage Clinical Asset
- Two attractive commercial licenses for VivaGel®-coated condom: Ansell (#2 globally) and Okamoto (Japanese market leader)

### Proprietary DEP™ Nanoparticle Delivery technology:

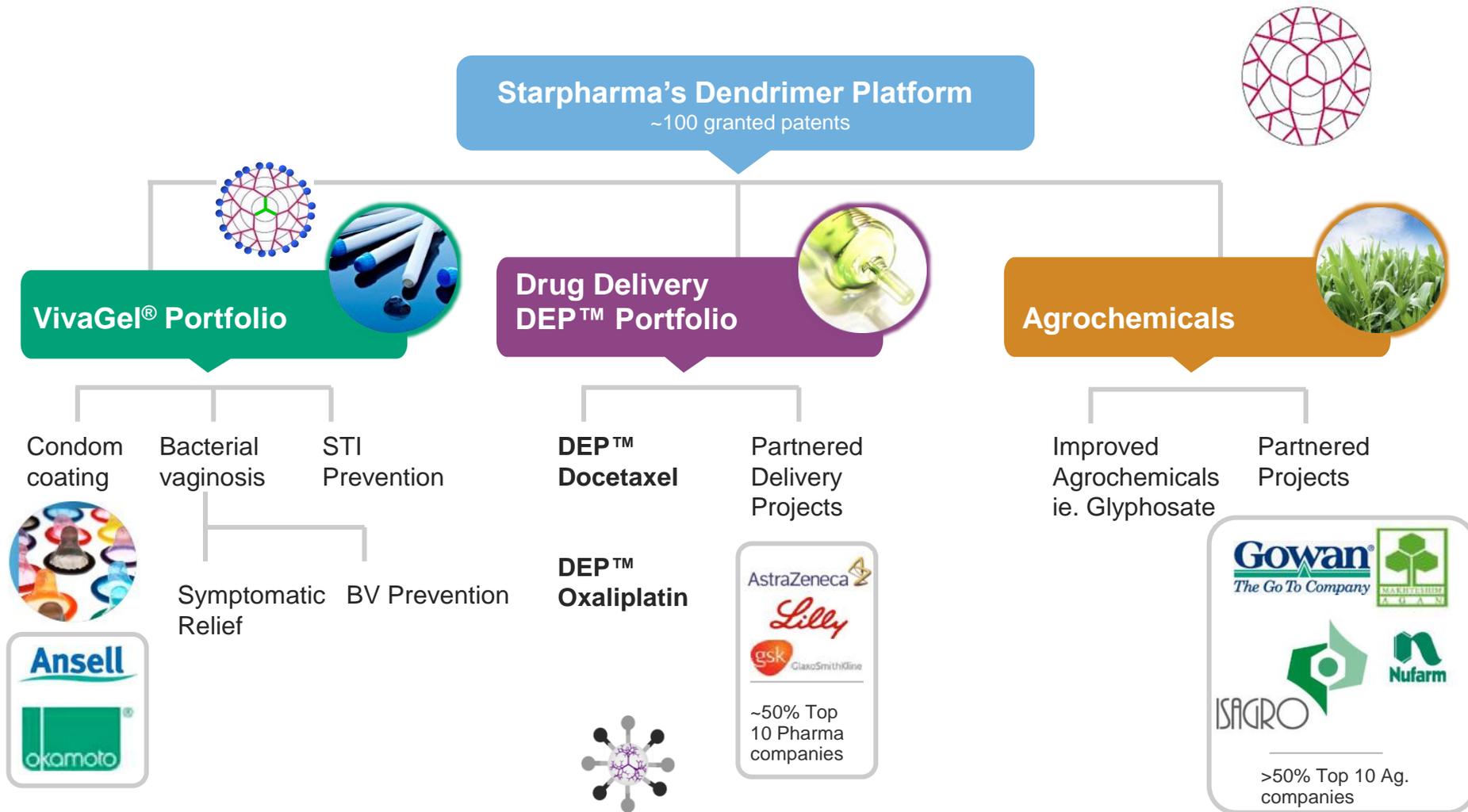
- DEP™ Docetaxel : significant advantages vs. Taxotere® now in the clinic
- DEP™ Oxaliplatin (preclinical): Better efficacy and less toxicity than Eloxatin®
- Multiple partnerships: ~ half Top 10 Pharma Companies (incl. Lilly, AstraZeneca, GSK)

### Dendrimers in Agrochemicals:

- Internal candidates in generic agrochemicals incl. market leading product glyphosate (Roundup®)
- Multiple agrochemical partnerships incl. Makhteshim Agan; >50% Top 10 Ag. companies

# A global leader in nanoscale polymers (dendrimers)

## Versatile technology platform & portfolio of commercial assets



# Starpharma - Corporate and financial

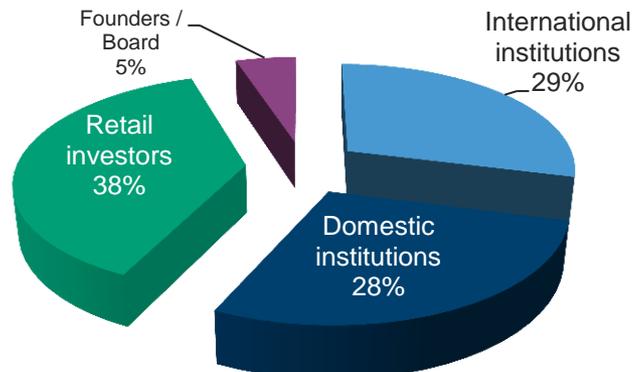
ASX Listed (SPL) & OTCQX (SPHRY)

Market Cap ~ A\$200M

Based in Melbourne, Australia

Strong institutional register

- 29% held by International Institutions
- Major Holders: M&G, Allan Gray, Acorn
- Top 20 shareholders hold ~62%



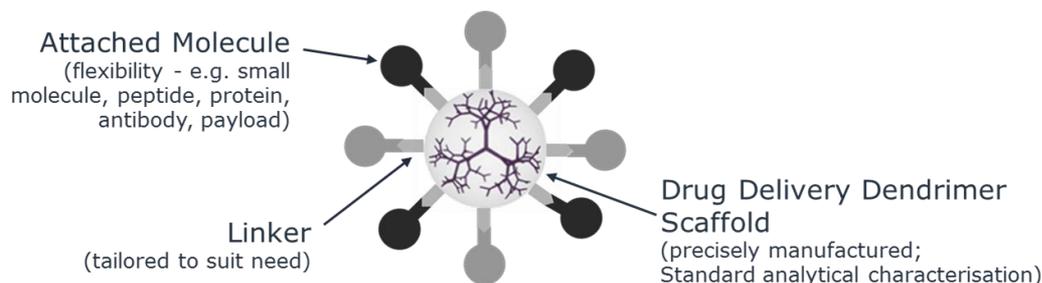
| Key Financial Data<br>(Financial Year to 30 June) | FY 2013 <sup>^</sup><br>AUD \$M |
|---|---------------------------------|
| Total revenue and income                          | 2.4                             |
| R&D Tax Incentive                                 | 8.7                             |
| Net loss after tax                                | (5.2)                           |
| Cash outflow from operations                      | (9.8)                           |
| <sup>^</sup> Cash (31 December 2013)              | 27.8                            |

| Analyst ratings   | Target Price        | Price Upside*   |
|---|---------------------|---|
|  <b>CIMB</b>              | Buy<br>(Outperform) | \$1.79<br>156%  |
|  <b>CANACORE Genuity</b>  | Buy                 | \$2.00<br>186%  |
|  <b>BELL POTTER</b>     | Buy                 | \$1.58<br>126%  |
|  <b>PhillipCapital</b>  | Buy                 | \$1.90<br>171%  |
|  <b>TAYLOR COLLISON</b> | Hold                | \$1.15<br>64%   |
| * Price upside based on closing at \$0.70   |                     | Average Target Price<br>\$1.68<br>Average Price Upside*<br>141% |



**Drug Delivery – DEP™**

# DEP™ (Dendrimer Enhanced Products): Nanoparticles with multiple advantages



**Multiple Partners  
including:**

AstraZeneca 

*Lilly*

 GlaxoSmithKline

|                                | Target Profile                                       | DEP™ Docetaxel   | DEP™ Oxaliplatin  |
|--------------------------------|--|--|---|
| <b>Therapeutic Performance</b> | Enhanced Pharmacokinetics                            | ✓ Plasma half life >60x Taxotere®                              | ✓ Plasma half life >50x Eloxatin®                             |
|                                | Enhanced Efficacy                                    | ✓ Enhanced efficacy in Breast, Prostate, Ovarian cancer models | ✓ Efficacy in platinum-insensitive colon cancer model         |
|                                | Targeted Drug Delivery                               | ✓ Tumor accumulation 40x Taxotere®                             | ✓ Expect enhanced accumulation in tumor                       |
|                                | Better Side Effect profile                           | ✓ Protection against neutropenia<br>No Polysorbate 80          | ✓ Protection against Neutropenia and Peripheral Neurotoxicity |
| <b>Commercial Performance</b>  | Extend Patent Life                                   | ✓ Filings to 2032  | ✓ Filings to 2034   |
|                                | Accelerated development                              | ✓  | ✓   |
|                                | Robust, scalable manufacturing & excellent stability | ✓  | ✓   |
|                                | Competitive advantages                               | ✓  | ✓   |
|                                | Elevated ROI   | ✓  | ✓   |
|                                | Lower Technical and Financial Risk than NCEs         | ✓  | ✓   |

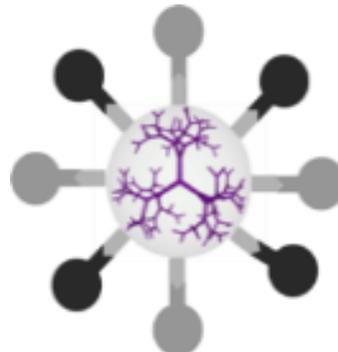
## Starpharma's DEP™ Docetaxel: Multiple benefits

- Docetaxel (Taxotere®) is a blockbuster oncology agent: docetaxel sales US\$3.1Bi (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™ Docetaxel is a nanoparticle formulation with multiple advantages compared to Taxotere®
- DEP™ Docetaxel Phase 1 Trial underway
- Patents filed will offer coverage to 2032



### DEP™ Docetaxel vs. Taxotere®

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



The frequency of hypersensitivity reactions, anaphylaxis and fluid retention with docetaxel, despite premedication, led the FDA to issue a “black box” warning on the package insert.

**“100% of the patients in Japan and the United States who died of docetaxel-associated anaphylaxis\* had received prophylaxis”**  
(\*anaphylaxis is believed to be caused by polysorbate 80)

|                                 | United States |                 | Japan       |                 |
|---------------------------------|---------------|-----------------|-------------|-----------------|
|                                 | Dead (n=3)    | Survived (n=33) | Dead (n=20) | Survived (n=11) |
| % patients received prophylaxis | 100%          | 74%             | 100%        | 50%             |

**“This observation reinforces the importance of developing pharmaceutical agents that do not contain stabilizers such as polysorbate 80”**

Table adapted from: Polysorbate 80 hypersensitivity reactions: a renewed call to action. Norris, LB et al; September 2010; COMMUNITY ONCOLOGY



Starpharma's water soluble DEP™-Docetaxel:  
solubility >↑ 20,000x  
(polysorbate 80-free)

**WARNING: TOXIC DEATHS, HEPATOTOXICITY, NEUTROPENIA, HYPERSENSITIVITY REACTIONS, and FLUID RETENTION**

The incidence of treatment-related mortality associated with TAXOTERE therapy is increased in patients with abnormal liver function, in patients receiving higher doses, and in patients with non-small cell lung carcinoma and a history of prior treatment with platinum-based chemotherapy who receive TAXOTERE as a single agent at a dose of 100 mg/m<sup>2</sup> [see [Warnings and Precautions \(5.1\)](#)].

TAXOTERE should not be given to patients with bilirubin > upper limit of normal (ULN), or to patients with AST and/or ALT >1.5 × ULN concomitant with alkaline phosphatase >2.5 × ULN. Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at increased risk for the development of grade 4 neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death. Patients with isolated elevations of transaminase >1.5 × ULN also had a higher rate of febrile neutropenia grade 4 but did not have an increased incidence of toxic death. Bilirubin, AST or ALT, and alkaline phosphatase values should be obtained prior to each cycle of TAXOTERE therapy [see [Warnings and Precautions \(5.2\)](#)].

TAXOTERE therapy should not be given to patients with neutrophil counts of <1500 cells/mm<sup>3</sup>. In order to monitor the occurrence of neutropenia, which may be severe and result in infection, frequent blood cell counts should be performed on all patients receiving TAXOTERE [see [Warnings and Precautions \(5.3\)](#)].

Severe hypersensitivity reactions characterized by generalized rash/erythema, hypotension and/or bronchospasm, or very rarely fatal anaphylaxis, have been reported in patients who received a 3-day dexamethasone premedication. Hypersensitivity reactions require immediate discontinuation of the TAXOTERE infusion and administration of appropriate therapy [see [Warnings and Precautions \(5.4\)](#)]. TAXOTERE must not be given to patients who have a history of severe hypersensitivity reactions to TAXOTERE or to other drugs formulated with polysorbate 80 [see [Contraindications \(4\)](#)].

Severe fluid retention occurred in 6.5% (6/92) of patients despite use of a 3-day dexamethasone premedication regimen. It was characterized by one or more of the following events: poorly tolerated peripheral edema, generalized edema, pleural effusion requiring urgent drainage, dyspnea at rest, cardiac tamponade, or pronounced abdominal distention (due to ascites) [see [Warnings and Precautions \(5.5\)](#)].

## DEP™ Docetaxel: Improved efficacy and less toxicity

- DEP™ Docetaxel shows significantly better efficacy than Taxotere®

Improved Efficacy: At 94 days:

- 60% DEP™ Docetaxel mice - no evidence of tumour
- 100% Taxotere® mice had tumour re-growth

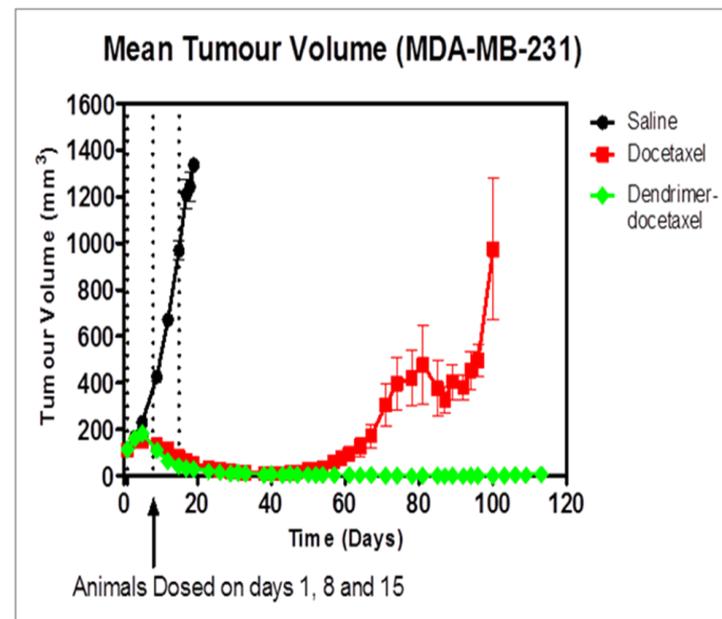
DEP™ Docetaxel has demonstrated activity in a range of common tumour types (breast, prostate, ovarian and lung)

### Efficacy: Breast Cancer Model\*



Saline Control 19d

DEP™ Docetaxel 19d

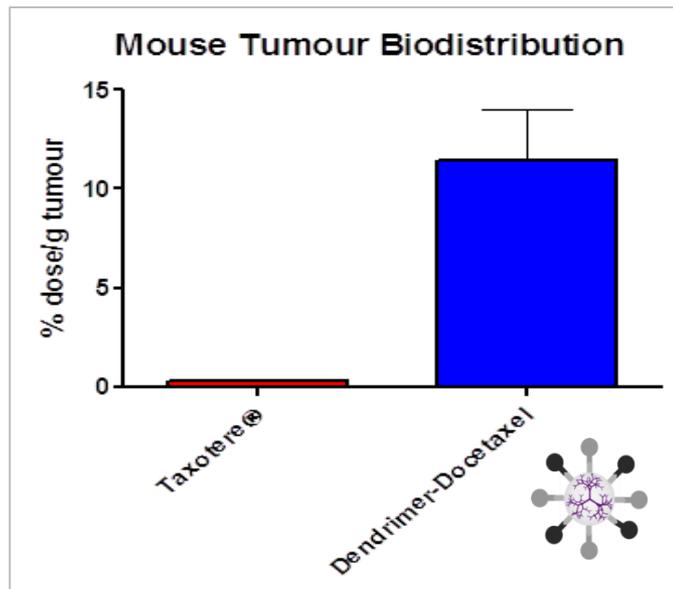


\*Mouse Xenograft (MDA- MB 231); N= 10/group ;  
^ p< 0.0001

## DEP™ Docetaxel: Multiple benefits- Longer half-life, tumor targeting and reduced neutropenia

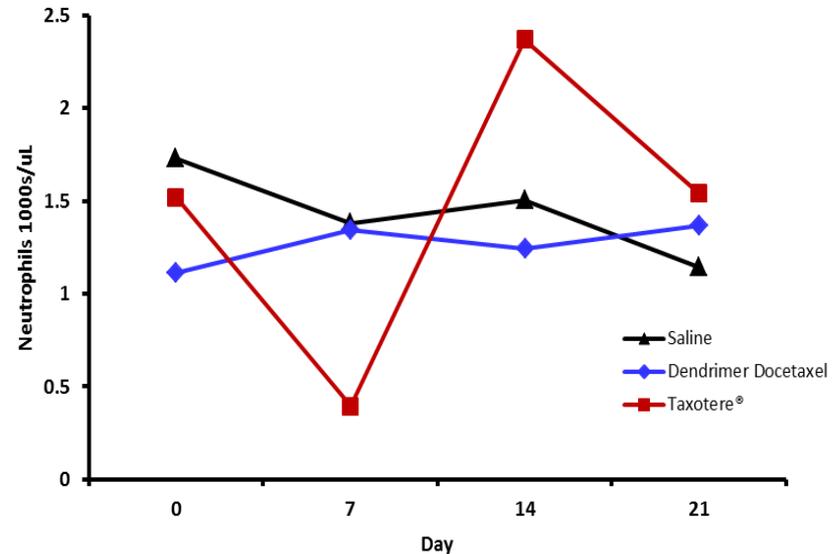
- DEP™ Docetaxel: extends plasma half life by >60 fold vs. Taxotere® enabling sustained delivery of docetaxel ( 39 hours vs. 30 mins)
- DEP™ Docetaxel : > 40 fold greater docetaxel in tumour tissue compared to Taxotere®

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



^3 days post administration; n = 5 mice per group

Studies carried out in collaboration with Monash Institute of Pharmaceutical Science



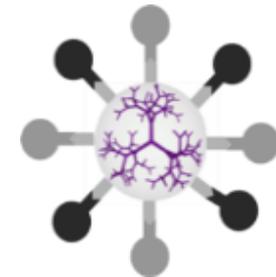
DEP™ Docetaxel formulation and Taxotere® at equivalent doses  
(based on docetaxel; 9mg/kg); n=6 rats/group

## DEP™ Docetaxel: Phase 1 Clinical Trial (underway)

- DEP™ Docetaxel Phase 1 trial underway in Australia (eligible 45% rebate under tax credit scheme)
- Dose escalation and expansion study in cancer patients (various tumours)
- Estimated sample size: 25-30 patients
- Open label study - allowing progressive results
  
- **Primary Objectives:**
  - Establish the maximum tolerated dose (MTD) and dose limiting toxicities (DLT) for DEP™ Docetaxel
  
- **Secondary Objectives:**
  - Characterise safety and tolerability (including observations regarding neutropenia, alopecia, etc.)
  - Explore preliminary anti-tumour efficacy with CT scans, bone scans, tumour markers etc.
  - Characterise pharmacokinetics
  - Define recommended dose for Phase 2

## DEP™ Oxaliplatin: Multiple benefits

- 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®



### SPL's DEP™ Oxaliplatin:

- Several important benefits vs. Eloxatin®
- Granted patents to 2028; additional filings to 2034
- Preclinical; Planning underway to enter the clinic

#### 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

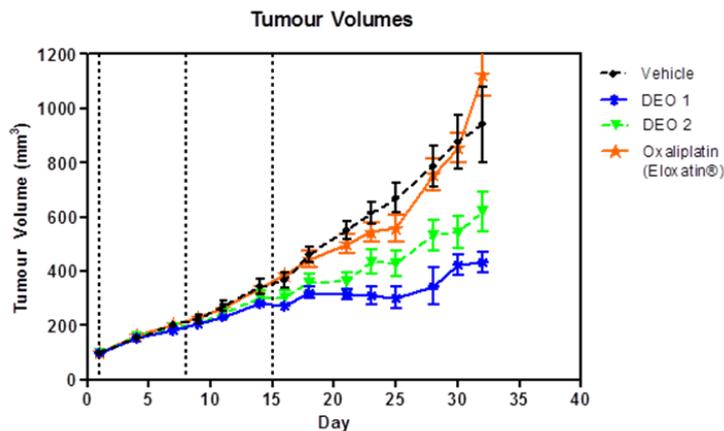
**Eloxatin**  
(OXALIPLATIN injection)

# DEP™ Oxaliplatin: Improved efficacy and reduced toxicity

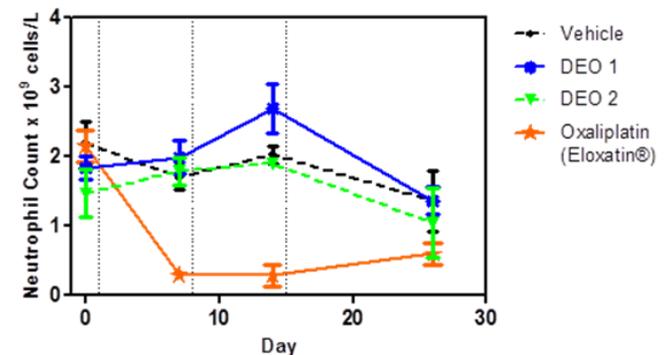
DEP™ Oxaliplatin (DEO) achieved:

- significantly better tumour-inhibiting efficacy cf. ELOXATIN® in a colon cancer model\*
- reduced bone marrow toxicity (neutropenia and thrombocytopenia) cf. ELOXATIN®

## Improved Efficacy\*: Mouse xenograft – (colon SW620)



## Reduced Neutropenia#



DEP™ Oxaliplatin treated animals exhibited significantly reduced neurotoxicity compared to Eloxatin® even at twice the dose of oxaliplatin<sup>1</sup>

Neurotoxicity is the dose limiting toxicity for Eloxatin® occurring in 85-95% patients

<sup>1</sup> conducted in a validated mouse model at the University of Maryland, Baltimore

# N= 5/group Tumour bearing mice (SW620); p< 0.0001

\*Mouse Xenograft (SW620); N= 12/group ; p< 0.0001

## DEP™: Broad potential to improve major drugs

- Starpharma's **dendrimer enhanced products (DEP™)** nanoparticle technology has broad applicability
- Analysis shows dendrimers applicable to >50% of leading pharmaceuticals
- Significant potential in oncology
- Proof of concept for **DEP™ docetaxel, doxorubicin, oxaliplatin, methotrexate, gemcitabine, paclitaxel and testosterone**

### Also applicable to:

- **Proteins (eg. Insulin – partnered program), peptides**
- **Antibody Drug Conjugates or ADCs (Chemotherapeutic + antibody)**

| Brand        | Molecule                 | Innovator Company | 2012 Branded Sales (\$M USD) |
|--------------|--------------------------|-------------------|------------------------------|
| Alimta       | Pemetrexed               | Eli Lilly         | 2,594                        |
| Eloxatin     | Oxaliplatin              | Sanofi Aventis    | 1,570                        |
| Vidaza       | Azacitidine              | Celgene           | 910                          |
| Taxotere     | Docetaxel                | Sanofi Aventis    | 760                          |
| Treanda      | Bendamustine             | Cephalon/Astellas | 651                          |
| Abraxane     | Albumin bound paclitaxel | Celgene           | 473                          |
| Gemzar       | Gemcitabine              | Eli Lilly         | 317                          |
| Camptosar    | Irinotecan               | Pfizer            | 176                          |
| Taxol        | Paclitaxel               | BMS               | 149                          |
| Doxil/caelyx | Pegylated doxorubicin    | JnJ/Merck         | 83                           |

*Nanomedicine-based oncology drug sales expected to grow to \$12.7B by 2016 (CAGR 18%)*

*Nanotechnology in Medical Applications: The Global Market BCC 2012*

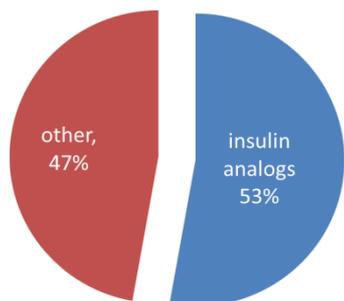
*Deals in Nanomedicine \$700M in 2013 Amgen, Pfizer, AZ (preclinical candidates)*

# DEP™ for proteins and peptides i.e. Insulin

## Opportunity

**US\$43B**

Global diabetes market (2013)  
(Reuters)

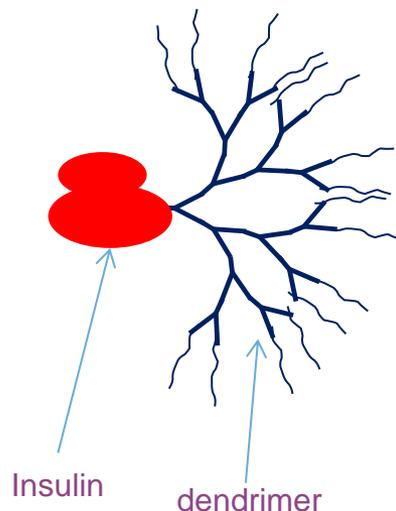


Market Share 2010  
(Business Insights)

**US\$6.3B**

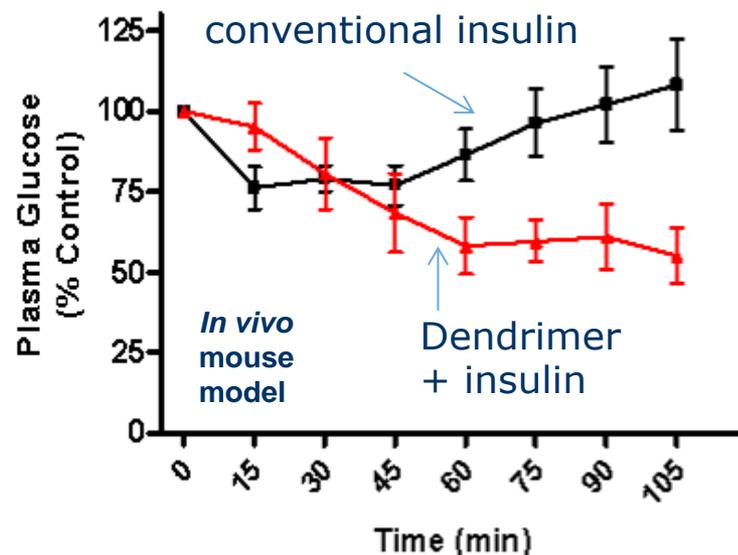
Sanofi's long acting insulin LANTUS (2012)  
(MedTrack)

## Technical Approach



|                 |   |
|-----------------|---|
| <b>Approach</b> | Conjugate protein or peptide to functionalised dendrimer  |
| <b>Benefit</b>  | Control half life of protein or peptide therapeutics<br>Reduce protein metabolism<br>Improve dosing regimen |

## Performance



|               |   |
|---------------|---|
| <b>Result</b> | DEP™ insulin shows prolonged suppression of blood glucose in vivo (early non-conf result shown above, only) |
| <b>Status</b> | Co-development program with undisclosed partner   |



**VivaGel® Portfolio**



# 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: low cure rates and nasty side effects
- No approved products for Recurrent BV

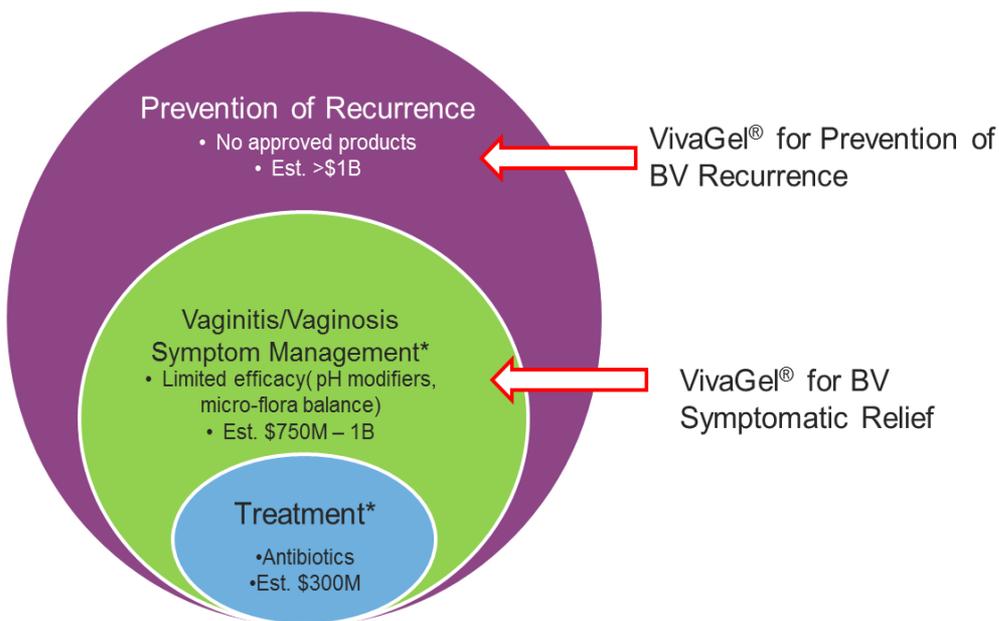
### Product Proposition:

VivaGel® is:

- a non-antibiotic therapy for the management of BV symptoms *and* prevention of BV recurrence

VivaGel® has:

- a selective antimicrobial effect for pathogens that cause BV
- a local effect and is not systemically absorbed
- a comprehensive pre-clinical and clinical package
- Potential short term opportunity for the management of BV symptoms (ex. USA)



\* Global Data – IMS & various Industry reports

## Phase 2 BV Prevention of Recurrence: Results summary

- Double-blind exploratory Phase 2 trial in 205 US women (VivaGel® vs. placebo)
- 1% VivaGel® demonstrated reduced risk of recurrent BV and delayed time to first recurrence (35d vs. 5d)
- More than 80% of 1% VivaGel® users remained BV free at 16 weeks and had excellent symptomatic relief
- High levels of patient satisfaction (79% satisfied/extremely satisfied)
- VivaGel® was safe and well tolerated
- Phase 3 Trial planning well advanced, set-up activities underway

| R-BV Def. | R-BV Criteria                      | Treatment             |                    | Relative Risk Reduction (1% VivaGel® vs. Placebo) |
|-----------|------------------------------------|-----------------------|--------------------|---|
|           |                                    | 1% SPL7013 Gel (N=65) | Placebo Gel (N=61) |   |
| 1         | FDA stipulated Amsel               | 12%                   | 28%                | 56%   |
| 2         | Patient symptoms & Amsel           | 17%                   | 28%                | 39%   |
| 3         | At least 3 of the 4 Amsel criteria | 22%                   | 34%                | 38%   |
| 4         | Investigator's determination       | 20%                   | 31%                | 36%   |

*“ as a clinician  
I am very encouraged by the  
data for 1% VivaGel®.*

*In this group of women almost all  
would have been expected to  
experience recurrent BV during  
the study. However  
**80% of VivaGel® users  
remained BV free at 16 weeks.***

*I see this finding as highly  
promising  
– both for the management of  
women with this condition and for  
recurrent BV sufferers.”*

BV Expert (Prof. George Kinghorn, Dept. GU Medicine, Royal Hallamshire and Sheffield, UK)

# BV Prevention of Recurrence: Partnering and market opportunity for VivaGel®

*“It was like gone almost overnight”*

*“I would definitely use it again....its very effective”*

*“The next day I noticed a huge difference.”*

*“I would use it....I will use it indefinitely...”*

*“ Anything that can treat this quickly and not have it come back sounds like a winner to me”*

– VivaGel® Trial and Market Research Participants#

*“ It is estimated that 1 in 3 women will develop the condition [BV] at some point in their lives” \*\**

## Benefits of VivaGel®:

1. Designed for long term use
2. Not a conventional antibiotic
3. Not systemically absorbed
4. Lack toxicities associated with antibiotics
5. Selective antimicrobial effect
6. Odorless and colorless water-based gel
7. Rapid resolution of symptoms

### Prevention of Recurrence

- No approved products
- Est. >\$1B

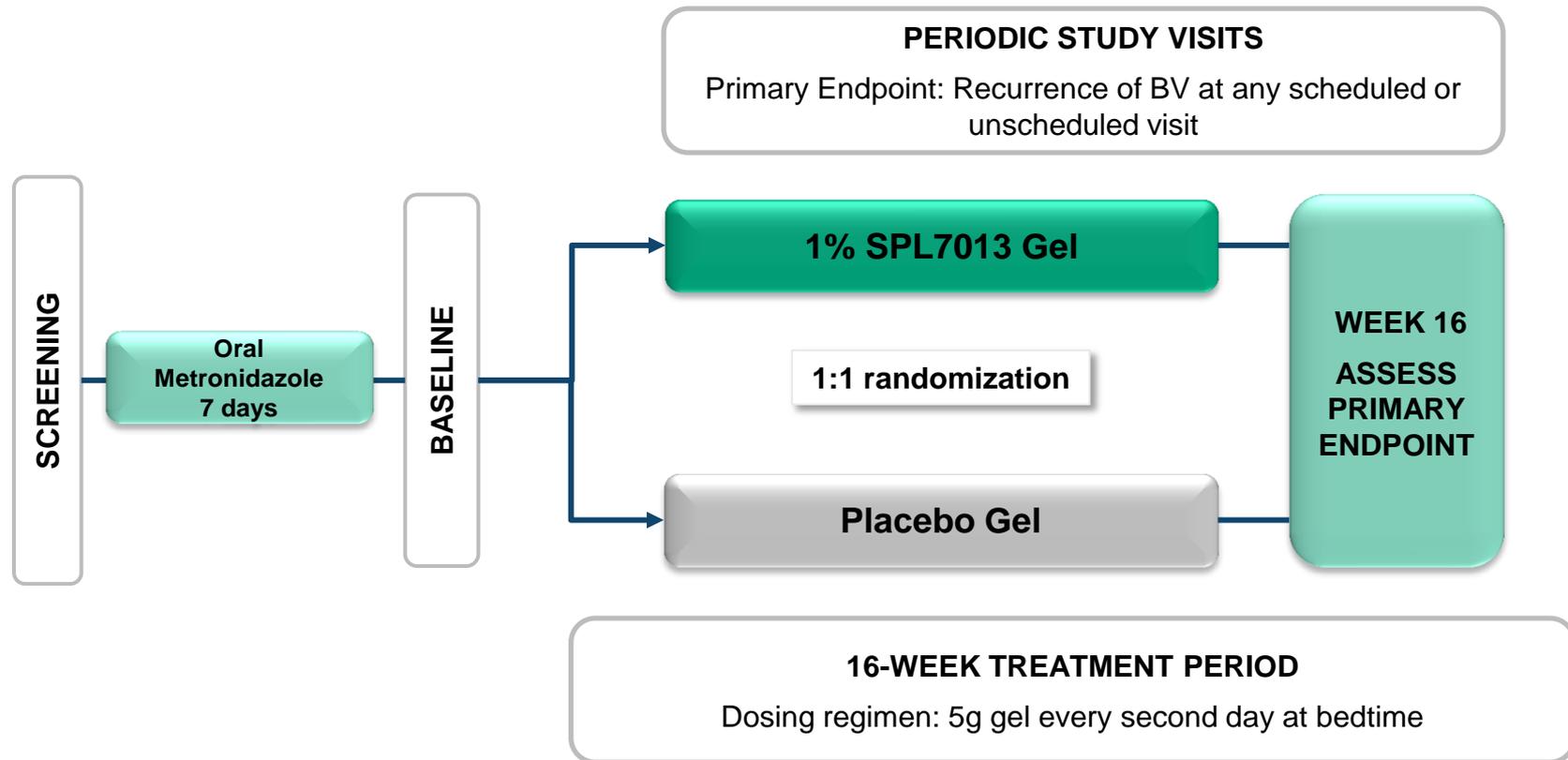
### Vaginitis/Vaginosis Symptom Management\*

- Limited efficacy (pH modifiers, micro-flora balance)
- Est. \$750M – 1B



\*\*The Family Planning Association; # patient market research

# BV Prevention of Recurrence : Proposed Phase 3 Trial Design



**Phase 3 Trial set-up activities already well underway; trial expected to commence in the next few months**

## VivaGel®: Symptomatic Relief of BV

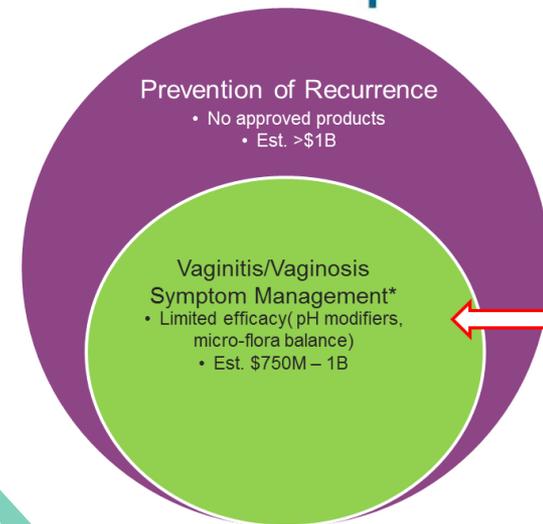
### VivaGel® (once a day for 7 days):

- Two large (250p/trial) US/EU trials of VivaGel® under IND demonstrated Clinical Cure at the end of treatment and effectiveness in treating symptoms of BV
- Resulted in rapid and sustained relief from symptoms
- Patient acceptability data was very positive
- Excellent safety profile including very low rates of candidiasis
- FDA Treatment endpoint (Cure@ 2-3 wks > cessation of Rx) not met

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

- Alternative claim strategies (Symptomatic Relief) are being pursued and submissions are planned in a number of regions

*Symptomatic Relief and Prevention of Recurrence product rights under active discussion with a number of commercial partners*



***“It was like gone almost overnight”***

***“I would definitely use it again....its very effective”***

***“The next day I noticed a huge difference.”***

***– VivaGel® Trial Participants***

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

- Condom coated with patented antiviral (VivaGel®) which has been shown to kill  $\geq 99.99\%$  HIV & Herpes
- Licensed to Ansell and Okamoto
  - Consumer research, product positioning, package design, manufacturing validation undertaken
- Combination product /device route: regulatory reviews underway
- Branded condom market: \$1.1B
- VivaGel® Patents to 2027

| Partner   | Market Position/Share  | Major Brands   |
|---|--|--|
| <p><u>Okamoto Industries</u><br/>(listed on TSE)</p>  | <ul style="list-style-type: none"> <li>• No. 1 in Japan with ~60% Japanese market (the 2nd largest condom mkt. Est. ~US\$500M)</li> <li>• Total company revenues &gt;US\$760M</li> </ul> | <p>Skinless®</p>  <p>003®</p>   |
| <p><u>Ansell Limited</u><br/>ASX:ANN</p>              | <ul style="list-style-type: none"> <li>• No. 2 globally for condom sales ~ 20% global share of branded market ~\$1.1B</li> </ul>   | <p>Lifestyles®</p>  <p>SKYN®</p> <p>ZERO®</p>  <p>Manix®</p>  |

# VivaGel® coated condom: A compelling and differentiated product

## *Extensive international consumer research confirms strong interest in a condom with a coating to inactivate STIs*

- 86% of participants rated the VivaGel®-coated condom as “very interesting” with >90% saying they would buy it
- Consumer appeal was high for the VivaGel® coated condom - independent of gender, relationship status and age

*“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 has partnered with Starpharma to validate a process of coating an Ansell condom with unique VivaGel®. This ground breaking technology has been shown in lab trials to deactivate many viruses that cause STI’s. The dendrimer technology perfected by Starpharma over many years is supported by millions of dollars of clinical trials, and Ansell is fortunate enough to be the partner to help bring the resulting condom product to market. Regulatory review processes are already underway for this product with plans to commercialise this world-leading Condom technology in the near future.*



**2013 Ansell Annual Report**

**Ansell**



# Agrochemicals

US\$47B

Crop protection  
market (2012)  
Phillips McDougall



## Dendrimers in Agrochemicals

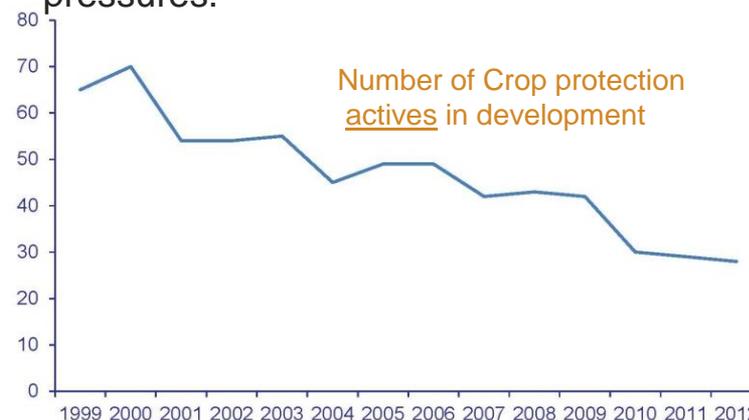
Dendrimers enhance existing agrochemicals and create patentable formulations in at least two ways:

- Improved formulation characteristics:
  - Solubility enhancement
  - Increased loading
  - Formulation stability
  - Reduction/removal solvents – “greener” formulations
- Improved biological performance:
  - Increased efficacy
  - Modification of soil penetration
  - Protection of Actives/Sequestration



### Significance for the agrochemical industry:

- Number of new actives in development by the industry are dropping due to regulatory and other pressures.



- **New formulations using Priostar® dendrimers to create:**
  - superior agrochemical formulations
  - a strong patent position as a barrier to entry for competing products.

# Starpharma's Agrochemical Programs

## Partnered Programs

- Agreements now signed with majority of top 10 agrochem companies and many others.
- Further agreements in coming months
- Many "shots on goal"
- Limited SPL investment required

**>\$2B**

Estimate of value of those products as sold **by our existing partners** today (the available market is much larger)

**40**

Approximate number of actives that are now under agreement for evaluating / development with Priostar® by partners



**3 New Partnerships announced plus others with well known global Ag. companies (undisclosed)**

## Update on Internal Development Programs

- SPL is developing its own complete formulations of selected generic actives with enhanced characteristics
- A number of programs including glyphosate are underway with additional glyphosate field trials ongoing

### Programs including:

| Active                    | Global Market | Proposition          | Stage        |
|---------------------------|---------------|----------------------|--------------|
| Glyphosate                | \$4-5B        | Improved efficacy    | Field Trials |
| Metolachlor               | ~\$550M       | Improved formulation | Glasshouse   |
| Pendamethalin             | ~\$350M       | Improved formulation | Glasshouse   |
| (herbicide)               | ~\$300M       | Loading / Stability  | Glasshouse   |
| Imidacloprid              | >\$1B         | Improved efficacy    | Lab testing  |
| Carfentrazone             | ~\$100M       | Improved formulation | Lab testing  |
| (insecticide)             | ~\$600M       | Improved efficacy    | Lab testing  |
| + others (inc fungicides) |               |                      |              |

**...the value of products coming off patent 2011-16**

Phillips McDougall, 2010 Sales Value, US\$

**>\$5B**

## Starpharma's Dendrimer glyphosate formulation: Improved Efficacy

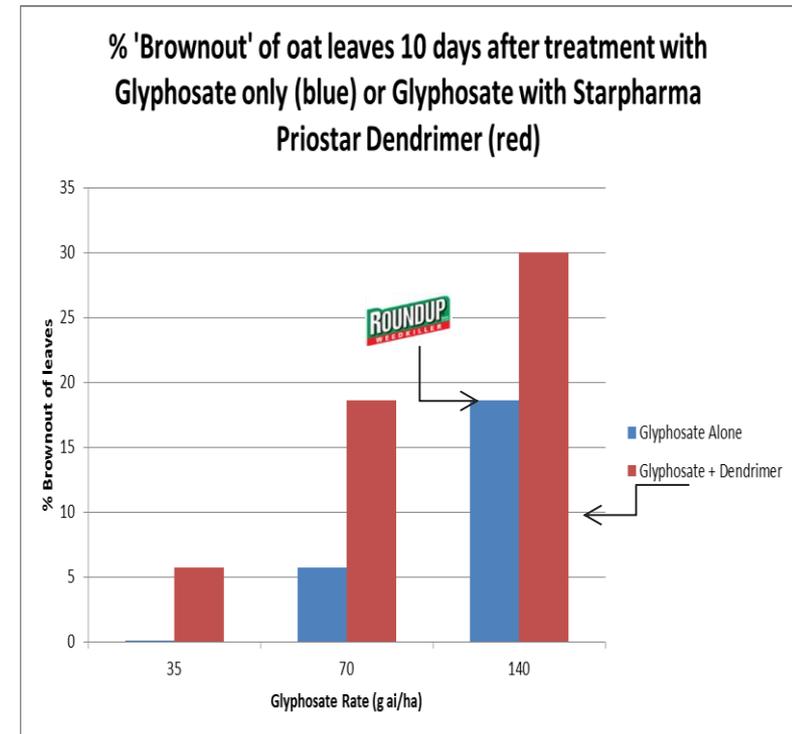
Glyphosate market is US\$5B globally



- Glyphosate (e.g. Roundup®) effectiveness measured using “brownout” (vegetation dying):

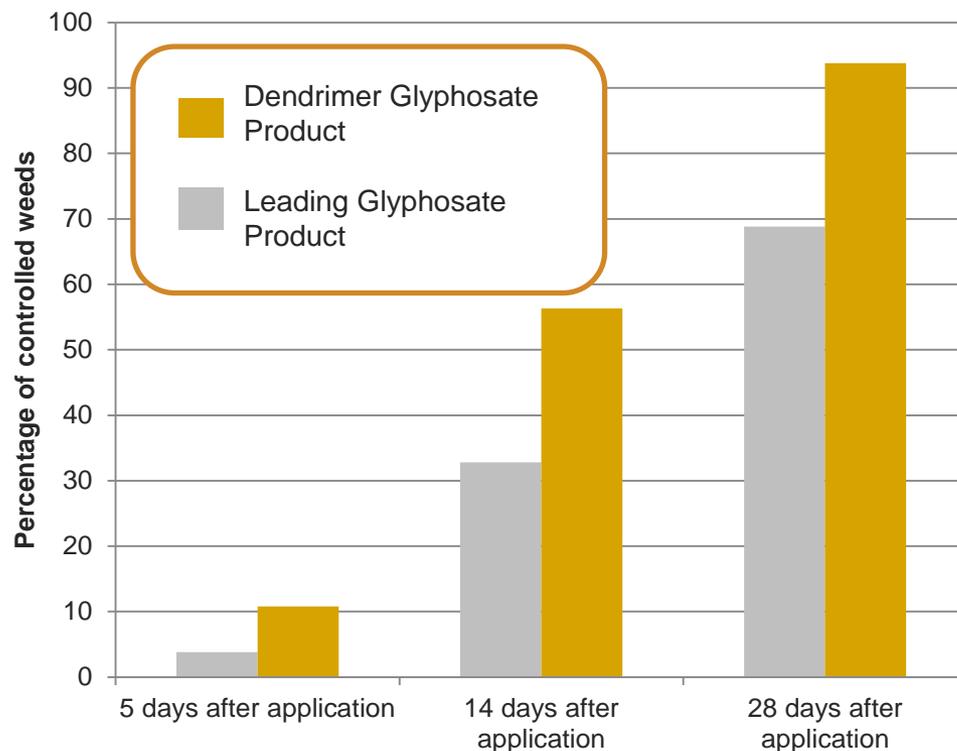


- Starpharma's dendrimers improved performance of glyphosate by ~160-320% compared to glyphosate alone



## Dendrimer Glyphosate (recent field trial data)

More effective in hard-to-kill weeds and faster knockdown cf. marketed formulation



- **Dendrimer product more effective in a number of hard-to-kill weeds than comparable marketed glyphosate product.**

- Two key benefits:

- **Better overall effectiveness**

Dendrimer formulation leaves only minimal number of weeds alive at end of study whereas the marketed product had > 30% survival.

- **Early feedback of effectiveness to grower**

3 to 4 times as much “brownout” after 5 days than marketed product.

## Expected Short-Medium Term News flow

### VivaGel® Portfolio:

- Commence Phase 3 Prevention of Recurrence BV VivaGel® trial
- Progress regulatory submissions for Symptomatic Relief BV product in selected regions
- Advance license discussions for Symptomatic Relief BV product
- VivaGel®-coated Condom approvals and launch by partners

### Drug Delivery - DEP™ :

- Report interim data from DEP™ Docetaxel clinical trial
- Complete preclinical development for DEP™ Oxaliplatin and advance to Phase 1
- Additional DEP™ candidates identified and progressed into pre-clinical studies
- Partnered program announcements (existing) and new deals

### Dendrimers in Agrochemicals:

- Advance internal candidates in agrochemicals incl. glyphosate (Roundup®) based on field trial data
- Partnered program announcements (existing) and new deals

# A global leader in nanoscale polymers called dendrimers: Versatile technology platform & portfolio of commercial assets

## VivaGel®

### Lead internal program:

VivaGel® for the management and prevention of Bacterial Vaginosis.

### Partnered development programs:

**Ansell**



## Agrochemical

## Drug Delivery

### Lead internal program:

DEP™ Docetaxel  
(Taxotere®)

### Partnered development programs:

AstraZeneca



*Lilly*



GlaxoSmithKline

### Lead internal program:

dendrimer-glyphosate  
(Roundup®)

**Gowan**  
The Go To Company



MAKHTESHIM  
A G G A N

### Partnered development programs:

**Nufarm**

