



## ASX ANNOUNCEMENT

### AGM – Chair address and CEO's presentation

**Melbourne, Australia; Friday 30 November 2012:** Attached is the Chairman's address together with the CEO's presentation to the Annual General Meeting of Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY), to be held at 10.00am today.

#### 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

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## **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.

## **Chairman's Address – Peter Bartels**

**Annual General Meeting**

**of**

**Starpharma Holdings Limited,**

**30 November 2012**

It is with pleasure that I again welcome you to our Annual General Meeting.

As I'm sure you can appreciate, before the activities of the last few days I was expecting to deliver quite a different speech to you today. One that highlighted an exceptionally successful year across our entire portfolio, and I will certainly be touching on our successes.

But as I stand here I can understand, and I share, your disappointment and surprise that our Phase 3 trial for the treatment of bacterial vaginosis has not met the end point required to obtain FDA approval.

It is a stark reminder of the challenges drug developers face but it also allows me to remind investors why they have placed their faith in Starpharma. The fundamentals of this company remain – we have a platform technology that has allowed us to support a diverse and robust portfolio of products at different stages on the development curve and across multiple industries. We have attracted some of the world's leading companies as partners and in the last year we have undertaken deals with AstraZeneca and NuFarm and extended our relationship with Lilly.

Starpharma has a management team that has already proved its ability to manage the various challenges that a company operating in biotechnology inevitably faces. I firmly believe that the strength of this team and the resilience of our business hold us in good stead to deal with the disappointments of this result and to use it to our advantage as we continue to pursue the development of VivaGel as important product for women.

One of the many positives that emerged from the Phase 3 result was that women reported rapid and sustained resolution of their symptoms. There was also a statistically relevant clinical cure rate at the End of Treatment assessment which was within five days of completion of treatment. Both of these factors bode well for the BV prevention of recurrence indication.

This program has seen the recent completion of recruitment of the Phase 2 clinical trial with the results from this trial expected in the first quarter of next year. The prevention of recurrence market is significantly larger than the treatment market due to the high prevalence of recurrence experienced by up to 50% of women. Estimates have put a dollar figure of more than \$1 billion globally on this indication and there are currently no registered products.

Now turning to other events of fiscal 2011-12, around this time last year we staged a major and successful capital raising of A\$35 million. This was achieved via a A\$32 million Placement and A\$3 million Share Purchase Plan.

The additional capital gave us additional capacity to further advance the various opportunities for VivaGel® as well as our drug delivery and agrochemicals development programs.

Our agrochemical and crop protection program continues to produce impressive data in the improvement of major products including the signing of a commercial partnership with the ASX listed NuFarm. The parties will apply Starpharma's Priostar® dendrimer technology to develop innovative crop protection formulations for NuFarm's product portfolio. NuFarm is one of the world's leading crop protection companies and produces products to help farmers protect their crops against damage caused by weeds, pests and disease. NuFarm's group sales for FY2011 exceeded \$2billion.

The drug delivery program has yielded results demonstrating Starpharma's ability to improve the delivery of major cancer drugs and hormones.

It was particularly pleasing during the year to extend our collaboration with Lilly and to receive the first data in a breast cancer model which clearly demonstrated the improvement in efficacy of anti-cancer drug docetaxel using dendrimer enhancement. We also announced a new partnership with AstraZeneca to apply dendrimers to anticancer therapies.

The capital raising also underpinned the growing international profile of the company.

M&G Investments – which is Prudential's UK and European fund management business with assets of more than A\$300 billion under management – made a significant investment leading our capital raising and have continued to build their shareholding to more than 10%.

Attracting investors of this stature arises from a strong belief in Starpharma's technology platform, the commercial opportunities it supports across multiple products and industries, and the concerted efforts of our CEO, Dr Jackie Fairley and her management team in elevating the company's profile.

Finally, I'd like to officially welcome Peter Turvey to the Starpharma board. Peter has significant pharmaceutical licensing and commercial law experience, primarily at CSL – and we are already benefitting from his experiences. I'd also like to thank departing director Ross Dobinson for his services to the board over the last 15 years. As a founding board member Ross has certainly seen the transformation of the Starpharma business over that period.

In summary, I remain confident about the year ahead. Of course, the last 24 hours has seen the value of our company impacted from the phase 3 results and we understand, and are mindful that this presents challenges to you. We thank our shareholders who are committed to riding this period out with us and maintain our commitment to you to continue to pursue rapidly the vast and varied opportunities in front of us.

Thank you.

Peter T Bartels, AO



# Starpharma Holdings Limited

ASX:SPL

## Annual General Meeting



30 November 2012

Dr. Jackie Fairley CEO





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## 2011/2012 Key Highlights



### VivaGel®

- ✓ 2 Pivotal Phase 3 BV treatment trials commenced, fully recruited and completed.
- ✓ FDA Special Protocol Assessment for BV Trials
- ✓ Phase 2 BV prevention of recurrence trial commenced
- ✓ Phase 2 BV prevention of recurrence trial fully recruited.



### Drug Delivery

- ✓ Dendrimer-docetaxel program shows improved efficacy, significant tumour targeting.
- ✓ Signs cancer drug agreement with AstraZeneca.
- ✓ Drug delivery program with Lilly expands.



### Agrochemical and Crop Protection

- ✓ Crop Protection Agreement signed with NuFarm.
- ✓ Dendrimer-glyphosate internal programs advanced improved efficacy and rain-fastness.



### Corporate

- ✓ \$35M financing ; \$6m cash for overseas R&D recouped via R&D Tax Credit scheme
- ✓ Experienced ex-CSL Licensing Executive Peter Turvey joins the Board
- ✓ Wins Janssen 2012 Company of the Year Award.





## Shareholding, Performance, and Financial Position

- SPL growth year-on-year (as at 29/11/12):
  - CAGR (5 years) 26%
  - CAGR (3 years) 27%
- Institutional Shareholding increasingly global
  - 29% - up from 5% in 2005
  - Substantial holders include Acorn, M&G and Allan Gray
- Strong cash position \$37.6M
  - additional \$6M R&D tax credit



Current Register Profile





A platform technology with broad optionality and applicability

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

## VivaGel®

### Lead internal program:

VivaGel for the treatment and prevention of Bacterial Vaginosis.

### Partnered development programs:

**Ansell**



## Agrochemical

## Drug Delivery

### Lead internal program:

dendrimer-docetaxel (Taxotere)

### Partnered development programs:



### Lead internal program:

dendrimer-glyphosate (RoundUp®)

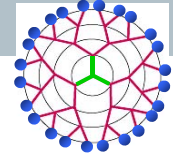
### Partnered development programs:





## VivaGel® Portfolio

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



### VivaGel®-Coated Condom



**Ansell**



### VivaGel®



Condom coated with patented antiviral  
**VivaGel® Kills ≥99.99% viral STIs**  
( HIV & Herpes)

Ansell & Okamoto (Japan)

Branded Condom Market: \$1.1Bi

Combination Product  
(Device Branch review)

#### Product

#### Commercialization Strategy

#### Market Size

#### Regulatory path

1. Bacterial Vaginosis (BV) Gel
2. Topical Microbicide Gel: for viral STIs (HIV, Herpes, HPV)

Late stage license

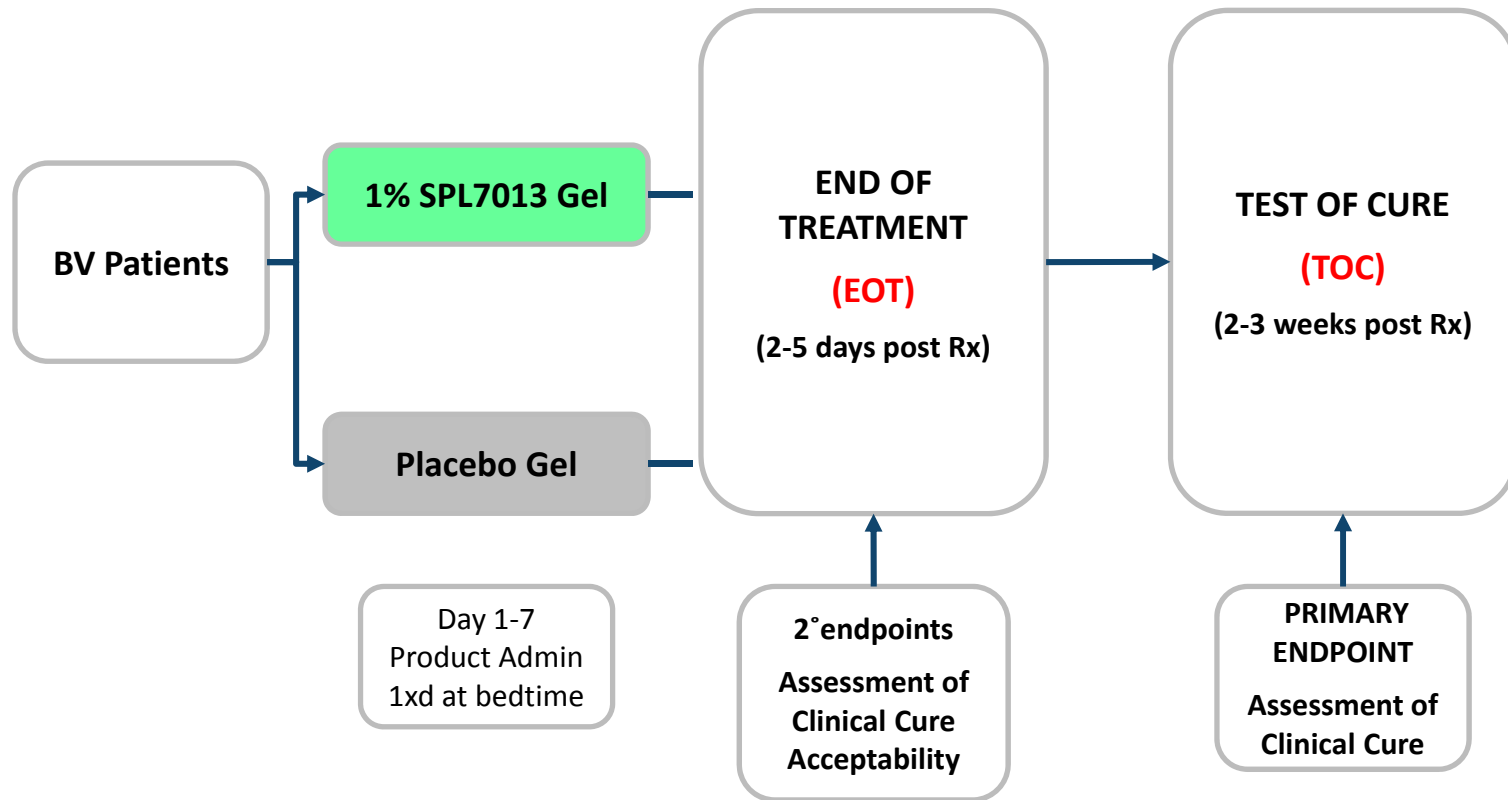
BV(treatment): \$350M  
BV(Prevention): >\$1 Bi

Pharmaceutical;  
FDA Fast Track



## Clinical Trial Summary

### PHASE 3 BV TREATMENT TRIAL DESIGN





## Clinical Trial Summary

### CLINICAL CURE OF BV – PHASE 3

Clinical Cure:	SPL7013-015		SPL7013-016	
	1% SPL7013 Gel	Placebo Gel	1% SPL7013 Gel	Placebo Gel
<b>EOT</b> (2-5 days post $R_x$ )	<b>50%**</b>	17%	<b>57%**</b>	21%
<b>TOC</b> (2-3 weeks post $R_x$ )	27%	21%	28%	28%

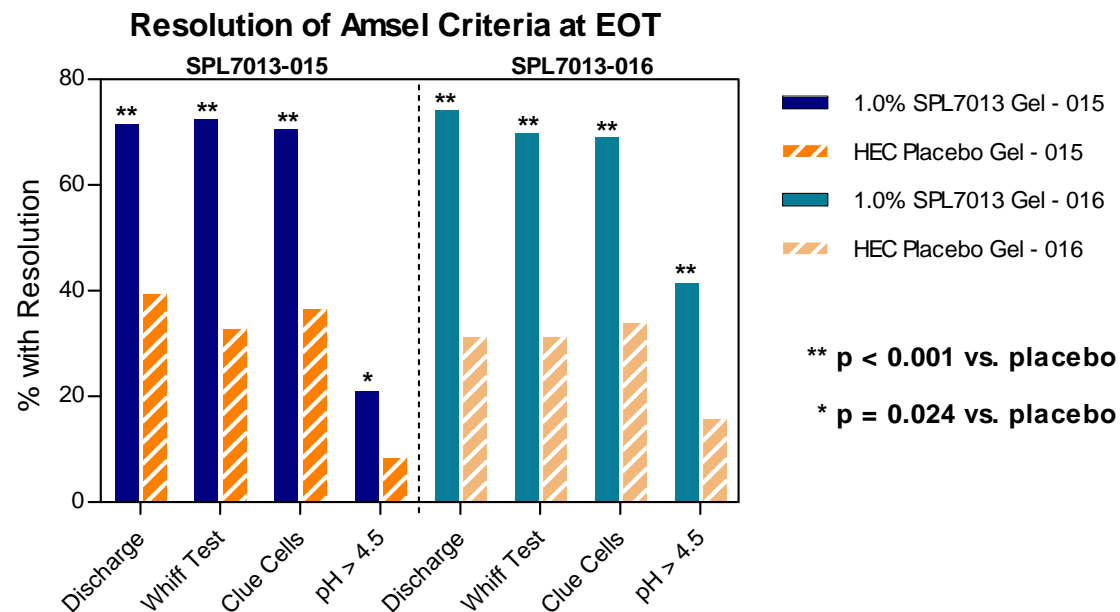
**\*\* Statistically significant result compared with placebo,  $p < 0.001$**

- Highly statistically significant Clinical Cure of BV at EOT
  - key secondary endpoint
  - Indicative of suppression of bacterial pathogens – highly supportive of prevention of recurrence
- No significant difference in Clinical Cure at TOC (primary endpoint)



## Clinical Trial Summary

### RESOLUTION OF CLINICAL SIGNS – AMSEL CRITERIA – PHASE 3



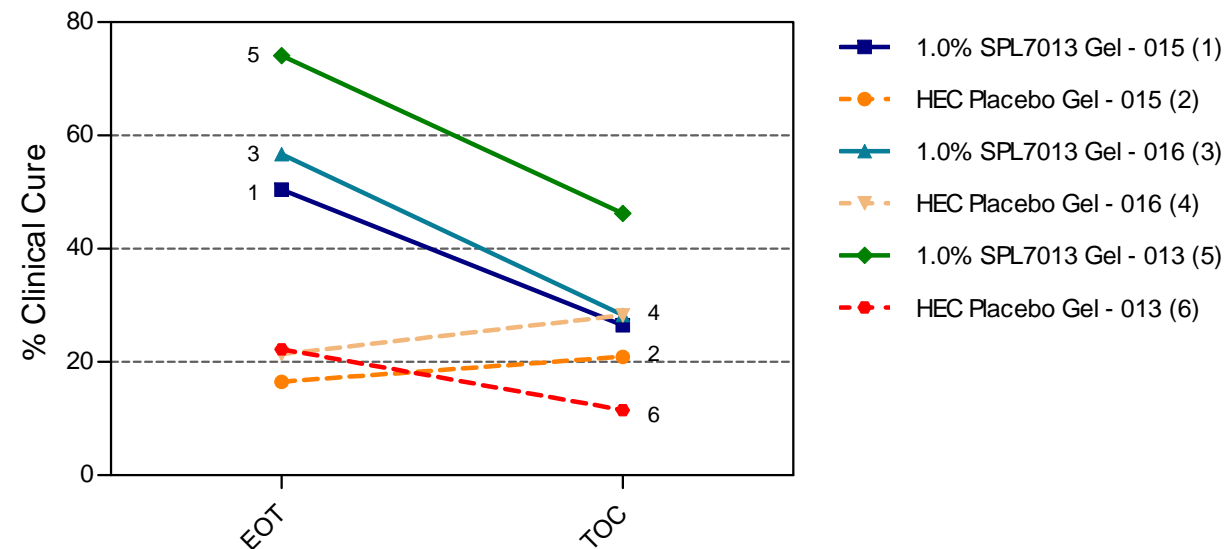
- Highly statistically significant resolution of Amsel criteria with 1% SPL7013 Gel compared with placebo
- Diagnosis/enrolment required presence of all 4 Amsel criteria and Nugent score 4-10
- Clinical Cure required resolution of discharge, whiff and clue cells criteria



## Clinical Trial Summary

### CLINICAL CURE OF BV – PHASE 2 & PHASE 3 COMPARISON

Clinical Cure in Phase 2 (013) and Phase 3 (015 and 016)

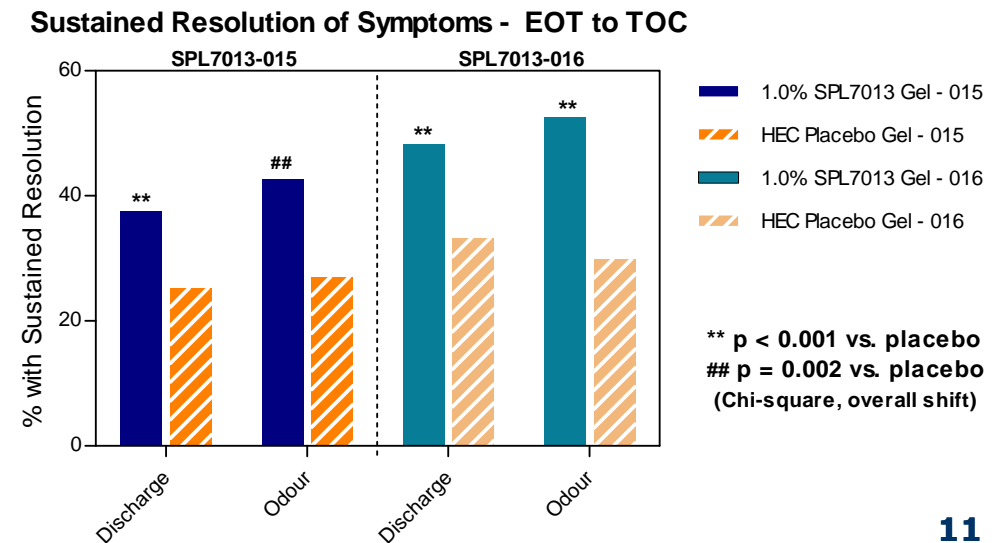
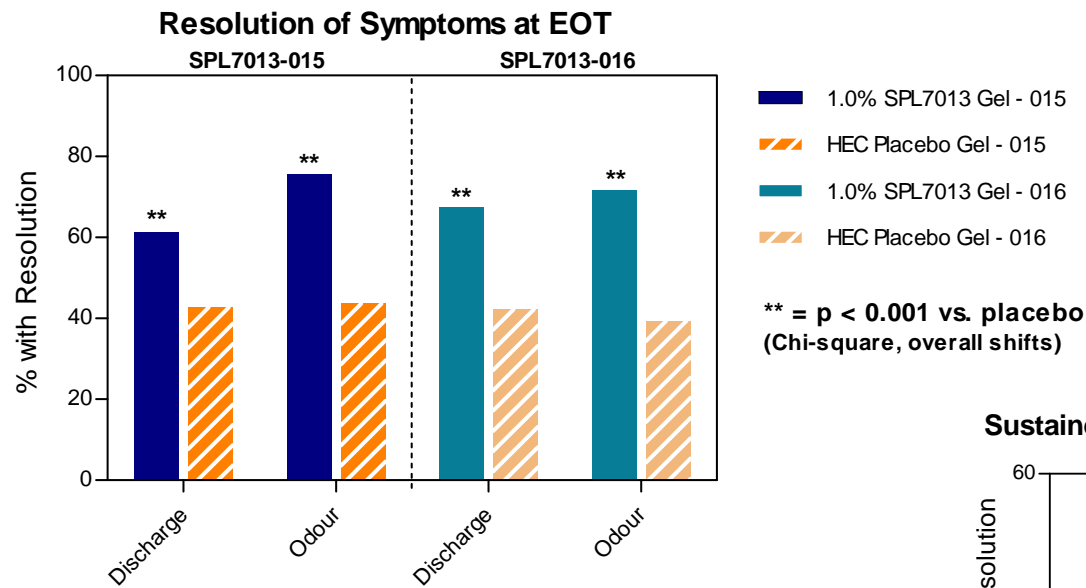


- Placebo Clinical Cure rates behave differently in Phase 3 compared with expected and actual Phase 2 results
- Potential factors include changes in behaviour (e.g. increased sexual activity, alternative therapy, differences between sites)



## Clinical Trial Summary

### Symptomatic Relief: RESOLUTION OF BV SYMPTOMS – PHASE 3





## High level of Patient Acceptability and Experience of VivaGel®

### Formal market research with trial participants

- BV is a life impacting, debilitating infection that affects nearly 1 in 3 women

*“It takes a lot away from your self-esteem, you know, especially when you’re in a relationship because it’s just not pleasant all the way around ...it’s really uncomfortable, and it kind of brings down your self-esteem....makes you feel inadequate ...” – Patient*

*“I’ve been going through bacterial vaginosis for a few years now. On and off, on and off, it comes it goes, it comes it goes...and I have it now. a whole headache, dealing with it...” – Patient*



- Women treated with VivaGel® reported **quick relief from symptoms** and high levels of **satisfaction** with the product (including compared to past experiences with other products)
- **Twice** as many women were satisfied to **extremely satisfied** with VivaGel® compared to placebo.



*“I would definitely use it again. Especially since I know that it works, it’s very effective.” – Patient*

*“Like I said, I thought it was effective ‘cause within the first day I noticed a change already. It was like gone almost overnight....” -Patient*





## Phase 3 BV Treatment Clinical Trial – Conclusions and next steps

### **Key Findings:**

- *VivaGel® demonstrates statistically significant Clinical Cure and effectiveness in treating symptoms of BV at the end of treatment (EOT)*
- *Primary FDA endpoint (Clinical Cure 2-3 weeks after cessation of treatment) not met*
- *Excellent safety profile including very low rates of candidiasis (cf. other products)*
- *Patient acceptability research undertaken at the end of the trial was very positive with VivaGel® treated women reporting rapid and sustained relief from symptoms.*

### **Implications and next steps:**

- *Confounding factors including unusually high efficacy in placebo at some trial sites will be fully investigated and discussed with FDA*
- *Given the efficacy shown for VivaGel®, other claims such as symptomatic relief and treatment claims in other regulatory jurisdictions will be explored*
- *Phase 2 trial of VivaGel® for the prevention of BV re-occurrence is on track, with results anticipated Q1 2013, and is not negatively impacted*
- *Clinical Cure, resolution of patient symptoms of BV and excellent safety profile all support the prevention of BV recurrence indication for VivaGel®.*
- *No negative impact on other products based on SPL7013 (VivaGel®); BV symptom resolution and safety data support other product lines (e.g. condom).*



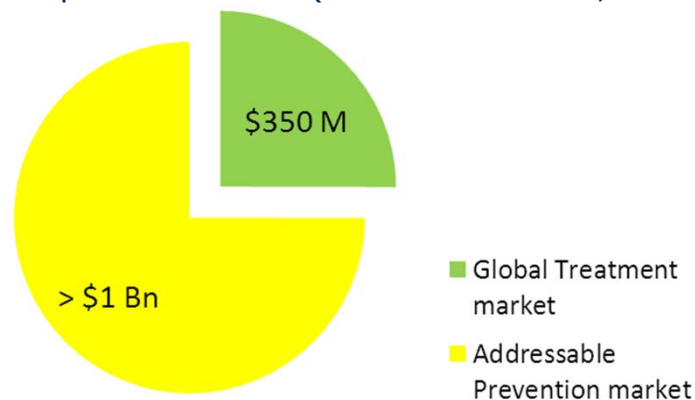
## VivaGel® - Bacterial Vaginosis (BV)

### Partnering and the market opportunity for Prevention of Recurrence

- Active engagement with ~10 top tier companies in the women's health field
- Potential partners see Prevention of Recurrence (PoR) as a "game changing" indication

Phase 2 studies complete; results Q1 2013

- Phase 2 trial dosing of *VivaGel* every 2nd day
- Primary endpoint is at EOT (end of treatment, 16 weeks)



#### VivaGel for Prevention of Recurrence indication:

- No approved competitors
- Off label use of existing products have considerable shortcomings
- High unmet need from physicians and patients with significant population of affected women
- VivaGel exhibited strong efficacy at the end of treatment (EOT)
- VivaGel demonstrated to be very safe in clinical studies in over 500 women
- VivaGel is applied topically and not systemically absorbed therefore considered a better option for long term therapy



## 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)

\* Mouse Xenograft (MDA- MB 231)



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

Significant Tumour targeting and extended half-life

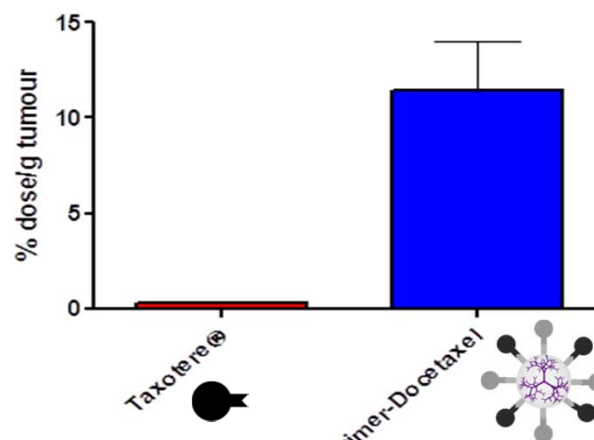
- Pharmacokinetic studies with radiolabelled drug demonstrate that the **Dendrimer-Docetaxel formulation extends the docetaxel plasma half life by at least 60 fold vs. Taxotere®**
- Greater half life will enable **sustained and greater delivery of docetaxel** to the tumour
- Dendrimer-Docetaxel formulation 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 rats per group

Mouse Tumour Biodistribution



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

n = 5 mice per group



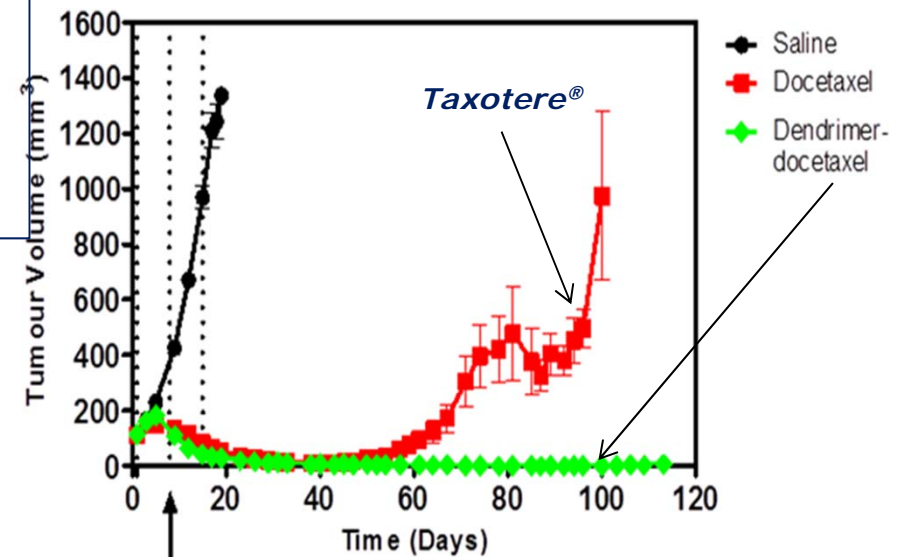
## Starpharma's Dendrimer-Docetaxel formulation

**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

## Efficacy: Breast Cancer Model\*

Mean Tumour Volume (MDA-MB-231)



Animals Dosed on days 1, 8 and 15

N=10/group

\*P < 0.0001

**PBS  
(Vehicle control)  
19d**



**SPL's  
Dendrimer-Docetaxel  
19d**





## 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

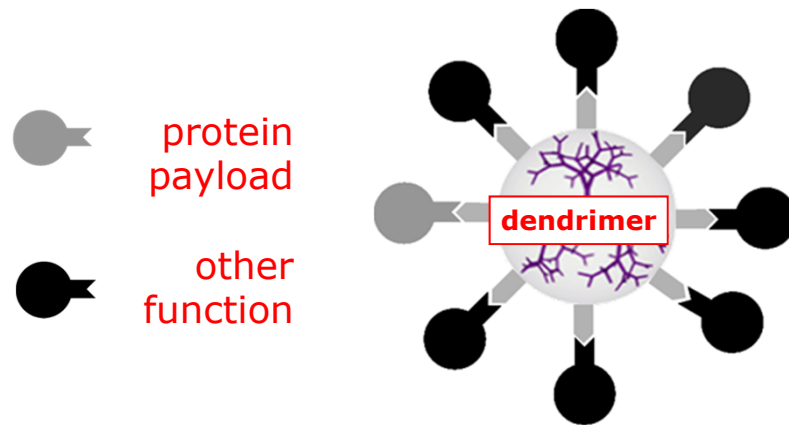
Brand	Molecule	Innovator Company	2009 Sales (\$ M USD)
Taxotere	Docetaxel	Sanofi Aventis	2,140
Eloxatin	Oxaliplatin	Sanofi Aventis	1,484
Alimta	Pemetrexed	Eli Lilly	1,306
Gemzar	Gemcitabine	Eli Lilly	1,107
Doxil/ caelyx	Pegylated doxorubicin	JnJ / Merck	384
Camptosar	Irinotecan	Pfizer	329
Abraxane	Albumin 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, platinumums, paclitaxel, doxorubicin
- Combination of chemotherapy loaded dendrimers and antibodies may enable further targeting to specific cancer cell populations in organs and metastases



## Dendrimers for Drug Delivery - Proteins and Peptide Drugs

Longer half life – less frequent dosing



### Approach

Conjugate protein or peptide to functionalised dendrimer

### Benefit

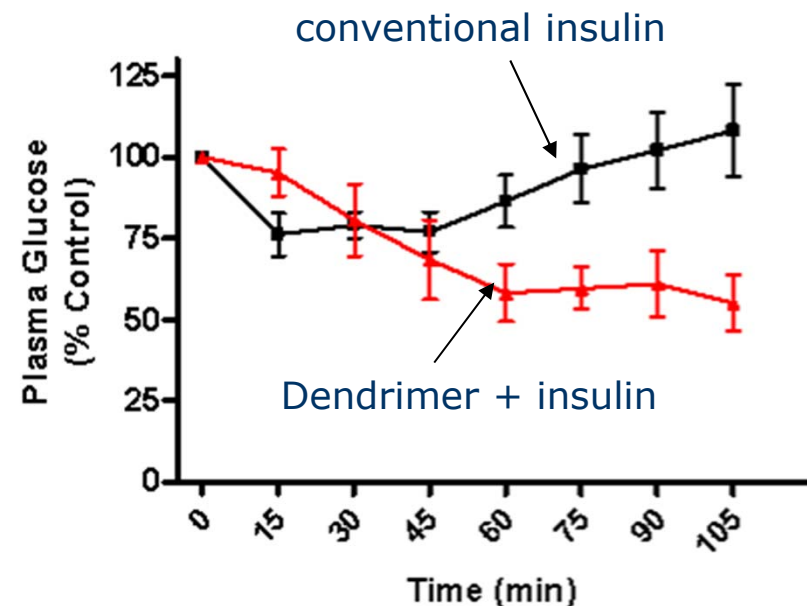
**Control half life** of protein or peptide therapeutics  
**Improve dosing regimen**  
**Reduce protein metabolism**

### Status

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

Co-development program with undisclosed partner

### *In vivo* mouse model



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





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

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

Dendrimers can enhance the performance of existing agrochemicals and create proprietary (patentable) formulations

- Extension/enhancement of effect
- Solubility 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**



## 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	<b>\$2,237M</b>
Insecticides	<b>\$1,858M</b>
Fungicides	<b>\$1,151M</b>

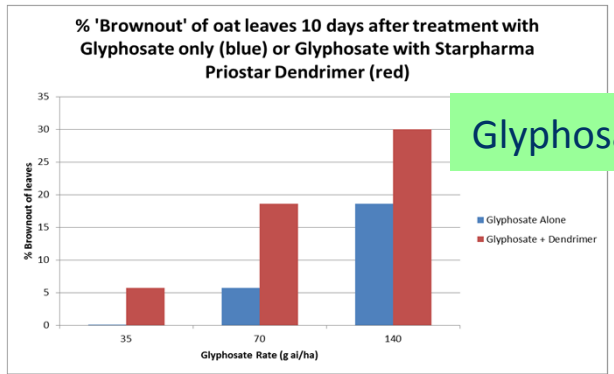
Active Ingredient	Activity	Market Value (\$M USD)
Glyphosate	Herbicide	5000
Imidacloprid	Insecticide	1000
Acephate	Insecticide	350
Pendimethalin	Herbicide	350
Acetochlor	Herbicide	300
Chlorpyrifos	Insecticide	300
Trifluralin	Herbicide	300



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

## Starpharma's Dendrimer formulations show significant advantages

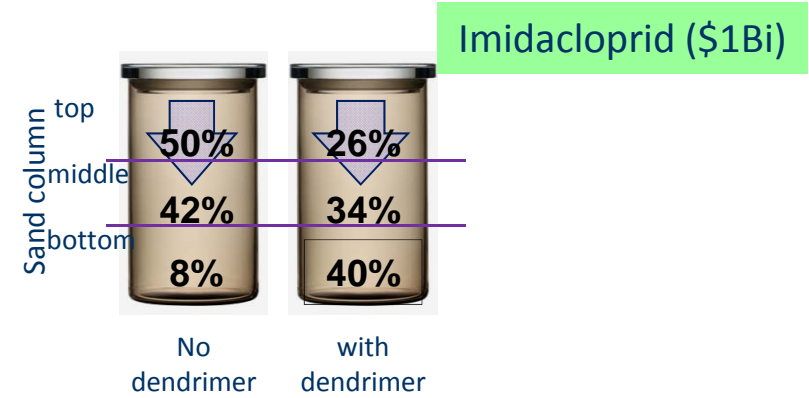
### Enhanced Efficacy



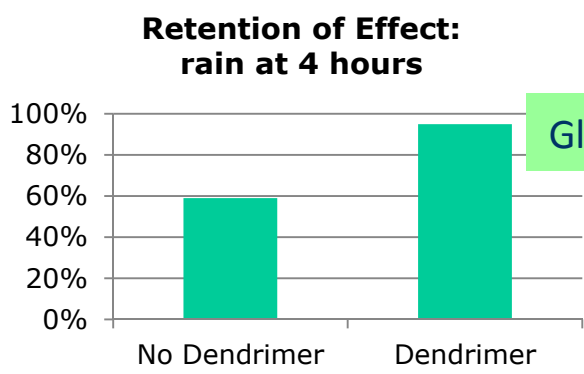
Glyphosate (\$5Bi)



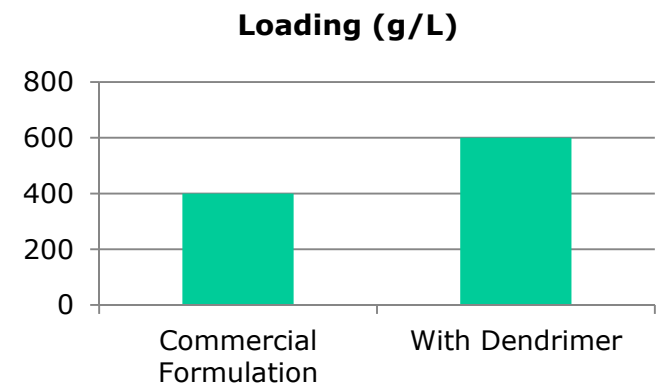
### Improved Soil Penetration



### Improved Rain-fastness



Glyphosate (\$5Bi)



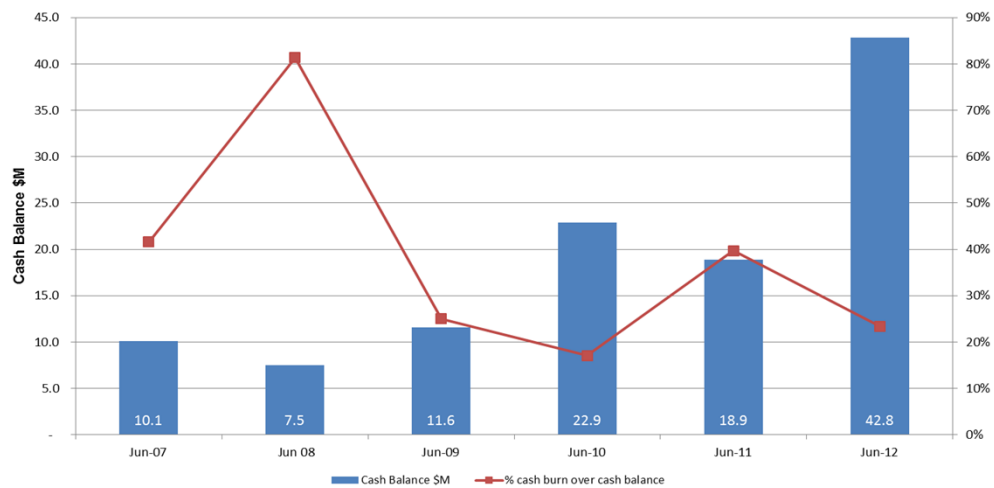
Improved Loading

Major Herbicide



## Summary

**Strategy: commercially exploit its platform to generate multiple, parallel revenue streams**



	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 30 June	18.9	42.8 <sup>^</sup>

<sup>^</sup>Cash Balance 30/9/12 \$37.6M (excluding tax credits)

- *A highly versatile, proprietary technology platform*
- *Deep and diversified portfolio*
- *Near term commercial and clinical milestones*
- *An impressive and growing portfolio of commercial partnerships*
- *Multiple, well advanced potential revenue streams*

