



## ASX ANNOUNCEMENT

### Starpharma presenting at Nomura Biotech Investment conference

- CEO Dr Jackie Fairley presenting at the *Nomura Biotech Conference for institutional investors* in Sydney, 24<sup>th</sup> July 2012.
- Presentation to include update on the rapidly advancing VivaGel<sup>®</sup> Bacterial Vaginosis Program, and advancements in Drug Delivery and Agrochemicals Programs.

**Melbourne, Australia; 24 July 2012:** Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is today presenting at the Nomura Biotech Investment conference for institutional investors in Sydney.

Dr Fairley will present in detail Starpharma's maturing development portfolio across sexual and women's health, drug delivery and agrochemical programs. Highlights of the presentation include:

**VivaGel<sup>®</sup> Bacterial Vaginosis program:** Starpharma is nearing its most significant milestone to date; the completion of two concurrent Phase 3 pivotal trials investigating VivaGel<sup>®</sup> as a treatment for bacterial vaginosis (BV). The company recently reported that it had passed already the halfway point for patient recruitment in these trials, with one now at 100 percent enrolment and the second now more than 70% enrolled. In addition, recruitment is complete for the Phase 2 prevention of recurrence trial. The Phase 3 treatment trials and the Phase 2 prevention trial are all expected to conclude later this year.

The completion of these pivotal Phase 3 trials will pave the way for Starpharma to seek regulatory approval for VivaGel<sup>®</sup> as a treatment for BV.

**Drug delivery program:** Starpharma's drug delivery program is making excellent progress, with the company recently announcing that its program to improve the blockbuster chemotherapy, docetaxel, is advancing rapidly with clinical trials anticipated to commence in 2013.

In parallel, Starpharma is investigating how its technology can be applied to improve the delivery of a number of other major therapeutics, including the areas of antibodies and hormones.

**Agrochemical program:** Starpharma's work in the improvement of chemicals used in agriculture, like pesticides and herbicides, is progressing into new areas. The lead candidate in Starpharma's internal agrochemical program is an enhanced reformulation of the best-selling herbicide glyphosate (RoundUp<sup>®</sup>), which has annual sales in excess of US\$5 billion.

In addition, Starpharma is now applying its dendrimer technology to selected other off-patent agrochemical agents with the potential to improve their performance and/or reduce or completely remove environmentally damaging solvents.

“We are pleased to have the opportunity to present Starpharma at this forum and to provide an update to investors on the rapid advancement across all three development programs supported by Starpharma, in particular the excellent progress on our pivotal trials for the treatment of bacterial vaginosis,” said Chief Executive Officer Dr Jackie Fairley.

The presentation is attached.

#### ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) 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. In addition, products for diagnostics and laboratory reagents are already on market through licence arrangements with partners including Siemens Healthcare and Merck KGaA.

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. Most recently Starpharma announced pre-clinical results in its Docetaxel (Taxotere®) program demonstrating significant improvements in that agent's anticancer efficacy and the enhancement of solubility offering potential safety benefits as well. The company is also exploring dendrimer opportunities in agrochemicals in a series of industry partnerships as well as with internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®).

Starpharma's headquarters and research facilities are located in Melbourne, Australia

#### 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.



**Starpharma Holdings Limited**  
ASX:SPL

**Nomura Biotech Conference**

Sydney

24 July 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 underway (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 including **Lilly, GSK**, plus several undisclosed
- Dendrimer-docetaxel demonstrated significantly improved efficacy vs. Taxotere®

### 3. Dendrimers in Agrochemicals:

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

**16 July 2012**

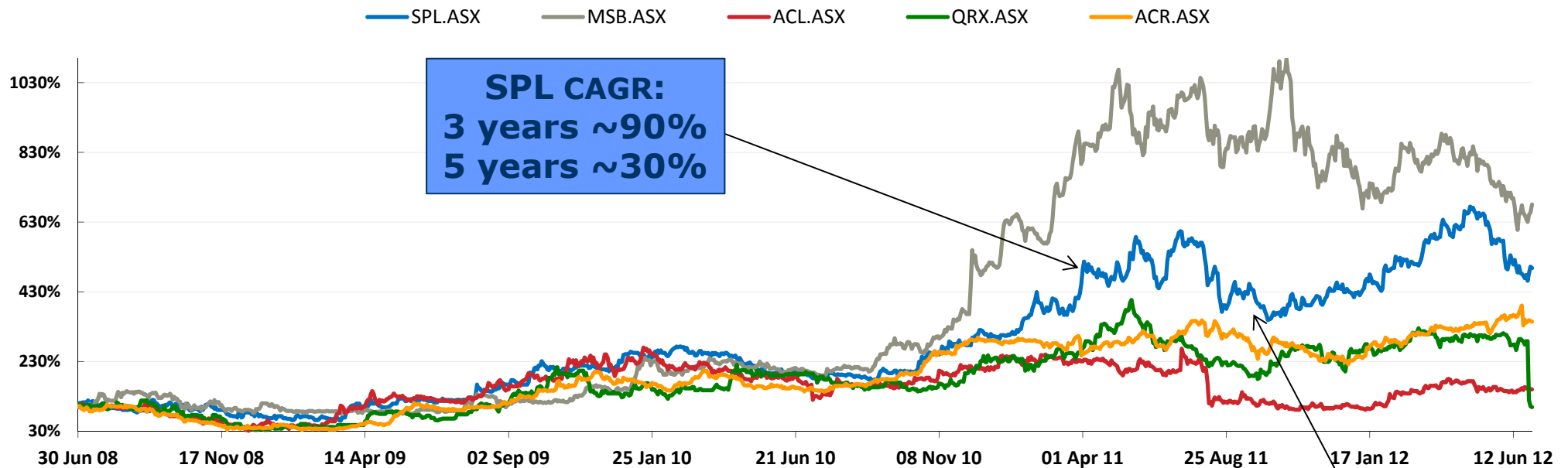
<b>Share Price SPL</b>	<b>A\$1.49</b>
<b>52 Week Range</b>	<b>A\$0.92-1.88</b>
<b>Shares on Issue</b>	<b>~281.7 M</b>
<b>Mkt. Cap.</b>	<b>~A\$420M</b>
<b>Cash 31/3/12</b>	<b>A\$46.6M</b>
<b>Major Shareholders</b>	<b>Acorn, M&amp;G, Orbis, Dow</b>
<b>5 Year CAGR (to 30/6/12)</b>	<b>~30%</b>





## Starpharma's position in the Australian biotech sector and price performance

Four year price performance versus peers (2008-2012)

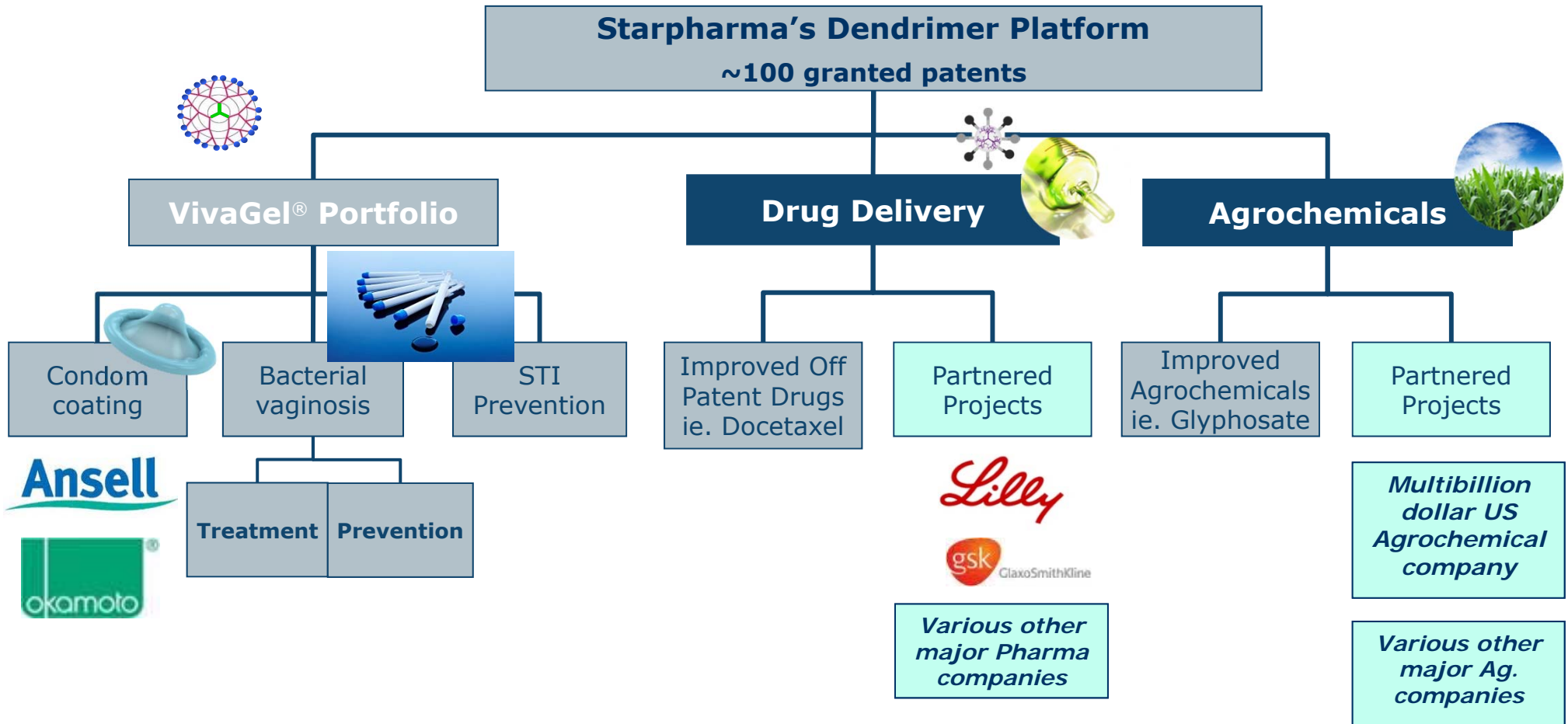


- SPL has shown growth year-on-year; joined ASX 300 2011
- Market cap. ~\$420M ranks SPL 4<sup>th</sup> in Biotechs (excluding devices)
- Strong cash position \$46.6M (\$35M raised Nov. 2011 *at market* \$ 1.075)
- Major near-term milestones to deliver significant inflection points
- Shareholding increasing 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**



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), GSK (Stiefel); Drug delivery collaborations  
- plus several undisclosed partnerships with Major Pharma. partners

*Multibillion dollar US  
Agrochemical company*

### Dendrimers for Agrochemicals

Major US Ag. Company -plus various undisclosed partnerships



### Stratus CS®

Various diagnostics licensed to Siemens Healthcare (Dade Behring)



### SuperFect®

Gene transfection technology licensed to Qiagen



### Starburst®

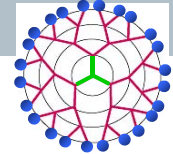
Dendrimers commercially available via Sigma Aldrich

**Priolect®** : 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)

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



## VivaGel® Coated Condom Partnerships

Ansell Limited (ASX:ANN) and Okamoto Industries

Partner	Market Position/Share	Major Brands
<p><u>Okamoto Industries</u> (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. ~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>	<p><i>Skinless</i>® </p> <p><i>003</i>® </p>
<p><u>Ansell Limited</u> ASX:ANN</p> 	<ul style="list-style-type: none"> <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>	<p><i>Lifestyles</i>® </p> <p><i>SKYN</i>® </p> <p><i>ZERO</i>®</p> <p><i>Manix</i>®</p>

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

**Global Branded condom market est. \$1.1-1.6Bi; growing 4-5% pa**



## VivaGel® - Bacterial Vaginosis (BV)

An Attractive Commercial Opportunity and Unmet Need



- Bacterial Vaginosis: the most common vaginal infection worldwide
- ~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 current antibiotic treatments have significant shortcomings:**
  - 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	<b>US \$300-350M</b> (topical agents)	Metronidazole Clindamycin (antibiotics)	FDA Granted SPA*  2 Pivotal Phase 3 trials underway (n~220 each - one fully recruited)	Late stage License
2. Prevention of BV recurrence	Significantly larger vs. treatment:  <b>Est. &gt; US\$1 Bi.</b>	None approved	Phase 2 Trial fully recruited and underway (n~200)	Late stage License

\*SPA: FDA's Special Protocol Assessment

### Benefits of VivaGel® :

*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 Cure <sup>^</sup>	EOT (2-5d post Rx)	<b>74% **</b> (P=0.0002)	<b>22%</b>
	TOC (2-3 wks post Rx)	<b>46% **</b> (P=0.006)	<b>12%</b>

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	✓

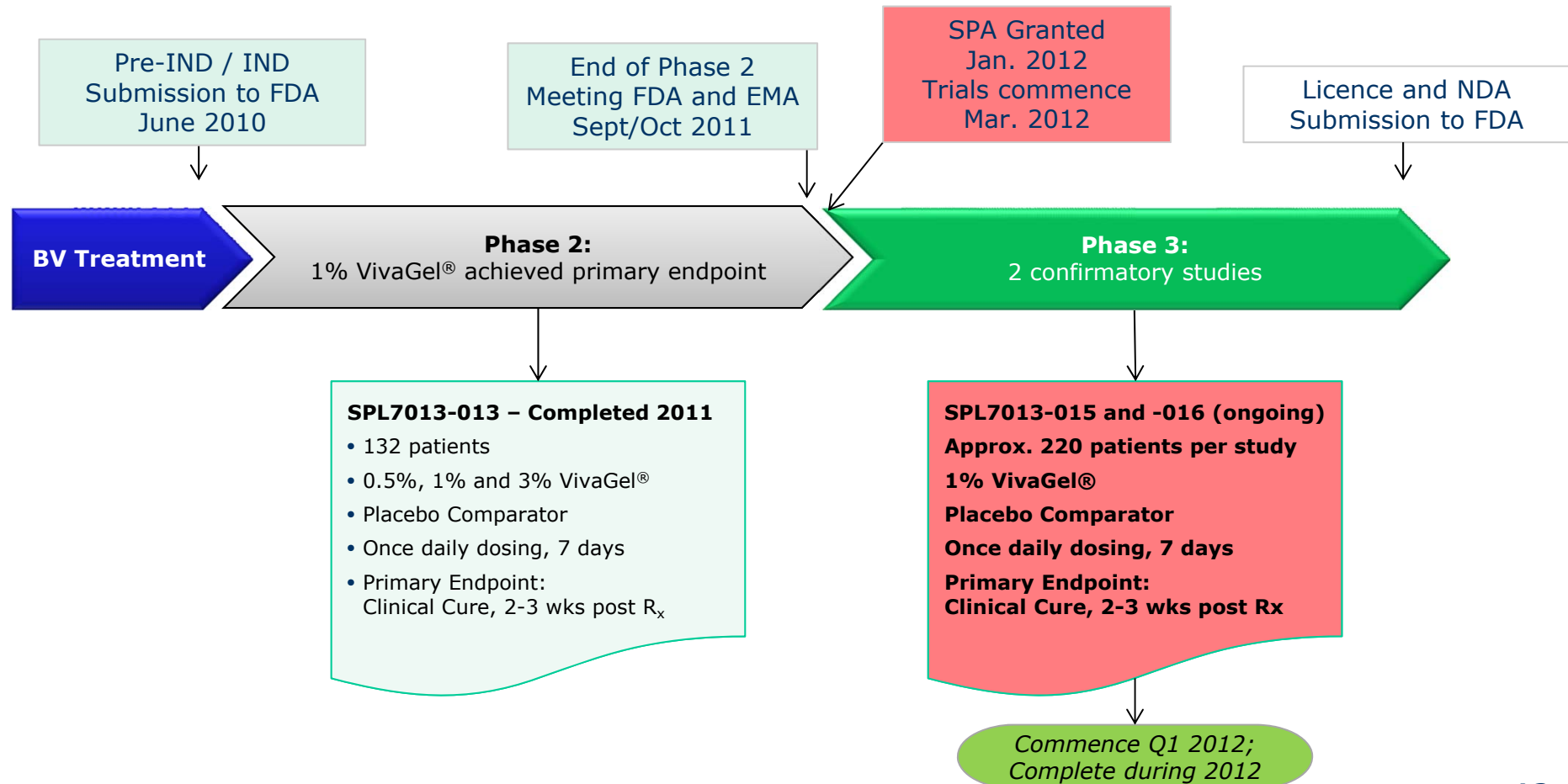
\*\* Statistically significant result compared with placebo;

<sup>^</sup>No abnormal discharge, and ≤ 1 other Amsel's criteria; \*1% SPL7013 <sup>^</sup>vs. 35% for placebo; <sup>^^</sup> Special Protocol Assessment



# VivaGel® - Bacterial Vaginosis (BV)

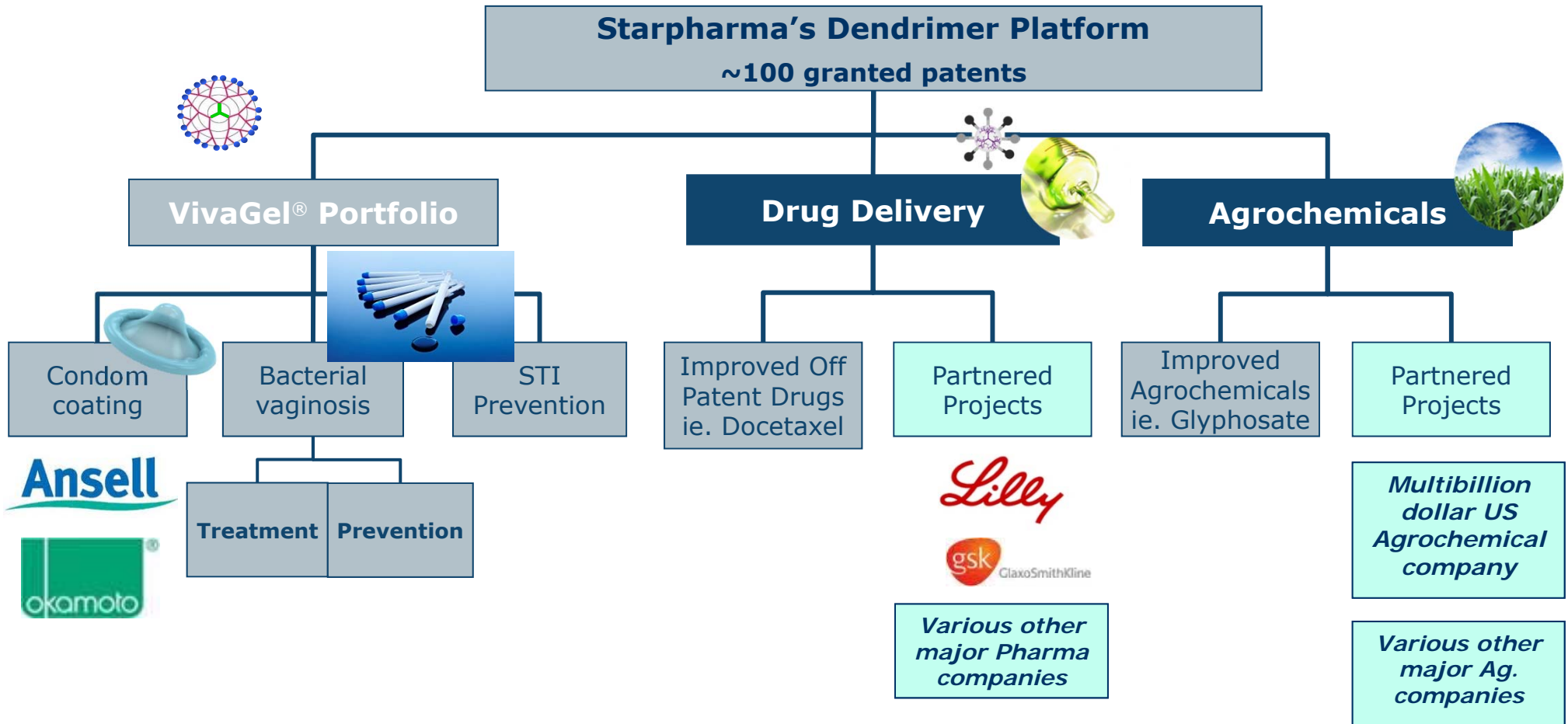
## Clinical Development Program





## SPL's Dendrimer technology platform

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



Other: **SIEMENS**

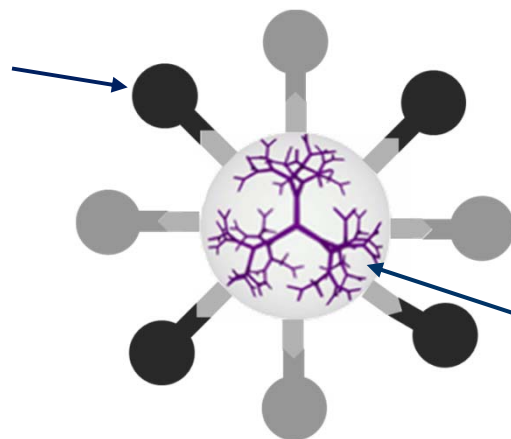




## Dendrimers for Drug Delivery

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

Attached Drug Molecule  
(small molecule, peptide, protein, antibody)



Drug Delivery Dendrimer

Partners including:

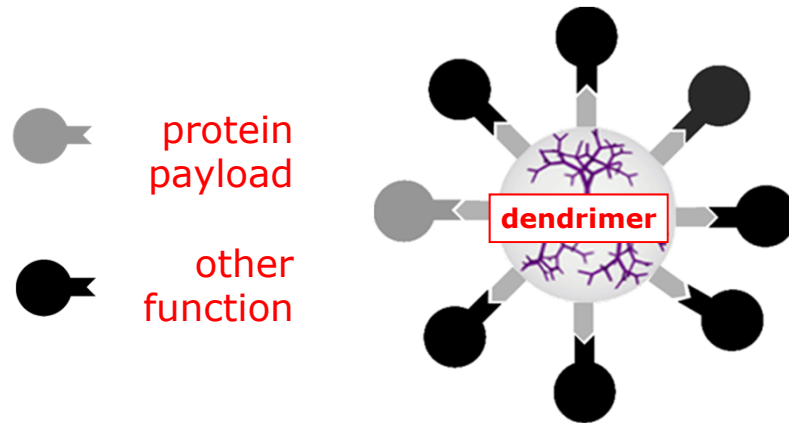


Feature	Potential Benefits for Patients and/or Manufacturers
Improved Drug Efficacy	More effective treatments or lower doses
Reduced Toxicity of Actives	Reduced side-effects
Improved Drug Solubilisation	Less toxic formulations (allowing removal of toxic excipients) Less painful injection formulations
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

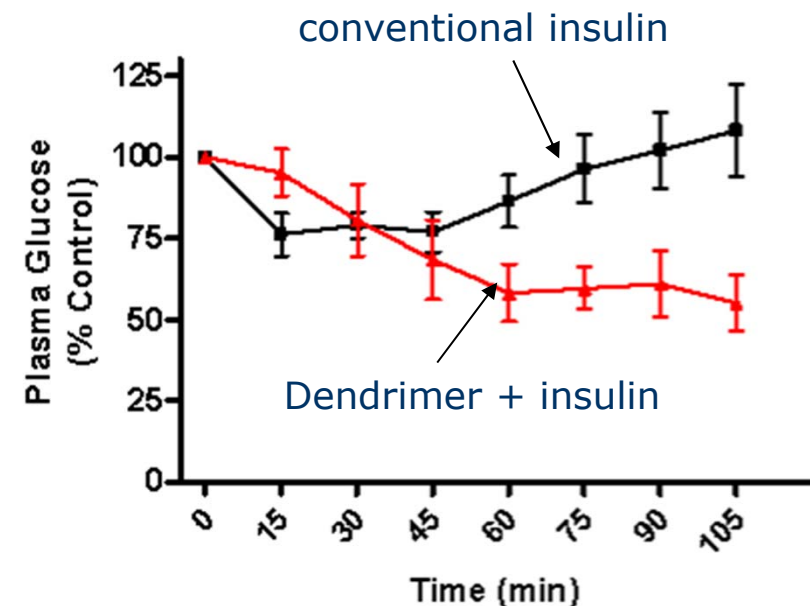
**Control half life** of protein or peptide therapeutics  
**Improve dosing regimen**  
**Reduce protein metabolism**

### 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***



## Starpharma's improved docetaxel formulation

Developing **major commercial value** with the drug delivery programs' **lead candidate**

- Docetaxel is a blockbuster chemotherapeutic (Taxotere<sup>®</sup>) with US\$ billion sales (\$3Bi 2010)
- It is off-patent but there is significant potential for improved (patented) formulations using SPL's dendrimers
- Starpharma's dendrimer-docetaxel has already demonstrated several significant advances which address undesirable characteristics of the original formulation of docetaxel

### **Improvements demonstrated for SPL's Dendrimer-docetaxel over commercial formulation Taxotere<sup>®</sup>:**

1. Improved solubility allowing removal of toxic components
2. Improved efficacy (human breast cancer model)
3. Extended half-life



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

Improved Docetaxel (Taxotere®) Formulation



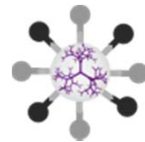
- Anti-cancer drug Docetaxel (Taxotere® - Sanofi Aventis) Sales: US\$3Bi pa. (2010)
- Docetaxel is insoluble; Taxotere® incorporates a detergent which is associated with significant toxicity
- Starpharma's aim: to develop a reformulation of docetaxel with benefits: longer half-life in the body, enhanced 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)



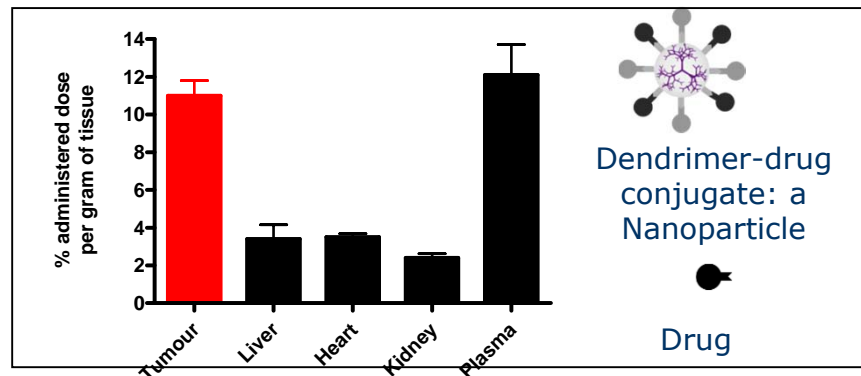
## Starpharma's Dendrimer-Docetaxel formulation: Significant improvement in efficacy

Improved Docetaxel (Taxotere®) Formulation

### Starpharma's dendrimer-docetaxel formulation:

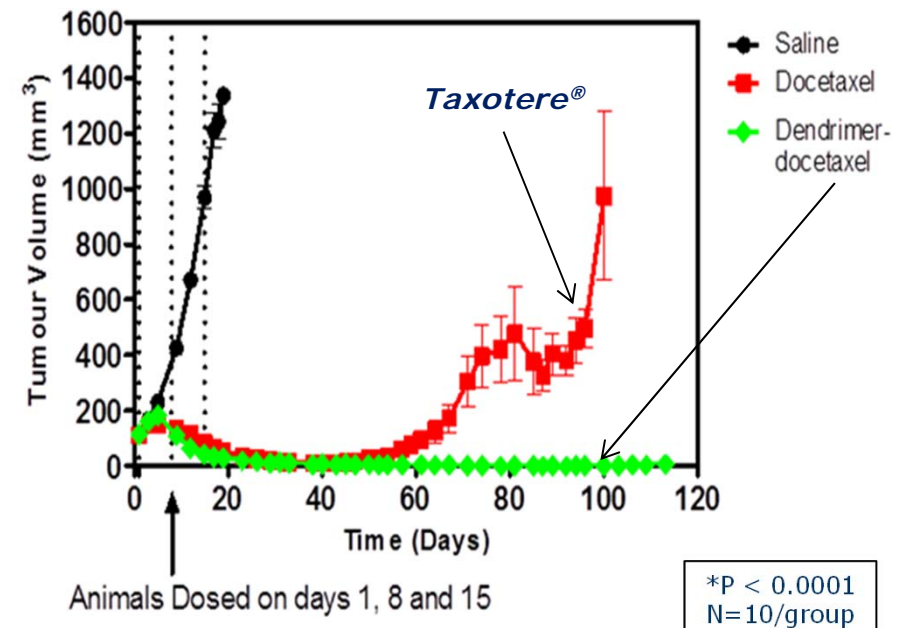
- Solubility ↑ 2,000–8,000X (allowing removal of detergent)
- **Significantly\* better efficacy than Taxotere® .....**
- **60%** dendrimer-docetaxel mice - **no evidence of tumour (94d)**
- Vs. Taxotere® 100% mice - tumour re-growth (94d)
- Patents filed will offer protection to 2032

Tissue Deposition  
of Dendrimer-drug conjugates  
(nanoparticles)



### Efficacy: Breast Cancer Model\*

Mean Tumour Volume (MDA-MB-231)





## Broad potential for dendrimer improvement of major drugs

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

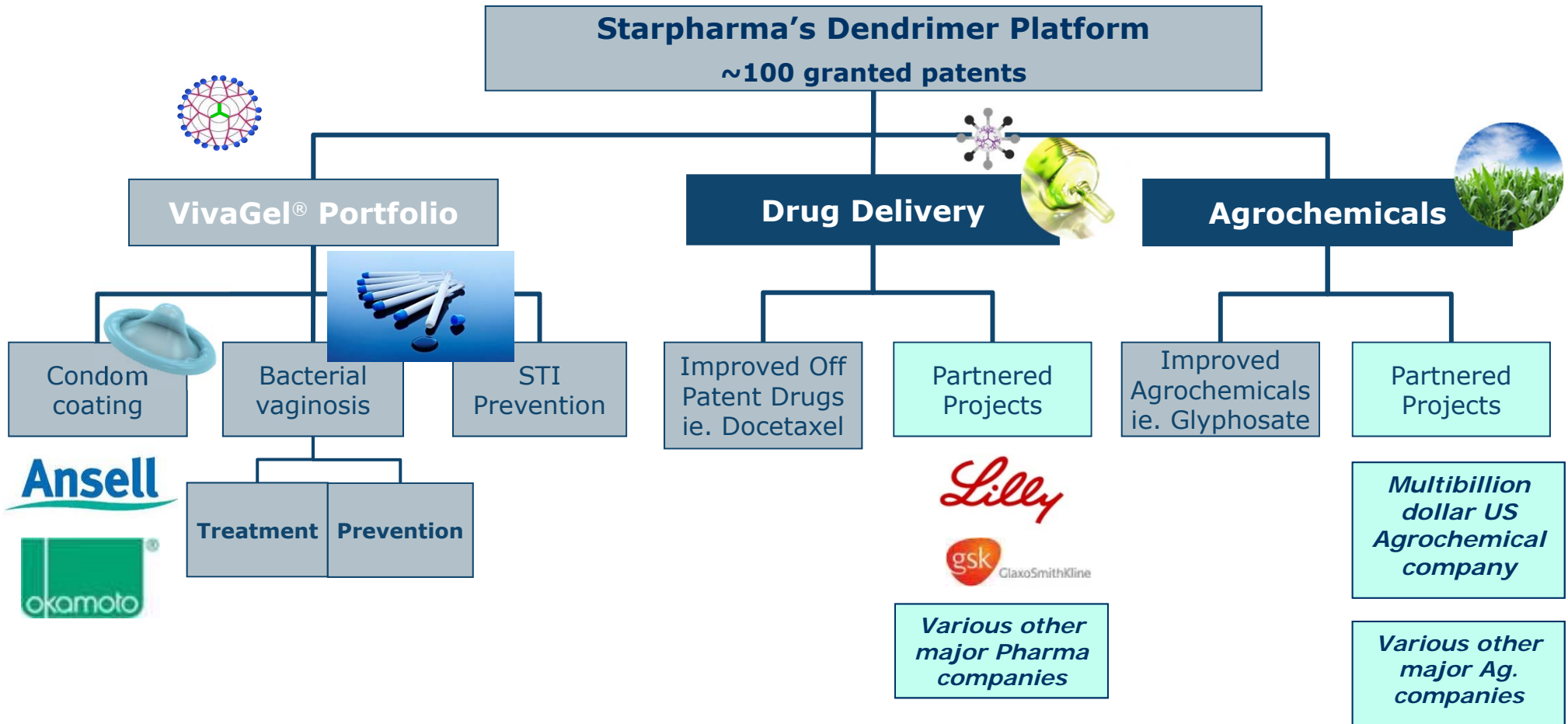
SPL has already applied its dendrimer technology to a range of drug candidates including:

1. Top-selling chemotherapeutics (e.g. docetaxel, gemcitabine, platinum, Taxol, doxorubicin, )
2. Hormones (e.g. insulin, testosterone)
3. Antibodies



# SPL's Dendrimer technology platform

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



Other: **SIEMENS**



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

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



### 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**

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

Initial Results: Improvement of Glyphosate and other actives



Starpharma's initial results -



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

Other results include:

- Modification of soil penetration properties
- solubility enhancement

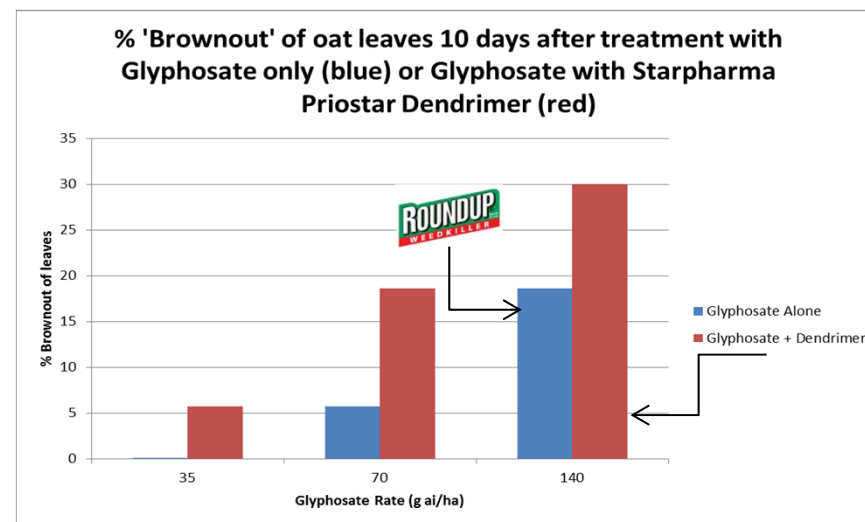


Photo depicting "brownout"



## 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 industry-experienced Management Team and Board*

	FY 2011 AUD \$M	H1 FY 2012 AUD \$M
Total revenue and income	3.3	1.2
Net loss after tax	8.9	4.7
Cash outflow from operations	(6.5)	(3.9)
Net cash inflow from financing	3.5	33.8
Cash at period end	18.9	49.0*

\* \$46.6M @ 31/3/12

*"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*

*"The numerous commercial options make Starpharma one of the most exciting biotech companies listed on the ASX." ...Shaw Stockbroking*





## ASX:SPL Highlights 2011 & H1 2012

- VivaGel® demonstrates efficacy as a treatment for bacterial vaginosis (BV)
- VivaGel®-coated condom deals signed with Okamoto, market leader in Japan, and Ansell (No. 2 Globally)
- Starpharma's dendrimers improve performance of leading agrochemicals including active in Roundup® (glyphosate)
- SPL Elevated to the S&P/ASX 300
- \$35M Capital Raising completed (at market, \$1.075)
- M&G / Prudential (UK) becomes a Substantial Holder
- Phase 3 BV design confirmed by FDA and EMA
- Special Protocol Assessment (SPA) received from FDA for Phase 3 BV Trials
- Starpharma's dendrimer- docetaxel shows significantly improved efficacy vs. Taxotere® in animals
- Pivotal Phase 3 BV Treatment Trials commenced: First trial now 100% recruited , Second >70%