



Dr. Jackie Fairley CEO

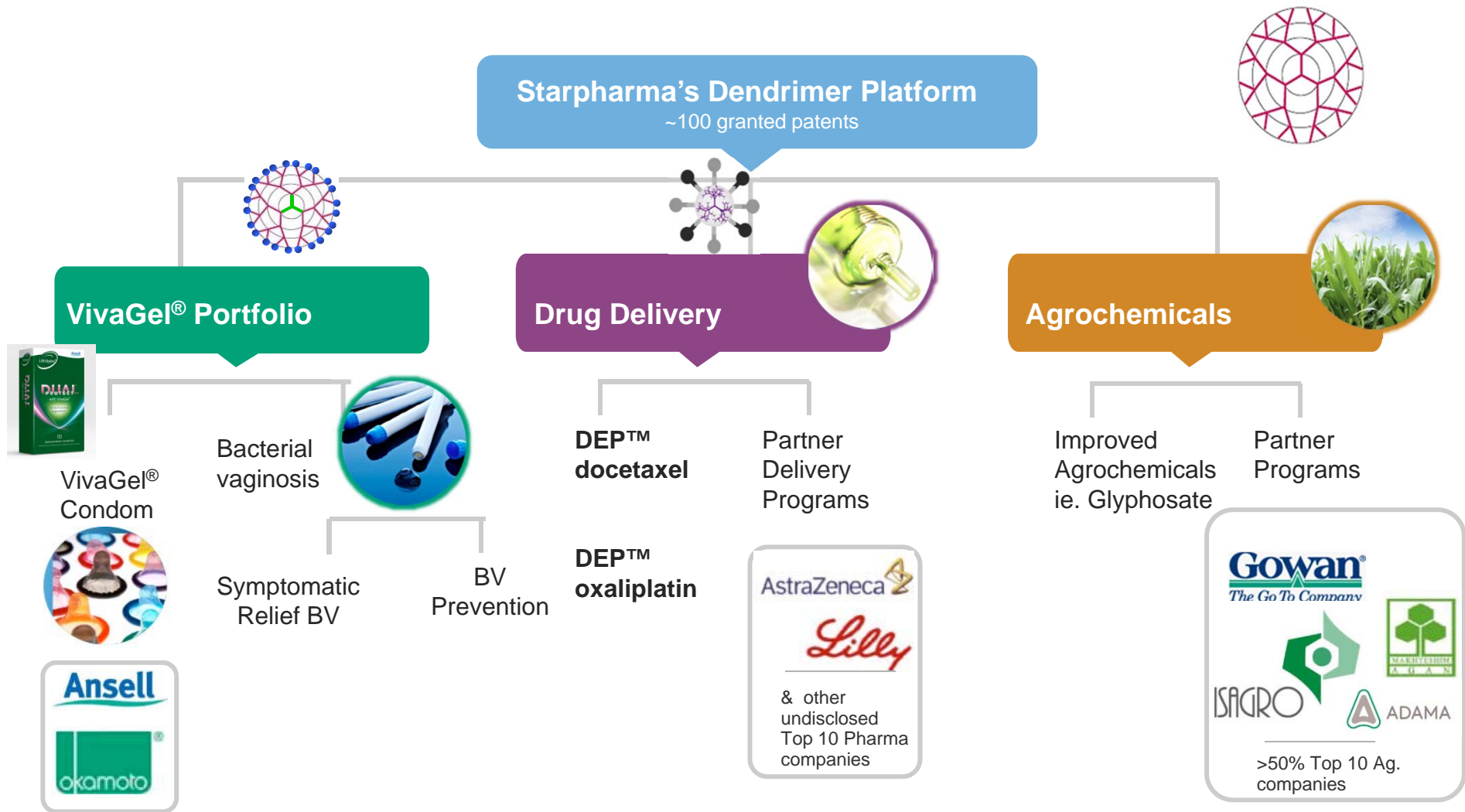


**STARPHARMA HOLDINGS LIMITED**  
ASX:SPL; OTCQX:SPHY

**Biotech Showcase  
January 2015**

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# A global leader in nanoscale polymers (dendrimers) Potential for multiple and parallel revenue streams



## Pharmaceutical Development Portfolio – Recent Progress and Plans

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

→ Completed

→ Planned

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



**Drug Delivery**

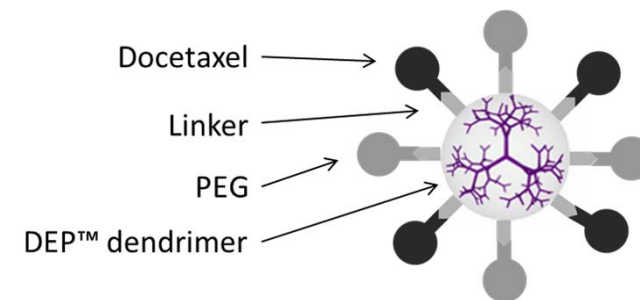
## Starpharma's DEP™ docetaxel: Multiple benefits

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



### 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)



# DEP™ docetaxel preclinical: Multiple Benefits

## Better efficacy and less toxicity

Enhanced Safety & Less toxicity

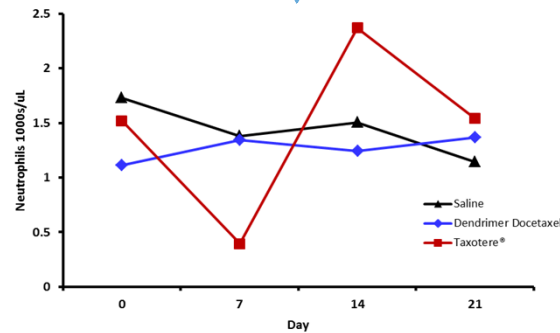
Enhanced Efficacy

Docetaxel + water



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

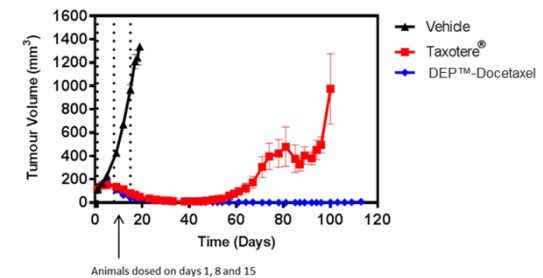
Complete lack of neutropenia with DEP™ docetaxel cf. severe neutropenia for Taxotere®



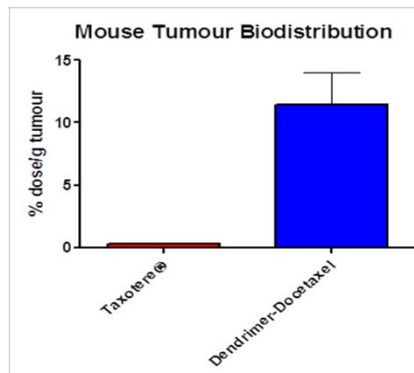
DEP™ Docetaxel formulation and Taxotere® at equivalent doses (based on docetaxel; 9mg/kg); n=6 rats/group

DEP™ docetaxel: improved pharmacokinetics vs. Taxotere®

Mean Tumour Volume



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



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

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

### Primary Objectives:

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

### Secondary Objectives:

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

### Current Status and Preliminary Findings

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

\*Alfred, Austin Health/Olivia Newton John CC and Royal Brisbane & Women's Hospital



# DEP docetaxel<sup>®</sup> Pharmacokinetics (PK) in humans cf. Taxotere<sup>®</sup><sup>^</sup>



## 1. Extended duration of exposure with DEP<sup>™</sup> docetaxel

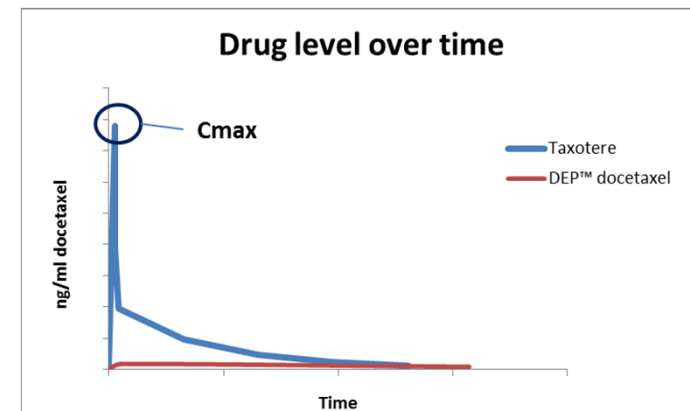
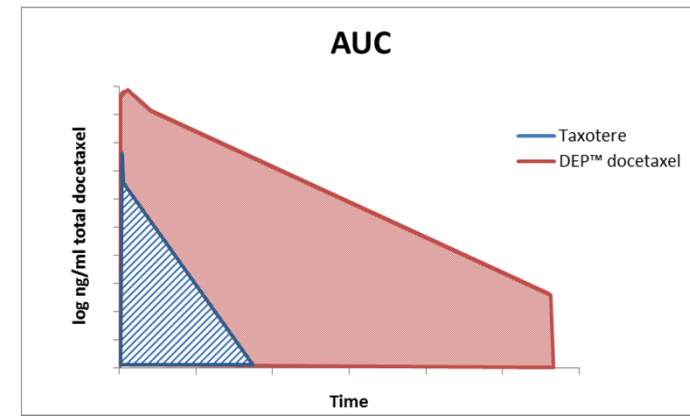
- DEP<sup>™</sup> docetaxel plasma half-life substantially longer (~8 x) than Taxotere<sup>®</sup> (~150x longer in the initial, rapid phases of plasma clearance)

## 2. Increased extent of exposure with DEP<sup>™</sup> docetaxel

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

## 3. Reduced peak drug levels with DEP<sup>™</sup> docetaxel

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

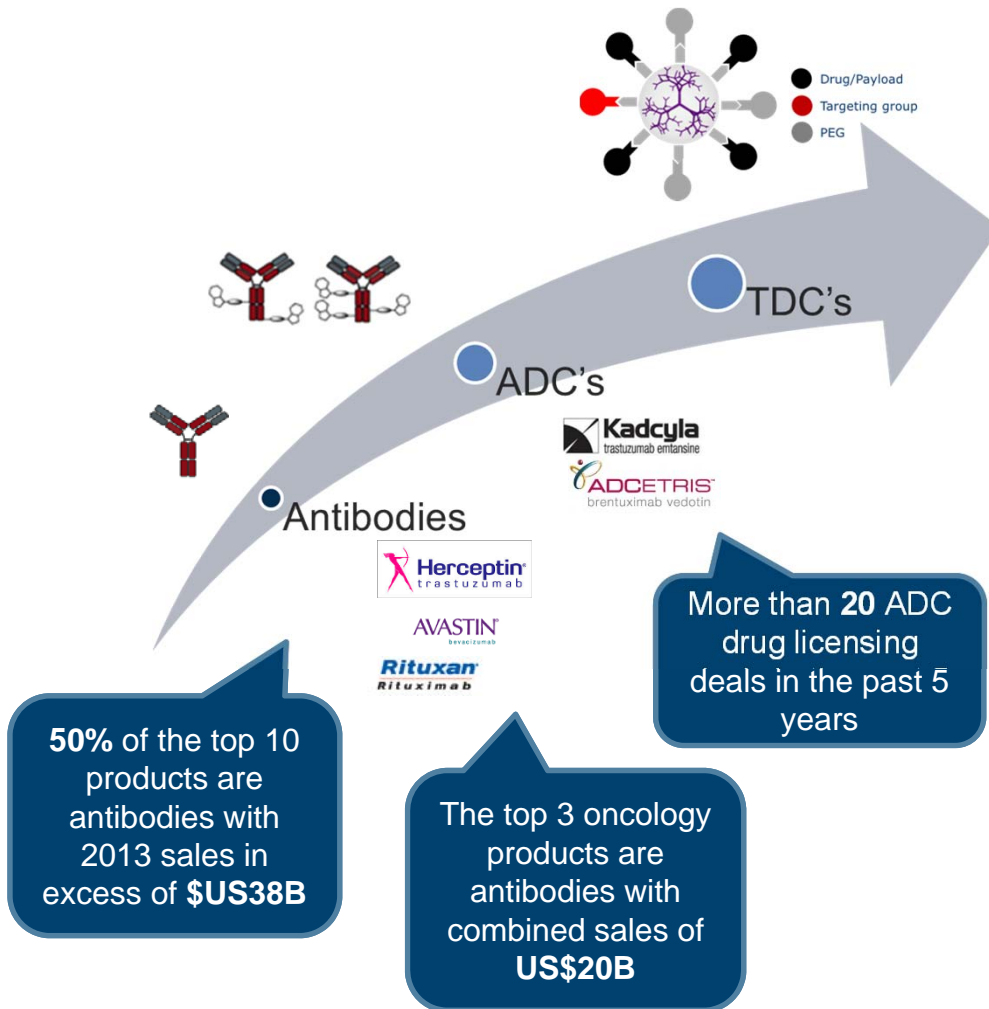


**Example plasma drug levels over time DEP<sup>™</sup> docetaxel vs. Taxotere<sup>®</sup>**

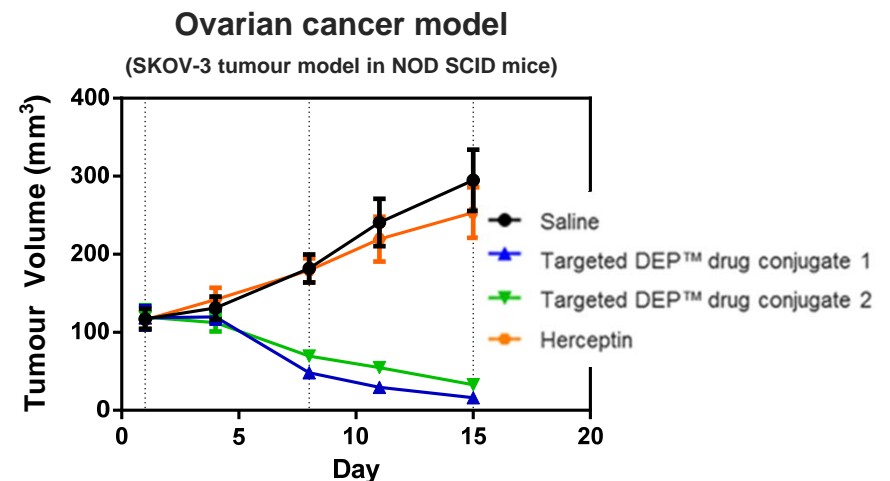
<sup>^</sup> Taxotere<sup>®</sup> parameters based on published data (Bruno et al, 1996)

# Targeted DEP™ Conjugates (TDCs)

## A new approach to drug conjugate design

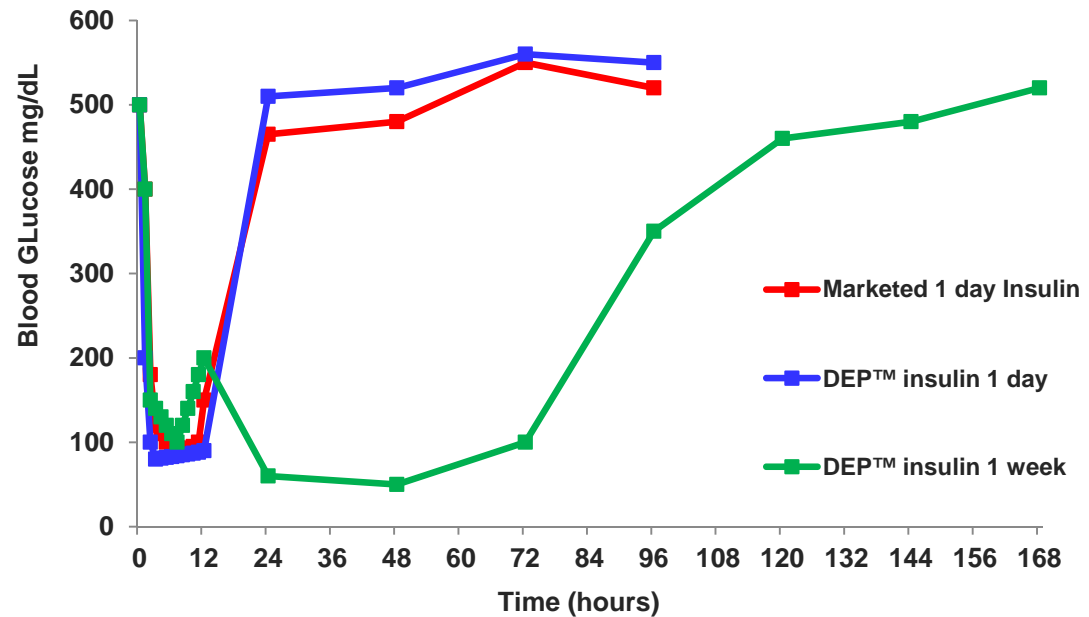


Starpharmas Targeted DEP™ conjugates	
Can use small molecule, whole antibody, antibody fragments or antibody mimetics	✓
Bind with high affinity and specificity	✓
Highly efficacious in cancer model in vivo	✓
Flexible and tailored to suit clinical requirements	✓
Homogeneous	✓
Standard Chemistry yielding consistent, reproducible, stable molecules	✓
Platform already in the clinic and demonstrated to be safe and well tolerated	✓



# DEP™ insulin – Improved pharmacokinetics (long acting)

**DEP™ insulin –  
Efficacy and Duration of action<sup>^</sup>**



### Diabetes Market

**\$43B**  
Global diabetes market  
(2013)  
(Reuters)

Insulin, 19

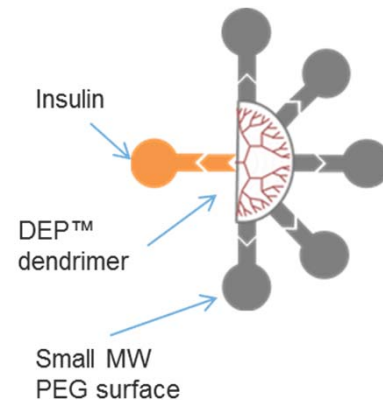
Non-insulin, 24

**\$19B**  
Global Insulin market<sup>^</sup>

**\$9.7B**  
Long acting (1 day) insulin market:<sup>^</sup>

- Lantus \$7.6B
- Levemir \$2.1B

<sup>^</sup>2013 MedTrack



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










**VivaGel® Portfolio**

## VivaGel® condom: A compelling and differentiated product

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





Partner	Market Position/Share	Major Brands
<u>Okamoto Industries</u> (listed on TSE) 	<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 revenues &gt;US\$760M</li> </ul>	Skinless®  003® 
<u>Ansell Limited</u> ASX:ANN 	<ul style="list-style-type: none"> <li>• No. 2 globally for condom sales ~ 20% global share of branded condom market (~\$1.1B)</li> </ul>	Lifestyles®  SKYN®  ZERO®  Manix®

# VivaGel® condom: A compelling and differentiated product



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

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

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

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

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

*"I would definitely buy this product without a shadow of a doubt....."*

VivaGel® Condom  
Consumer Research

*"I think that this product is amazing..... This product is very special and interesting."*

*"I have rated this product a 5/5 as this is a major breakthrough in the condom market and for world health..."*

VivaGel® Condom  
Consumer Research

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

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

Vice President, Asia Pacific –  
Sexual Wellness Division



>2,000 Tweets;  
including Perez Hilton to  
~5.9m followers



^ Formal research conducted in 1800 condom users across USA, Europe, Asia and Sth America

# VivaGel®- Bacterial Vaginosis (BV)

## Two attractive commercial opportunities



### Bacterial Vaginosis:

the most common vaginal infection worldwide

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

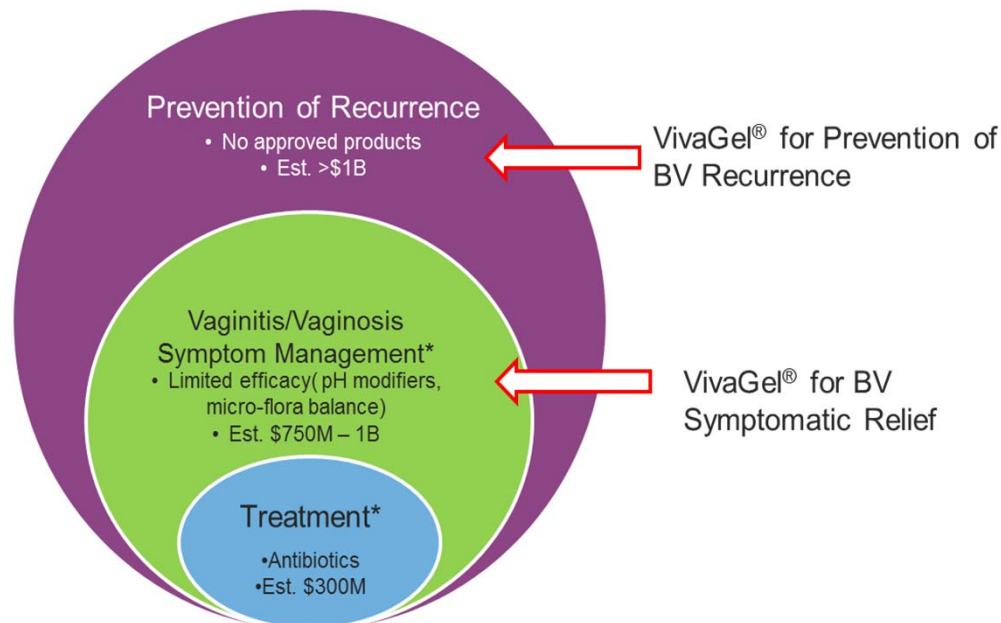
- ❖ “It was like gone almost overnight”
- ❖ “I would definitely use it again.”
- ❖ “The next day I noticed a huge difference.”
- ❖ “I would use it....I will use it indefinitely...”

*VivaGel® Trial Participants*

### Product Proposition:

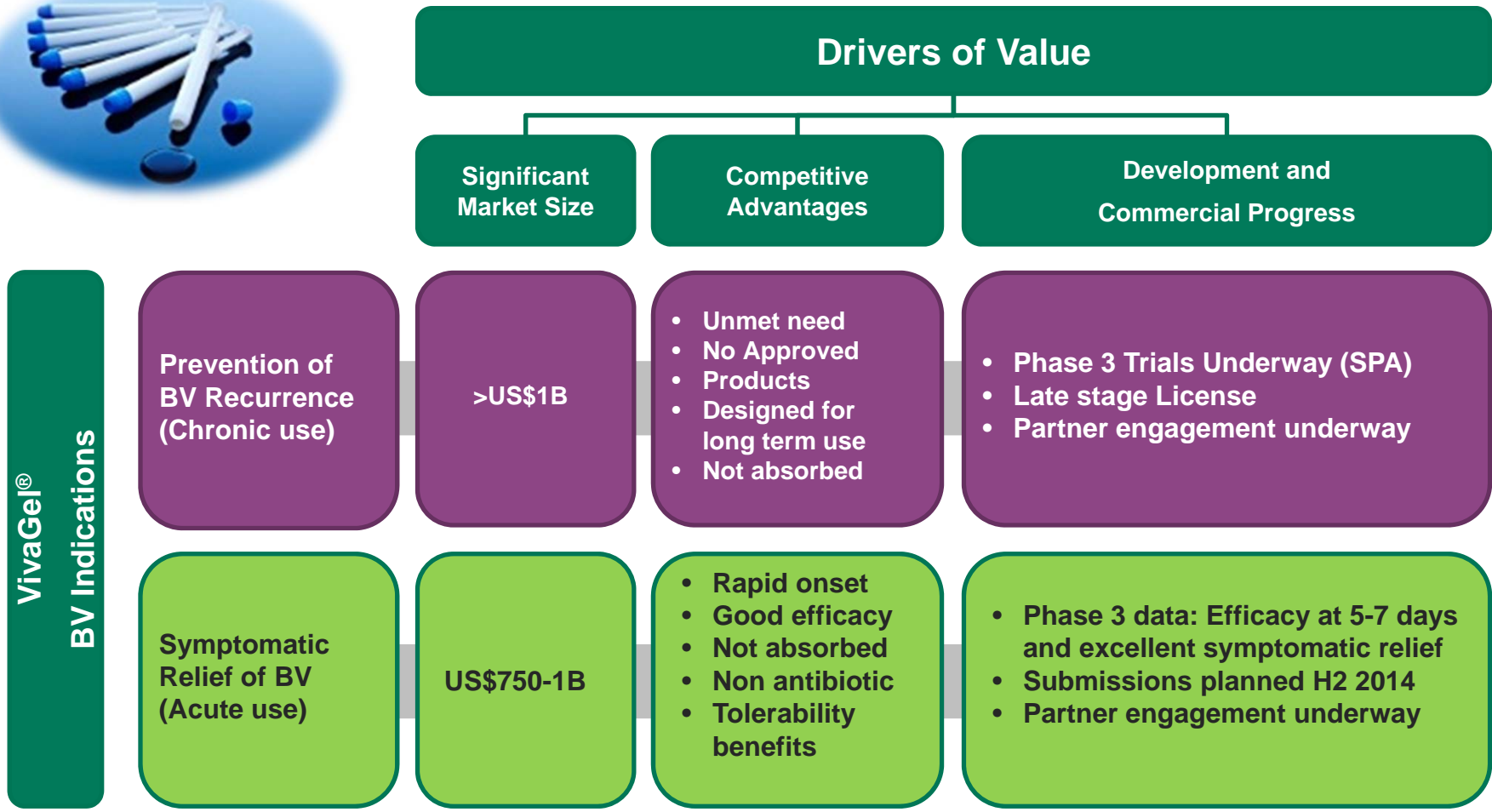
#### VivaGel® :

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



\* Global Data, IMS, various Industry reports,

# VivaGel® for Bacterial Vaginosis: Two product opportunities



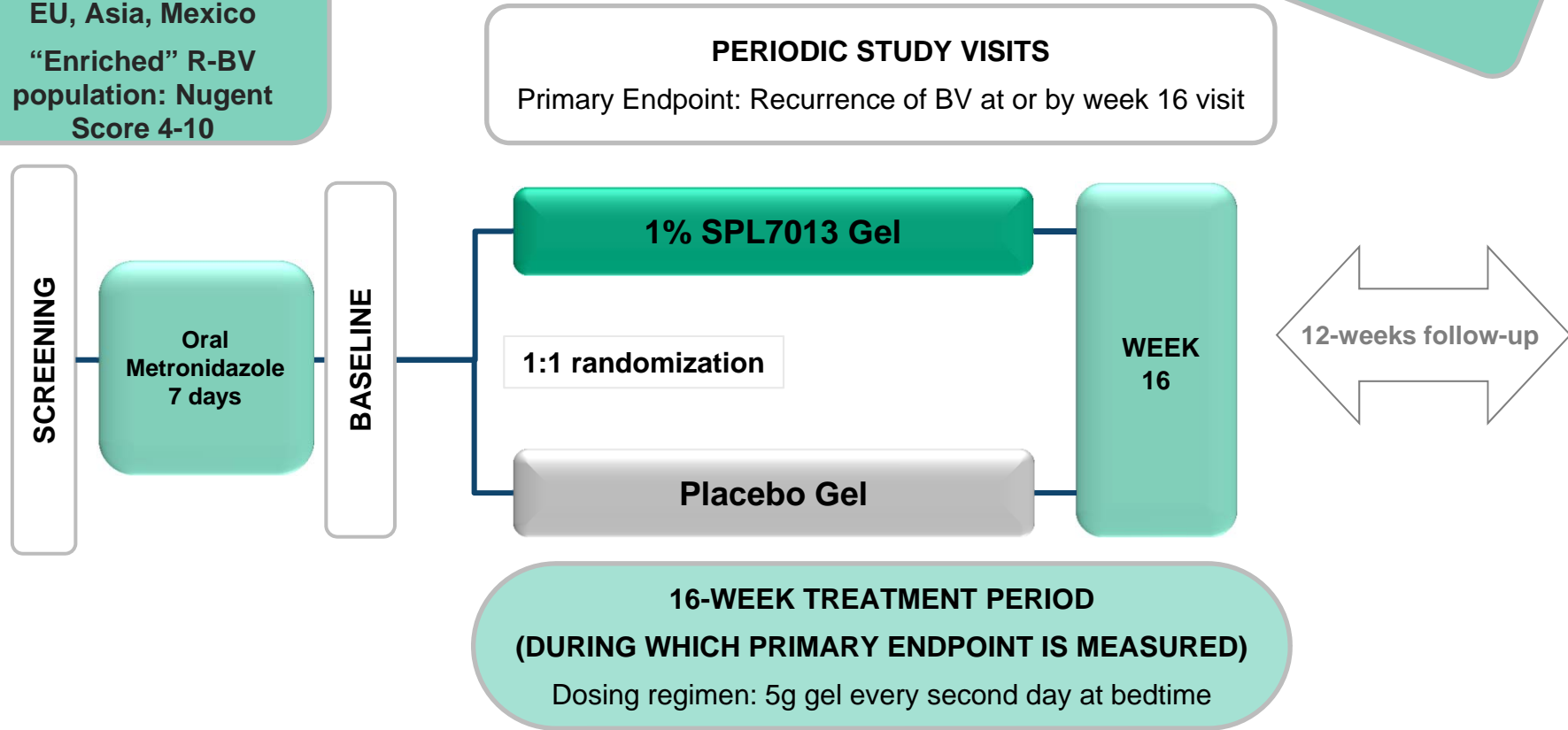


# BV Prevention of Recurrence Phase 3 Program

## Two double-blind, multi-centre, randomised trials

~600 p per trial  
 ~100 sites across USA, EU, Asia, Mexico  
 “Enriched” R-BV population: Nugent Score 4-10

SPA granted by FDA



SPA granted by FDA on trial design (EMA agreement also gained)  
 Phase 3 Trials underway with Quintiles

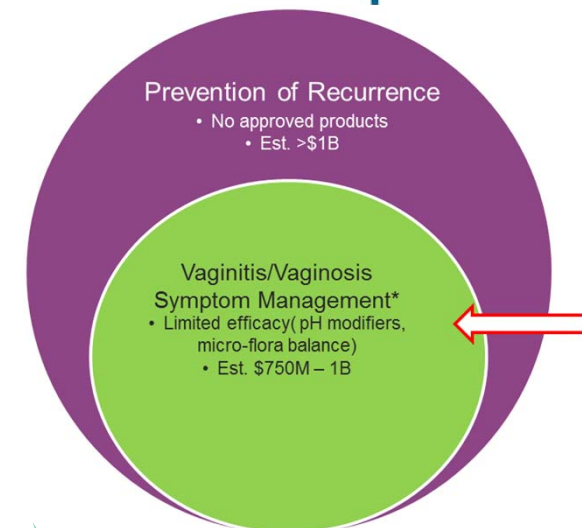
## VivaGel®: Symptomatic Relief of BV

### VivaGel® (once a day for 7 days):

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

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

- Symptomatic Relief product submissions are planned H2 2014
- Symptomatic Relief Product under active discussion with a number of interested commercial partners



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

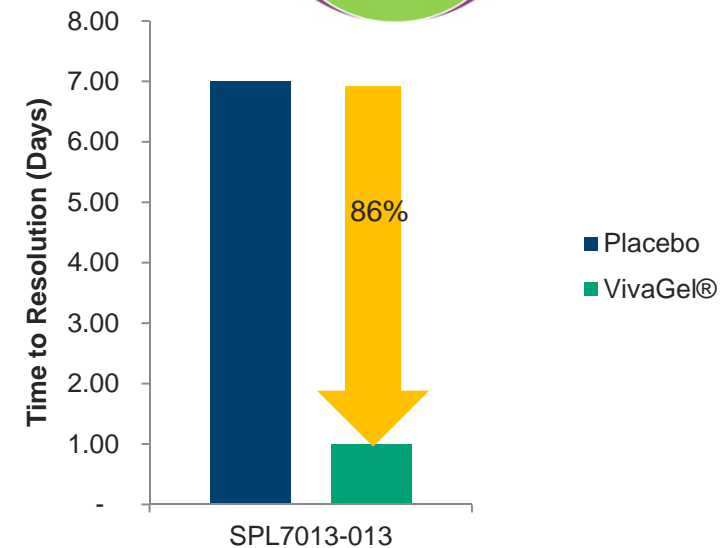
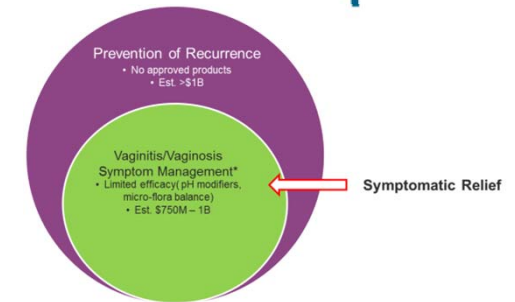
***“I would definitely use it again.”***

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

***– VivaGel® Trial Participants***

## VivaGel® - Symptomatic Relief

### Odour Resolution – % resolved and time to resolution



### VivaGel® - 3 Clinical trials

In 3 separate randomised, placebo-controlled trials

VivaGel® consistently provided a statistically significantly greater improvement in odour resolution as compared to placebo

Time to resolution of odour, as reported by patients, showed that VivaGel® resolved odour in 1 day, compared to 7 days for placebo

## Starpharma Holdings – Key Financials (A\$)

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

^Cash at 30 Sep 2014 \$37.2M  
(excludes \$3.4M SPP & \$4.2M R&D Tax incentive)

### Analyst Coverage



CANACCORD Genuity

BELL POTTER



PhillipCapital

## Expected Short-Medium Term News Flow

### VivaGel® Portfolio:

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

### DEP™ Delivery technology:

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

### Dendrimers in Agrochemicals:

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