
starpharma
Dr. Jackie Fairley CEO
STARPHARMA HOLDINGS LIMITED
ASX:SPL; OTCQX:SPHRY
ASX CEO Sessions
17 May 2016

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Summary

- **ASX300 company (ASX:SPL)** and (OTCQX:SPHRY); **Market Cap ~A$250M**

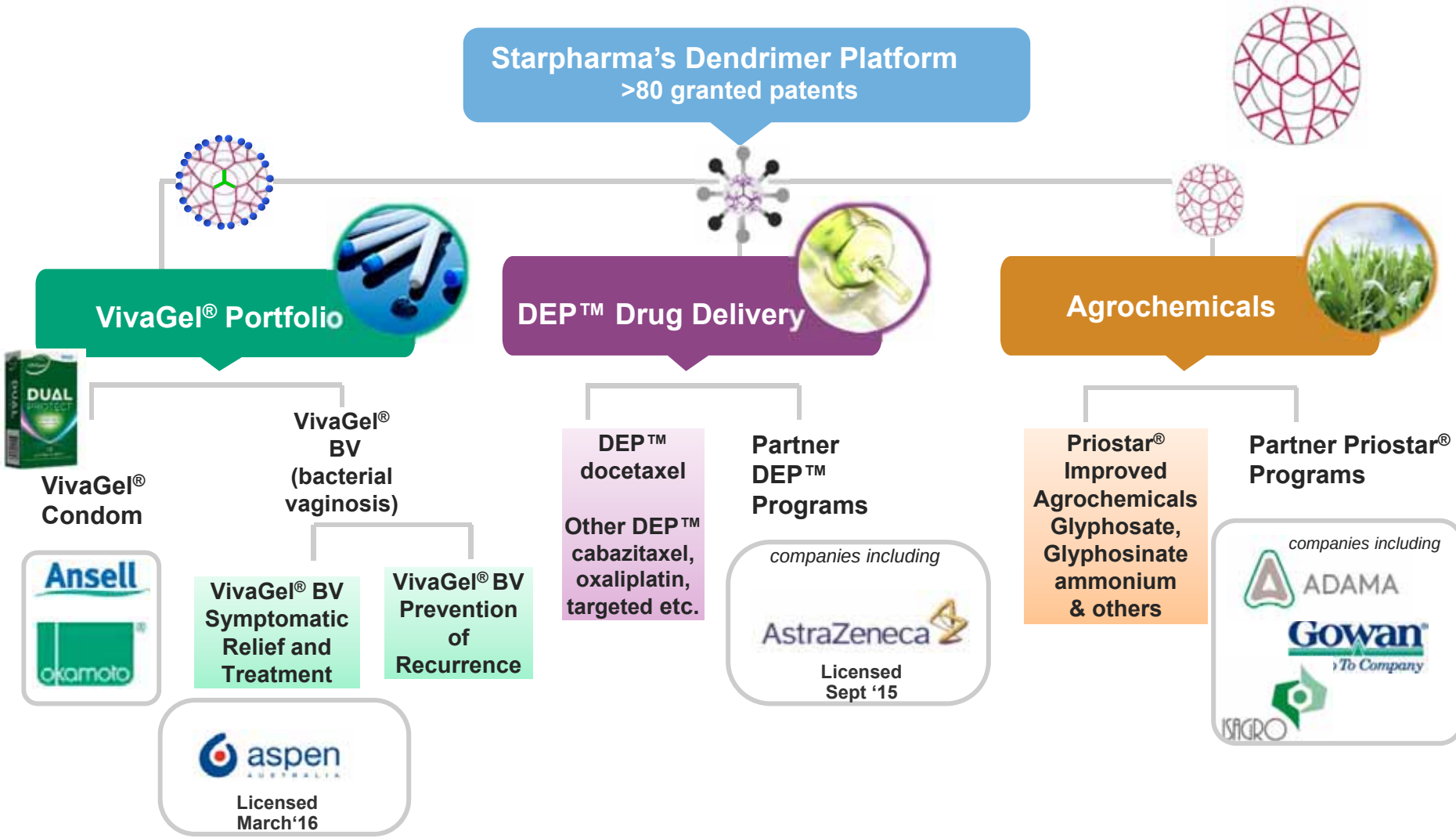
Three business areas: DEP™ drug delivery platform, VivaGel® and Agrochemicals supporting a deep portfolio of products under development or on market

- **DEP™ drug delivery platform** has the potential to produce a portfolio of new DEP™ products with multiple revenue streams
  - Multi product DEP™ license with AstraZeneca valued up to US$126M in milestones plus royalties (first product) and up to US$93M plus royalties for subsequent products
  - DEP™ docetaxel and internal DEP™ pipeline has potential to deliver multiple and high value additional deals
  - DEP™ based partnered programs in place and under discussion with multiple leading pharmaceutical companies
- **VivaGel® portfolio** focused on women's and sexual health
  - VivaGel® condom launched in Australia with further approvals and launches to follow
  - VivaGel® BV - Two products for Bacterial Vaginosis – first approved in Europe, second in phase 3 clinical trial
- **Agrochemical program** based on SPL's novel dendrimer technology with extensive commercial partnerships plus internal programs
- **Strong cash position:** Cash balance of A$51.1M (31/3/16)

Starpharma's headquarters and laboratories
Melbourne, Australia

Starpharma is a global leader in dendrimer nanoparticles

Starpharma's portfolio - internal programs and commercial partnerships with leading companies



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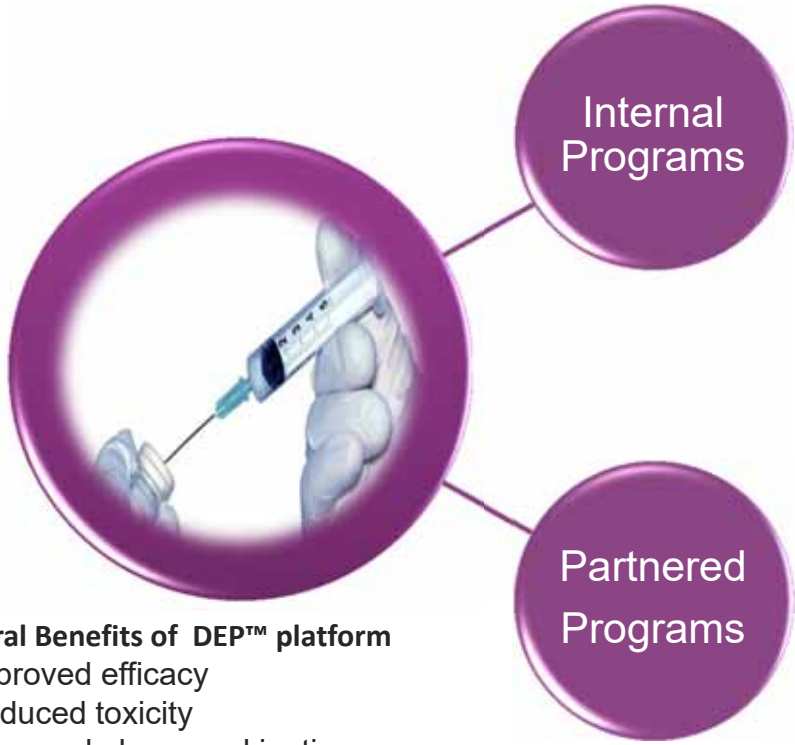
DEP™ Drug Delivery

DEP™ Drug Delivery

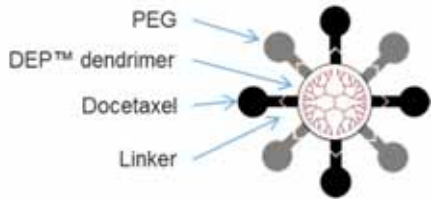
Dual Strategy

Provides technical, IP and financial leverage
Increases commercial opportunities
Reduces invested capital
De-risks



Internal Programs

- Application to established drugs
- Self funded
- Return through licensing after early clinical development
- eg. DEP™ docetaxel



Partnered Programs

- Application to partner drugs (typically proprietary)
- Platform with broad optionality
- Funded development
- Return through milestones and royalties
  - eg. AstraZeneca

General Benefits of DEP™ platform

- Improved efficacy
- Reduced toxicity
- Improved pharmacokinetics
- Improved solubility

Extensive partner engagement to maximise commercial outcomes

Starpharma's DEP™ Delivery License with AstraZeneca (LON:AZN)

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ASX ANNOUNCEMENT

Starpharma signs drug delivery license with AstraZeneca

- AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP® drug delivery platform in the development and commercialisation of an AstraZeneca oncology compound on signature, and with potential for follow on compounds directed at a defined family of targets.
- Under the agreement Starpharma will receive a signature payment of US$2 million (A$2.9 million), and is also eligible to receive potential development, launch and sales milestones for the first AstraZeneca DEP® product of USD$124 million (A$177 million).
- Subsequent qualifying products successfully developed and commercialised to specified annual sales levels could yield up to USD93.3 million (A$133 million) in milestone payments per product.
- In summary, signature and milestone payments could total USD$126 million (A$180 million) for the first AstraZeneca DEP® product and up to USD$93.3 million (A$133 million) for each subsequent qualifying product.
- Any AstraZeneca DEP® products would also attract tiered royalties on net sales.
- AstraZeneca will fund all development and commercialisation costs for AstraZeneca DEP® products under the agreement.

- **AZ multi-product license for use of DEP™ delivery platform for the development and commercialisation of proprietary AZ compounds directed at a defined family of targets**
- **SPL eligible to receive development, launch and sales milestones for the first AZ DEP™ product of up to USD$126m plus royalties & up to USD$93m in milestones for each subsequent qualifying AZ DEP™ products**
- **Tiered royalties on net sales**
- **AZ funds all development and commercialisation costs**
- **DEP™ docetaxel not impacted and agreement field allows for multiple other DEP™ licences**
- **Received US$2M in H1 FY2016**

"SPL estimates that each product successfully commercialised under this agreement could be worth around US$450m to Starpharma and, depending on the range of indications and degree of commercial success in the market, potentially significantly more"

"We already have a long-standing and successful working relationship with Starpharma. This license agreement will enable us to further harness the DEP™ technology and evaluate its potential across novel molecules within our oncology portfolio."

Dr Susan Galbraith,
Head of the Oncology Innovative Medicines Unit at AstraZeneca

AstraZeneca

AstraZeneca DEP™ Multi-Product License Potential Returns

AZ Candidate #1
- Indication #1
- Indication #2
- Indication #3

Candidate 1: US$126M milestones + royalties

AZ Candidate #2
- Indication #1
- Indication #2
- Indication #3

Candidate 2: US$93M milestones + royalties

AZ Candidate #3
- Indication #1
- Indication #2
- Indication #3

Candidate 3: US$93M milestones + royalties

AZ Candidate #4...
- Indication #1
- Indication #2
- Indication #3

Candidate 4: US$93M milestones + royalties

Nominated by AZ in September & November 2015 respectively

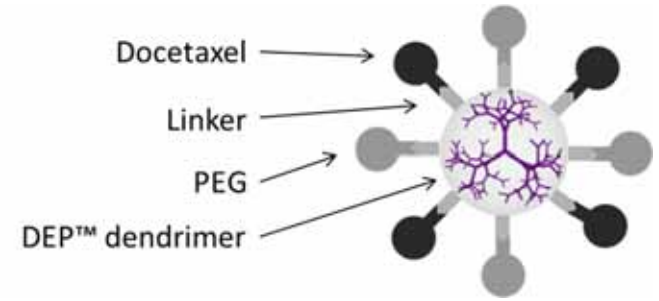
Starpharma's DEP™ Docetaxel: Multiple Benefits

- Docetaxel (Taxotere®) is a blockbuster chemotherapeutic
- **Docetaxel sales: US$3.1B (2012)**
- Docetaxel is used in major cancer types including breast, prostate, lung and ovarian cancer
- Starpharma's patented DEP™ docetaxel is a nanoparticle formulation with **multiple advantages compared to Taxotere®**
- **DEP™ patents filed will offer coverage to 2032 (potential for further filings)**
- **DEP™ docetaxel Phase 1 trial in Australia - promising preliminary findings with no neutropenia**

DEP™ docetaxel vs. Taxotere®

1. Elimination of major dose-limiting side effect (neutropenia)
2. Detergent-free formulation (less toxic)
3. Tumour-targeting (40-70x more)
4. Extended duration (half-life)
5. Improved efficacy (breast, ovarian, prostate)

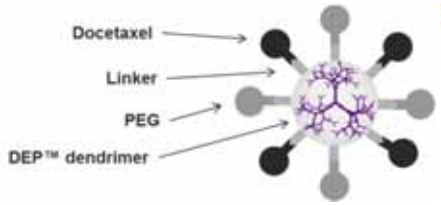
TAXOTERE® (docetaxel) Injection Concentrate



DEP™ docetaxel

DEP™ Docetaxel Preclinical Findings:

Multiple advantages - Better efficacy and less toxicity



$T_{1/2}$ and Targeting

	Plasma Half Life (hours)*
DEP™– Docetaxel	39
Taxotere®	0.5

*n = 4 rats per group

- DEP™ docetaxel formulation extends plasma $t_{1/2}$ by >75-fold vs. Taxotere®

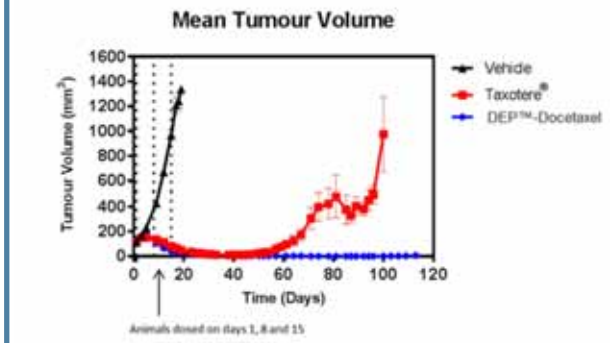
Safety

DEP™docetaxel
Polysorbate 80-free
and water soluble

Docetaxel

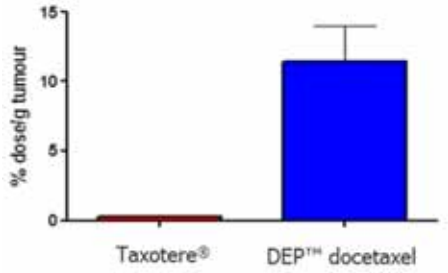
Starpharma's water soluble DEP™ docetaxel:
- solubility >↑ 20,000x
- polysorbate 80-free

Efficacy



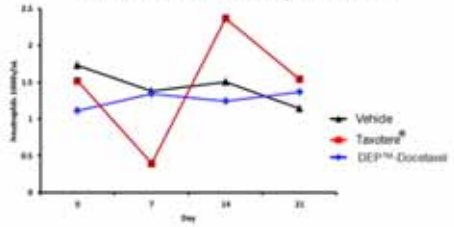
*Mouse Xenograft (MDA-MB 231); N= 10/group; p< 0.0001

Tumour accumulation



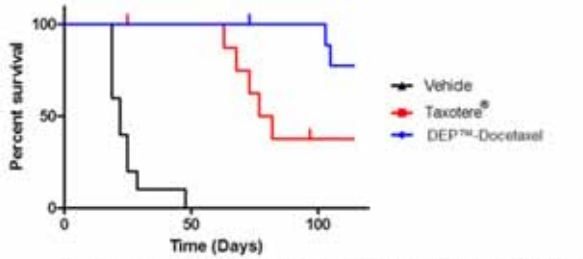
DEP™ docetaxel shows preferential uptake into mouse MDA-MB-231 xenograft (45-70 fold)

DEP™ docetaxel – Reduction of bone marrow toxicity and DLT's



- Neutrophil levels are expressed as the mean absolute count across all animals (n=6)
- drug (equivalent amounts based on docetaxel) was administered to Sprague Dawley rats by iv injection.

Improved Survival



Mantel-Cox log-rank test - Taxotere® vs DEP™ docetaxel (P=0.007).

Patents filed will offer coverage to 2032 (potential for further filings)

DEP™ Docetaxel Clinical Program

Phase 1 Clinical Trial: Encouraging anticancer activity and no neutropenia

- Open label study, ~25-30 cancer patients with advanced solid tumours
- DEP™ docetaxel administered intravenously *(unlike Taxotere® no steroid pre-treatment or anti-emetics required)*

Current Status:

- Patients dosed with multiple cycles (up to 6 cycles) ; dosed up to & above commonly used Taxotere® dose of 75mg/m^2
- Dose optimisation & expansion now underway to identify dose for Phase 2; more than 75% recruited

Interim Findings:

- ***No neutropenia*** **(docetaxel DLT) or alopecia reported**
  - *Compared to Taxotere® where* ***severe neutropenia is*** *suffered by* ***75% of patients dosed 60mg/m^2^***
- A significant proportion of DEP™ docetaxel patients have exhibited efficacy signals/anticancer activity including at low doses and in cancers not expected to be responsive to docetaxel:
  - Efficacy signals seen in pancreatic cancer (stable disease > 20 weeks), prostate, lung, H&N, gastro-oesophageal and glioblastoma (brain tumour)

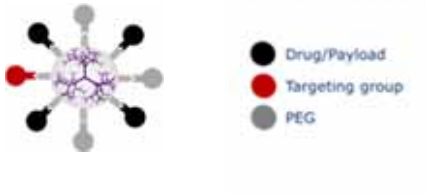
Phase 2:

Planning now underway with CROs and key opinion leaders for Phase 2 trial including design and indications; clinical trial material manufacture underway

^ Taxotere PI

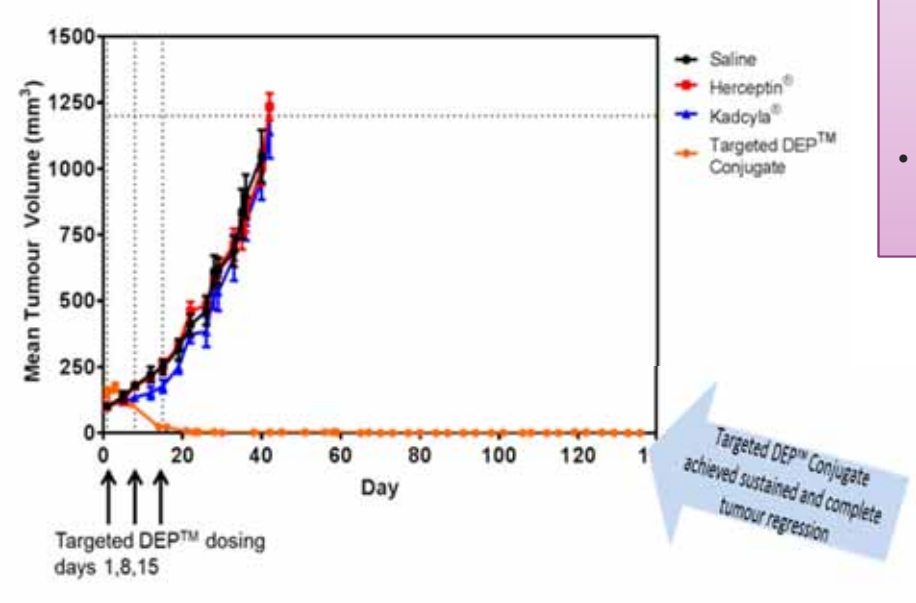
Targeted DEP™ outperforms leading treatments in ovarian cancer model

Targeted DEP™



- SPL's novel antibody-targeted DEP™ conjugate resulted in complete tumour regression and 100% survival in an ovarian cancer model
- The antibody-targeted DEP™ conjugate (using Herceptin as the targeting group) significantly outperformed both Roche's Kadcyla® (T-DM1) and the monoclonal antibody Herceptin® (Trastuzumab) alone
- Targeted DEP™ of significant commercial interest in partnering; patent filings underway

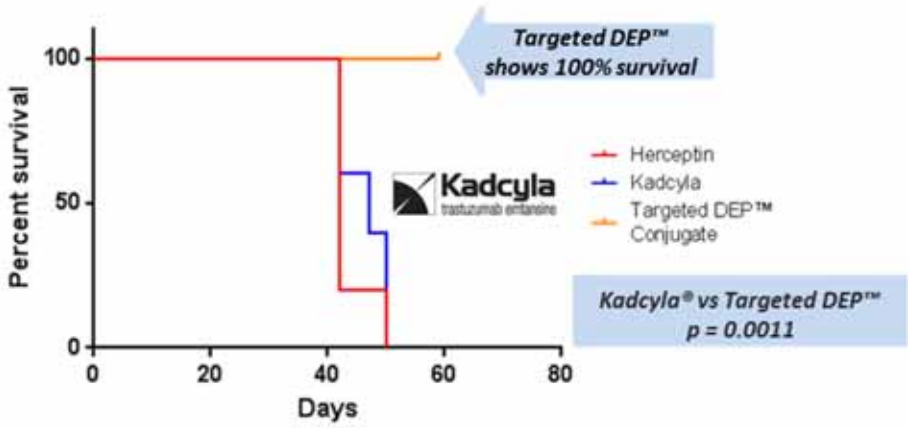
Efficacy of HER2-targeted DEP™ Conjugate vs Kadcyla® and Herceptin® in an Ovarian* Cancer Model



*SKOV-3 Ovarian cancer xenograft in NOD-SCID mice (5-6/group) Saline, Kadcyla® (10mg/kg) and Targeted DEP™ conjugate were dosed once/wk for 3 wks; Herceptin® (20mg/kg) dosed twice/wk for 3 wks.

Statistical analysis at day 40. Kadcyla® vs Targeted DEP™; P <0.0001. (ANOVA followed by Tukey's post hoc test).

Kaplan Meier Survival Curve



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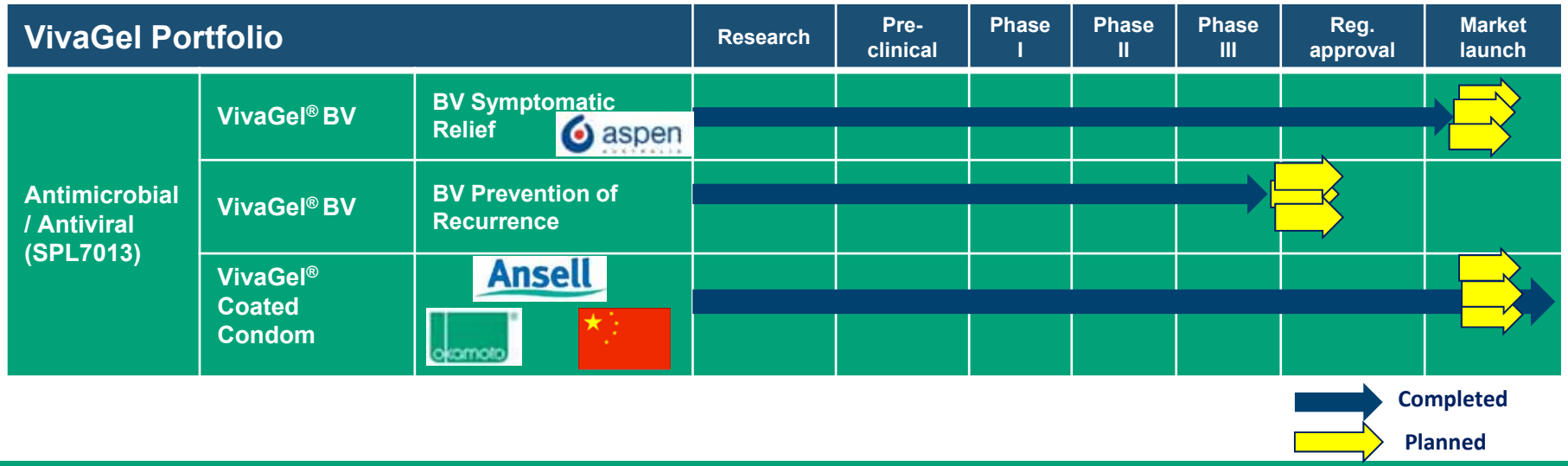
VivaGel® Portfolio

VivaGel® Portfolio

- VivaGel® is a proprietary antimicrobial dendrimer active in HIV,HSV, HPV and bacterial vaginosis (BV)
- VivaGel® BV (bacterial vaginosis)
  - Symptomatic Relief – EU approved, ANZ licence signed with further commercial discussions underway; launch expected 2016
  - Prevention of Recurrent BV – Phase 3 clinical program underway in North America, Europe, and Asia (under SPA)
- VivaGel® (antiviral) condom rights licensed to Ansell and Okamoto; launched in Australia, regulatory processes underway for multiple other regions,
- MOU signed for supply of VivaGel® condom to Chinese Government Market



VivaGel® Condom: A compelling, world-first product

- Based on innovative, Australian technology
- Typical condom use associated with an estimated:
  - 80% reduction in HIV infection, only a 30% lower risk of genital herpes (HSV-2) infection, and a 70% reduced risk of a new HPV infection
- VivaGel® Condom: contains the potent antiviral - VivaGel® shown in laboratory studies to inactivate up to 99.9% HIV, HPV & herpes - intended to help reduce risk of exposure to viruses via inactivation (as well as the STI barrier protection a condom provides)
- Licensed to global market leaders:
  - Ansell – No. 2 globally based on sales; leading brand in regions including Australia
  - Okamoto – No. 1 in Japan
  - Further commercial discussions underway including supply of VivaGel® condom to Chinese Government Market
- Currently selling in Australia in retail outlets and online under **LifeStyles® Dual Protect™** brand
- Regulatory processes underway and significantly advanced in additional regions
- Branded global condom market: $1.1B
- VivaGel® condom patents to 2027

THE WORLD'S FIRST ANTI-VIRAL CONDOM

DUAL PROTECT™ with VivaGel® : lubricated with VivaGel® which has been shown to inactivate up to 99.9% HIV, HPV and HSV (Herpes) in laboratory studies

VivaGel® shows potent activity against Zika virus

World Health Organization

Zika outbreak declared a 'global emergency' by **WHO**

US Congress calls for urgent action on Zika

WORLD BRAZIL

WHO Says Pregnant Women Should Avoid Rio Olympics Due to Zika TIME

Brazil has more than **1 Million reported cases**

Australian Team taking Dual Protect™ VivaGel® Condoms to Rio

Published 16 May 2016 (AEST)

AUSTRALIA

Aust Olympians get extra Zika protection

IMAGE

Australia's Olympians will be provided with condoms treated with a gel that in lab studies has shown "near-complete" antiviral protection against Zika.

National Geographic
@NatGeo

Follow

Scientists predict #Zika will become part of the new normal for Americans, requiring routine vaccinations.

Dual Protect™ the world's only antiviral condom

VivaGel® showed near complete antiviral protection against Zika virus in laboratory studies at **concentrations significantly below** that **used in the Dual Protect™ VivaGel® condom**

Daily Mail AUSTRALIA

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Australian Olympic team will be given double-strength condoms to take to Rio due to Zika virus fears

Bacterial Vaginosis and VivaGel® BV: Two product opportunities

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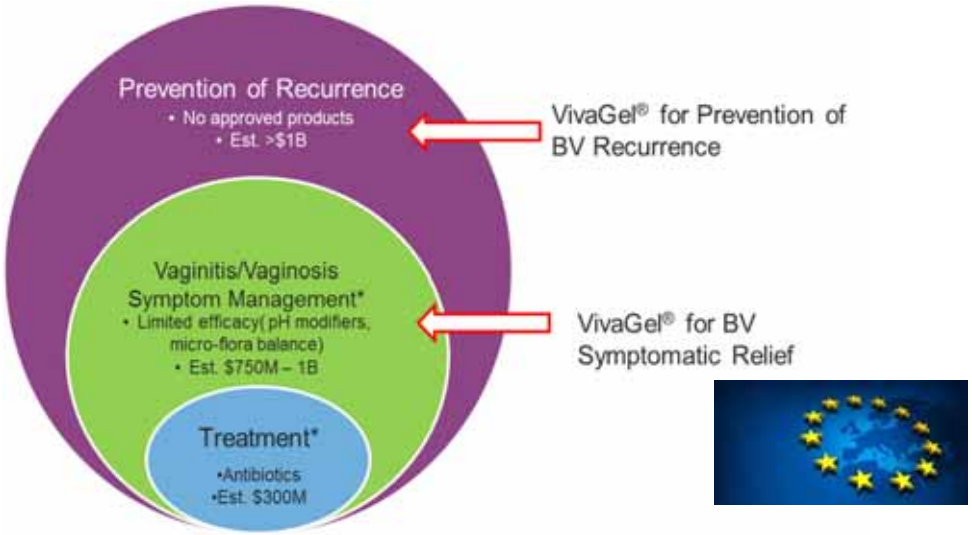
Bacterial Vaginosis (BV):

- **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)**

Large market opportunity for both prevention of R-BV and BV Symptomatic Relief

- *"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® BV Trial Participants



VivaGel® BV: Product Proposition

- **a non-antibiotic therapy**
- **management of BV symptoms *and* prevention of R-BV**
- **a selective antimicrobial effect for pathogens that cause BV**
- **a local effect and is not systemically absorbed**
- **bio- adhesive properties**

* Global Data, IMS, various Industry reports

VivaGel® BV: Two attractive commercial opportunities

- Acute use product
- Global market est. >US$750 m
- EU marketing approval achieved – Treatment of BV, including rapid relief of BV symptoms
- Regulatory approval processes leveraging EU approval underway in multiple geographical regions
- Licensed to Aspen for ANZ; Multiple partnering discussions well-advanced
- 2016 launch planned; commercial manufacture underway

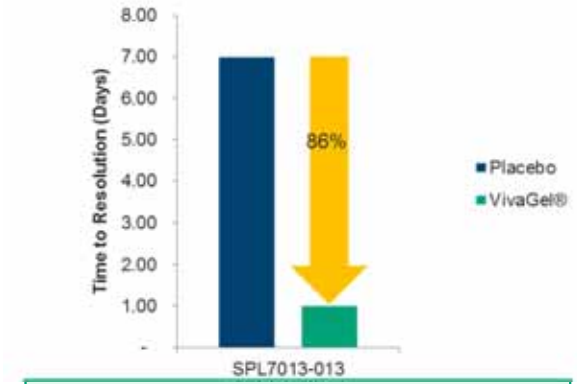
- Chronic use product
- Unmet need: no approved products; Global market est. >US$1 b
- Majority of BV sufferers experience recurrence
- Phase 3 programme in USA, Europe and Asia; > 75% recruited
- SPA agreement with FDA in place
- Partnering discussions ongoing, NDA planning underway

Benefits of VivaGel® BV
- Rapid resolution
- Non-antibiotic
- Not systemically absorbed
- Good tolerability
- Selective antimicrobial effect

Partner engagement underway for both opportunities

VivaGel® BV
Treatment & Symptomatic Relief of BV

- VivaGel® BV gains EU approval for the treatment and rapid relief of BV
- Allows for marketing in 28 EU countries & EFTA countries (population >260m women)
- EU approval will be used as the basis for obtaining marketing approvals for VivaGel® BV in other countries
- Discussions regarding marketing rights for VivaGel® BV underway with a number of potential commercial partners
- Current global market for the management of BV is estimated to be ~US$750 million annually



Time to resolution of odour as reported by clinical trial patients

VivaGel® BV is a unique topical vaginal gel. Its proprietary active is not absorbed and acts locally to suppress the pathogens that cause BV and the associated signs and symptoms.

- ***"It was like gone almost overnight"***
- ***"I would definitely use it again."***
- ***"The next day I noticed a huge difference."***
- ***"I will use it indefinitely…"***

VivaGel® BV Trial Participants

VivaGel® BV Commercial Status and Plans

Territories covered by commercial negotiations for VivaGel® BV (Symptomatic relief and PoR products)

- Licence signed with Aspen for ANZ for Symptomatic Relief product
- Commercial discussions for multiple other territories underway
- 2016 launch planned for Symptomatic Relief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Agrochemicals

Starpharma's Priostar® Agrochemical Programs

Partnered Priostar® Programs

- Adama have licensed SPL's Priostar® for novel and improved 2,4-D products for the US market
- Multiple new agreements have been signed or extended with major agrochemical companies for the European, Asian and North American markets
- Collaboration with major Japanese agrochemical company;

ADAMA

Gowan® The Go To Company

ISAGRO

- **Multiple potential opportunities for revenue streams**
- **Estimated value of partners share of market for actives under development: >US$5B**

Internal Priostar® Programs

- Regulatory compliant field trials of Priostar® enhanced versions of several major herbicide and fungicide formulations completed showing a number of commercially compelling benefits

Glyphosate	**($4-5B)**	**Improve efficacy**
Glyphosinate NH_4	**($400m)**	**Improve Efficacy**
Metolachlor	**($605m)**	**Improve efficacy**
Deltamethrin	**($340m)**	**Improve efficacy/ low solvent**
Propiconazole	**($350m)**	**Improve efficacy / Loading**
Imidacloprid	**(>$1B)**	**Improve efficacy / Loading**

Priostar® benefits for innovative crop protection formulations

Better in the can:

- Solubility enhancement
- Increased loading
- Formulation stability
- Reduction/removal of solvents – "greener" formulations

Better in the field:

- Increased efficacy
- Modification of soil penetration
- Protection of Actives

Adama Licenses Priostar® for novel 2,4-D products

- Adama have licensed SPL's Priostar® for novel, improved 2,4-D products for the US market
- Priostar® enhanced product expected to provide better flexibility, weed control and improved safety
- SPL to receive royalties; Adama to fund development and registration
- 2,4-D is the second largest herbicide globally with sales of US$680m

Adama is one of the world's leading crop protection companies with annual sales of US$3.2b and one of the most comprehensive portfolios of differentiated products sold in more than 120 countries.
Adama is privately held by ChemChina and Koor Industries.

ADAMA

"The innovative nature and superior performance of the Priostar® formulations fit well with our strategy to deliver simple and efficient solutions to farmers to help them grow."

Sami Shabtai,
Head of Innovative Development at Adama

Expected News Flow

VivaGel® Portfolio:

- Further regulatory approvals for VivaGel® BV for Treatment & Symptomatic Relief
- Further licenses for VivaGel® BV product marketing (multiple territories)
- Launch VivaGel® BV for Treatment & Symptomatic Relief
- Progress and completion of VivaGel® BV Phase 3 BV Prevention of Recurrence trials
- Further approvals/geographic roll-out of the VivaGel® condom and commercial developments post Zika activity

DEP™ Drug Delivery:

- Completion of DEP™ docetaxel Phase 1 clinical trial and commencement of Phase 2
- AZ and other Partnered program announcements (further compounds advanced) and new DEP™ deals
- Advance additional DEP™ candidates through preclinical and into clinic

Priostar® Dendrimers in Agrochemicals:

- Progress with Adama 2,4-D licence
- Further Priostar® licences with partners and regional expansion of existing deals
- Advance internal Priostar® candidates eg. glyphosate (Roundup®) ; regulatory-compliant field trials and re-registration activities to support commercialisation

For Further Information

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VivaGel®

Drug Delivery

Agrochemicals