



# OTCQX Virtual Investor Conference

DR JACKIE FAIRLEY
CEO

11 & 12 April 2018

STARPHARMA HOLDINGS LIMITED

ASX:SPL; OTC:SPHRY

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# Overview: Deep portfolio of products and extensive partnerships with industry leaders

- Melbourne-based ASX300 company; Market Cap ~A\$500M
- Unique proprietary polymer (dendrimer) platform
- Deep portfolio of products in large, high-value markets
- Proven track record of commercialisation
- VivaGel® BV approved in Australia and Europe for treatment, awaiting launch and US FDA New Drug Application lodged under Fast Track Status
- VivaGel® condom in-market (approved Australia & Canada)
- Added significant value to Priostar<sup>®</sup> (Agrochemicals) portfolio, sold to Agrium Inc. for \$35M
- Successful, long-standing global partnerships including with AstraZeneca, creating significant optionality, accelerating path to market & managing investment risk
- Well-funded, with >\$49.9M cash at 31 Dec 2017 (excludes R&D tax incentive \$3.7M and US\$2.4M FDA refund received)















Starpharma's headquarters and laboratories Melbourne, Australia



# Global leader in dendrimer products – multiple commercial partnerships with leading companies

#### **Starpharma's Dendrimer Platform**



MULTIPLE HIGH VALUE COMMERCIAL OPPORTUNITIES PROTECTED BY 100+ PATENTS



# Starpharma's deep pipeline of VivaGel® and DEP® products provides exceptional optionality

	Product	Preclinical	Clinical/Regulatory
VIVAGEL®	VIVAGEL® BV – Bacterial Vaginosis		6 aspen
	VIVAGEL® CONDOM – Anti-viral condom	LifeStyles	SICY & LAND SICY &
	VIVAGEL® – Viral conjunctivitis		
INTERNAL DEP®	DEP® DOCETAXEL – Oncology		
	DEP® CABAZITAXEL – Oncology		
	DEP® IRINOTECAN – Oncology		
	OTHER DEP® – Oncology (multiple)		
	TARGETED DEP® – Oncology		
PARTNERED DEP®	ASTRAZENECA #1 DEP® CANDIDATE – AZD0466		AstraZeneca 🕏
	ASTRAZENECA #2 DEP® CANDIDATE – Oncology		AstraZeneca
	OTHER ASTRAZENECA DEP® PROGRAM – Undisclosed		AstraZeneca €
	ADC PARTNERS – Oncology		Undisclosed global partners

### **Strong financial position**

Key Financial Data	1H FY 2018 A\$M	FY 2017 A\$M	FY 2016 <sup>1</sup> A\$M
Total revenue and income	1.2	3.6	4.6
Loss from continuing operations	(6.2)	(15.2)	(21.3)
Profit/(loss) from discontinued operation	-	23.4	(1.4)
Profit/(loss) for the period	(6.2)	8.2	(22.7)
Net operating & investing cash inflows/(outflows)	(11.5)	15.7	(17.8)
Net cash burn <sup>2</sup>	(11.3)	(18.0)	(17.5)
Closing Cash (at 31 Dec / 30 June)	49.9	61.2	46.0

### CASH AT 31 DEC 2017 EXCLUDES

- \$3.7M FY17 R&D tax incentive refund received Feb 2018
- US\$2.4M FDA NDA refund subsequently received

### OUTLOOK - Revenues expected to build with:

- Milestones (DEP® / VivaGel® BV)
- Receipts following VivaGel® BV launch and additional VivaGel® BV licence(s)
- VivaGel® condom geographic expansion

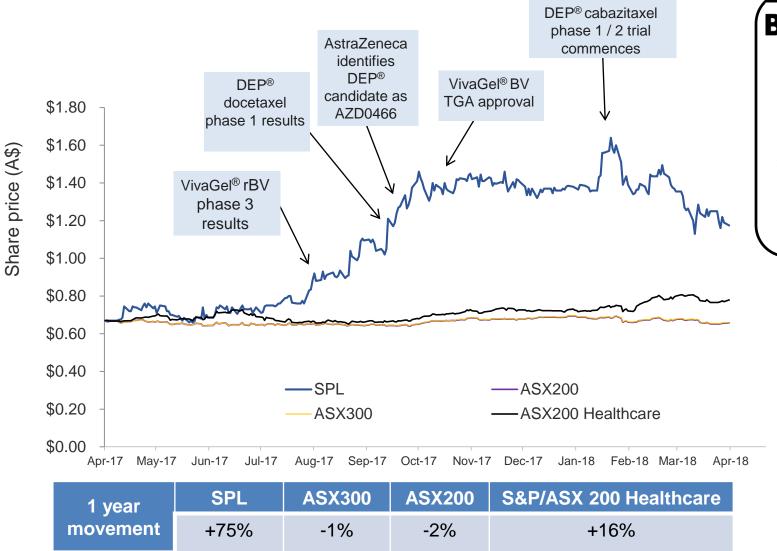
#### **OUTLOOK - Reduced R&D burn FY18:**

- Phase 3 VivaGel® rBV trials complete
- No R&D spend on Agrochemicals
- R&D spend now focused on DEP®



<sup>&</sup>lt;sup>1</sup> The prior year financial results are re-presented for the comparative results of the discontinued operations (Starpharma's agrochemicals business).

### **Share price performance**



#### **BELL POTTER**

22 Nov '17: SPL price target upgraded

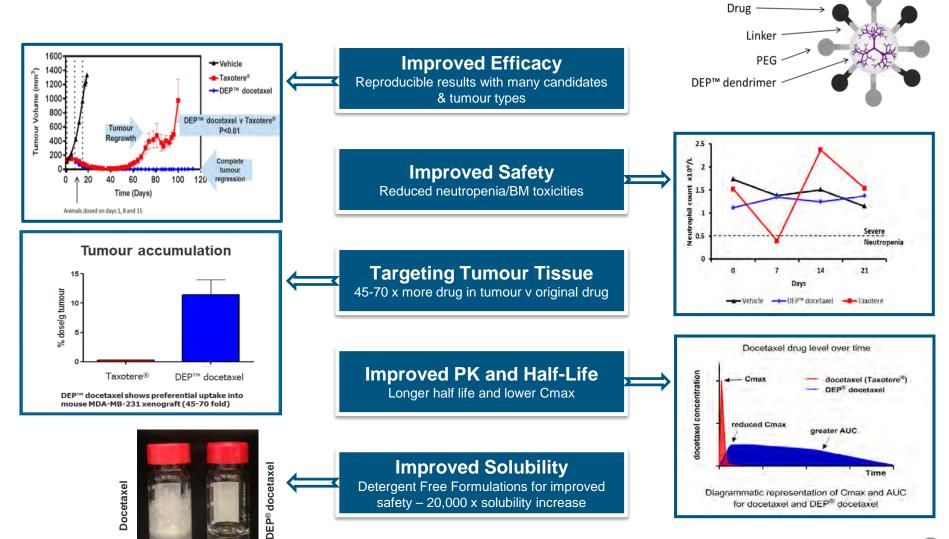
"FY18 to be a transformational year for SPL"

- Tanushree Jain Analyst, Healthcare & Biotech





DEP® platform: Superior drug delivery with highly reproducible benefits and new IP position



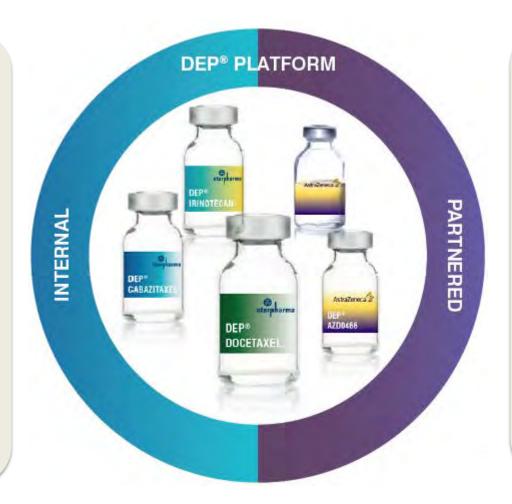


### Dendrimer Enhanced Products (DEP®) Dual Strategy

Starpharma's dual DEP® strategy provides technical, IP and financial leverage, as well as increasing commercial opportunities, improving ROI and de-risking development

#### INTERNAL DEP®

- Application to established drugs reduces risk and expedites development
- Patent life extension
- Self-funded
- Returns through licensing, milestones and royalties

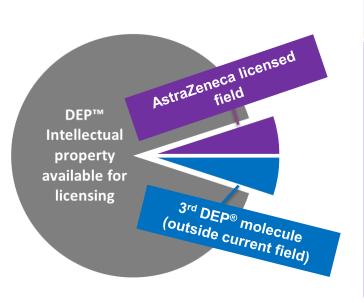


#### PARTNERED DEP®

- Application to partners' drugs, both novel (eg. AZD0466) and existing
- Patent life extension
- Funded development
- Returns through licensing, milestones and royalties



# AstraZeneca multiproduct licence and further program – Partnered DEP® momentum building



## AstraZeneca DEP® multiproduct licence

- First DEP<sup>®</sup> candidate, AZD0466: US\$126M + royalties
- Subsequent DEP® candidates US\$93M + royalties
- Tiered royalties on net sales on the resultant AstraZeneca DEP® products
- AstraZeneca funds all development and commercialisation costs
- Two further AstraZeneca programs added since multiproduct licence signed
- US\$4M received in milestone payments FY2016 & 2017

"We already have a long-standing and successful working relationship with Starpharma. This licence 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

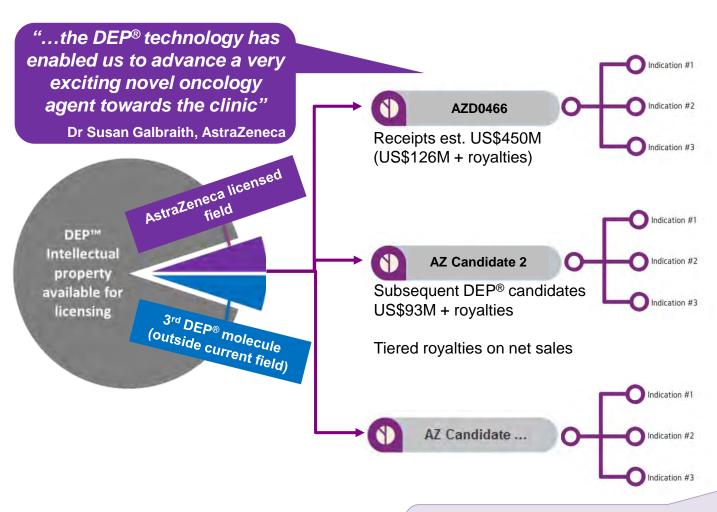
**Innovative Medicines Unit at AstraZeneca** 

"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."

Dr Jackie Fairley, CEO, Starpharma



## AstraZeneca's multiproduct licence 1<sup>st</sup> candidate AZD0466: An exciting novel oncology agent



- Bcl2 is an exciting and clinically validated oncology target
- Venetoclax (Venclexta), a first generation Bcl2 inhibitor (specific for Bcl2) was approved in 2016 with est. US sales to exceed US\$2B by 2021
- Targeting Bcl2 alone is not ideal in maximising cell kill – surviving cells exploit Bcl2/xl as a parallel survival mechanism
- AZD0466 is a dual Bcl2/xl inhibitor in a highly optimised DEP® formulation with the potential to be a best-in-class agent in this field

"...this blood cancer drug [AZD0466] has immense potential and broad applicability both as monotherapy and in combination"

Bell Potter Analyst



### Starpharma's DEP® pipeline – internal products

The optionality with the DEP® platform enables Starpharma to build a deep pipeline of enhanced drugs – a very attractive commercial strategy



DEP® cabazitaxel: Detergent-free version of leading anti-cancer drug Jevtana®



DEP® docetaxel:
Starpharma's most
advanced DEP® product
- a detergent-free,
enhanced version of
anti-cancer drug
Taxotere®



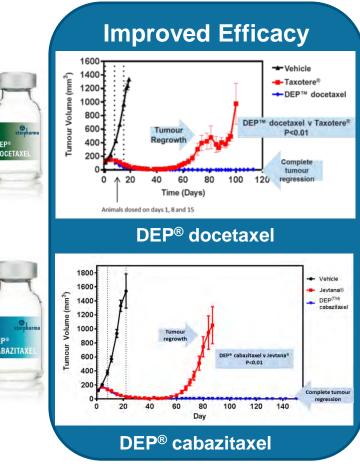
- ✓ Improved Efficacy
- ✓ Improved Safety
- ✓ Improved Survival
- ✓ Patent Life Extension.
- ✓ Detergent Free

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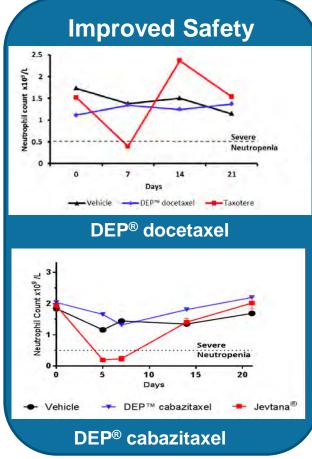
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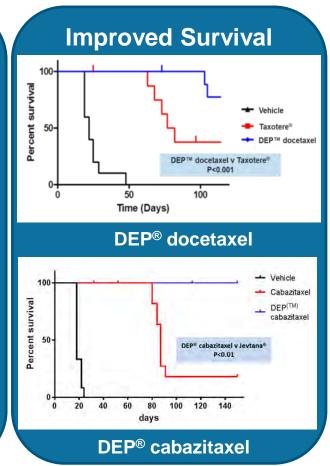
# DEP®: A true platform with highly reproducible benefits creating exceptional optionality



Mouse xenograft models using MBA-231 DEP® conjugate vs original – P<0.01 for both docetaxel and cabazitaxel



Lack of neutropenia – the DLT for both docetaxel and cabazitaxel – as seen with DEP® conjugates in rat model



Kaplan Meier survival curves
DEP® conjugate vs original – P<0.001
for both docetaxel and cabazitaxel



### **DEP®** docetaxel: Multiple benefits





Docetaxel (Taxotere®) is a blockbuster cancer drug with peak global sales >US\$3.1B despite having multiple US FDA "Black Box" warnings



Starpharma's patented DEP® docetaxel is an enhanced version of docetaxel, designed to reduce side-effects such as neutropenia while enhancing efficacy



Docetaxel is one of the most widely used cancer drugs for a range of tumours including breast, lung and prostate



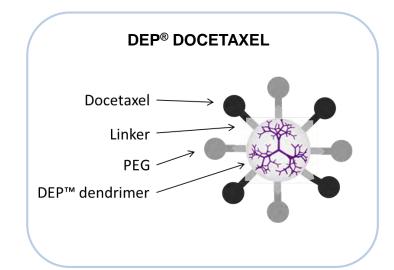
DEP® patents and applications provide coverage to 2032

#### **DEP®** docetaxel vs Taxotere®

- ✓ Elimination of major dose-limiting side effect (neutropenia)
- ✓ Detergent-free formulation (less toxic)
- √ Tumour-targeting (~70x more)
- ✓ Extended duration (half-life)
- ✓ Improved efficacy









# DEP® docetaxel Phase 2 underway; successful Phase 1 completed in 2017



#### Phase 1 trial completed n= 27 various solid tumours

- No neutropenia (compares to >>90% with Taxotere<sup>®</sup>)
- No protocol-defined DLTs
- Only one patient (1/27) with mild alopecia/hair loss compared to ~75% with Taxotere<sup>®</sup>
- No reports of other problematic adverse events observed with docetaxel treatment, including anaphylaxis, fluid retention, diarrhoea and nail disorders
- Recommended Phase 2 Dose 60mg/m2
- Encouraging efficacy signals in 13/27 DEP® docetaxel patients including:
- stable disease (SD) in multiple patients with lung, pancreatic (SD>20 wks), and gastro-oesophageal (SD >18 wks) cancers, and in other patients with brain and renal cancers
- No standard steroid pre-treatment required due to DEP® docetaxel's detergent-free formulation - unlike Taxotere®

#### PHASE 2 STUDY (currently recruiting in the UK)

- Multi-site trial 2 sites recruiting (Guy's Hospital London, UCLH) with 2 more to open shortly
- Open-label, two-stage design n=40 (20+20)
- Objective: establish anti-tumour activity (efficacy) and safety of DEP® docetaxel
- First stage will enrol approximately 20 patients with lung or prostate cancer (key approved indications for docetaxel)
- Second stage will enrol a further 20 patients with tumour types selected based on results from the first stage.
- In parallel, combination of DEP® docetaxel with nintedanib (Vargatef®) in lung cancer (~12 patients)





### **DEP®** cabazitaxel: Multiple benefits

## About cabazitaxel (Jevtana®)

- 2016 sales approx.US\$400M (est. US\$500M by 2018)
- Primary indication prostate cancer and in clinical development for other cancers including Breast, Bladder, Head & Neck
- Dose Limiting Toxicityneutropenia(FDA "Black Box" warning)
- FDA "Black Box" warning due to anaphylaxis (polysorbate 80 detergent)



#### **DEP®** cabazitaxel

Significantly enhanced efficacy versus Jevtana® (cabazitaxel) in human breast and prostate cancer models

Detergent (polysorbate 80) free formulation

Lack of neutropenia



DEP® CABAZITAXE

### DEP® cabazitaxel phase 1 / 2 trial underway

- Planning to enroll ~35 patients (solid tumours)
- Trial being conducted at multiple sites, including in the UK at Guy's Hospital and University College London Hospital (UCLH) – now open
- Phase 1: Open-label, sequential dose-escalation (accelerated) to establish the Maximum Tolerated Dose and Dose Limiting Toxicities, Recommended Phase 2 Dose and Pharmacokinetics
- Phase 2: Dose expansion to establish preliminary efficacy of DEP<sup>®</sup> cabazitaxel
- As the trial progresses, decisions will be made as to which tumour types to focus on and any additional patients required to further characterise efficacy in specific tumour types



Adaptive phase 1 / 2 trial design enables seamless transition from phase 1 to phase 2, to explore efficacy as early as possible.

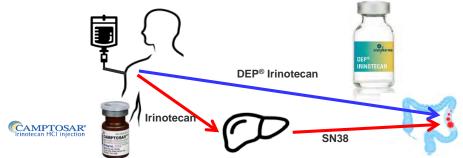






# Further validation of the DEP® platform – DEP® irinotecan outperformed Camptosar®

- Irinotecan (Camptosar®) is primarily used for the treatment of advanced colorectal cancer (peak sales US\$1.1B)
- Colorectal cancer is the third most common cancer and second leading cause of cancer death in the world, an area of significant unmet need with few treatment options
- Irinotecan has FDA "Black Box" warnings for severe diarrhoea and neutropenia
- DEP® irinotecan incorporates the irinotecan active moiety (SN-38) and shows enhanced tumour growth inhibition compared to irinotecan and near-complete tumour regression



	DEP <sup>®</sup> Benefits	
Manufacture	Readily scalable and validated through extensive FDA input	
Stability	Highly stable Long shelf-life	
Particle Size	DEP® nanoparticles selectively accumulate in tumour tissue	
Plasma Half life	DEP® platform consistently delivers longer duration of effect	
Enhanced Efficacy	Significantly enhanced efficacy in all tumor models tested (vs Camptosar®)	





## VivaGel® portfolio overview – late stage / commercial assets



## VivaGel® BV: A breakthrough product for Bacterial Vaginosis (BV) Treatment & Prevention of Recurrent BV (rBV)

- Approved in AUS and expected to be available in pharmacies in 2018 under the Fleurstat<sup>™</sup> brand
- Approved in EU for Treatment (rBV to be added with Phase 3 data now available)
- Prevention of Recurrent BV (rBV) Successful phase 3 trials (under SPA) reported in August
- FDA NDA for both treatment and prevention of rBV lodged through a rolling submission process
  - Fast Track status and QIDP designation will expedite approval
- Advanced licensing negotiations underway in multiple territories including Europe, USA, RoW





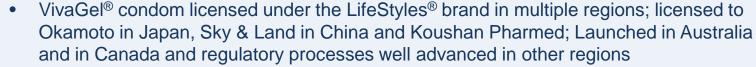






#### VivaGel® Condom: World's first and only anti-viral condom











# BV has serious health consequences and significant impact for patients

#### **Bacterial Vaginosis (BV)**

- Most common vaginal infection worldwide
- ~30% women infected in US; up to 51% in some groups
- Serious medical consequences (PID, infertility, miscarriage, increased risk of HIV and other STIs)
- Current therapies are inadequate with low cure rates and nasty side effects
- rBV occurs in 50-60% of BV sufferers
- Large market opportunity for both prevention of rBV and BV Treatment

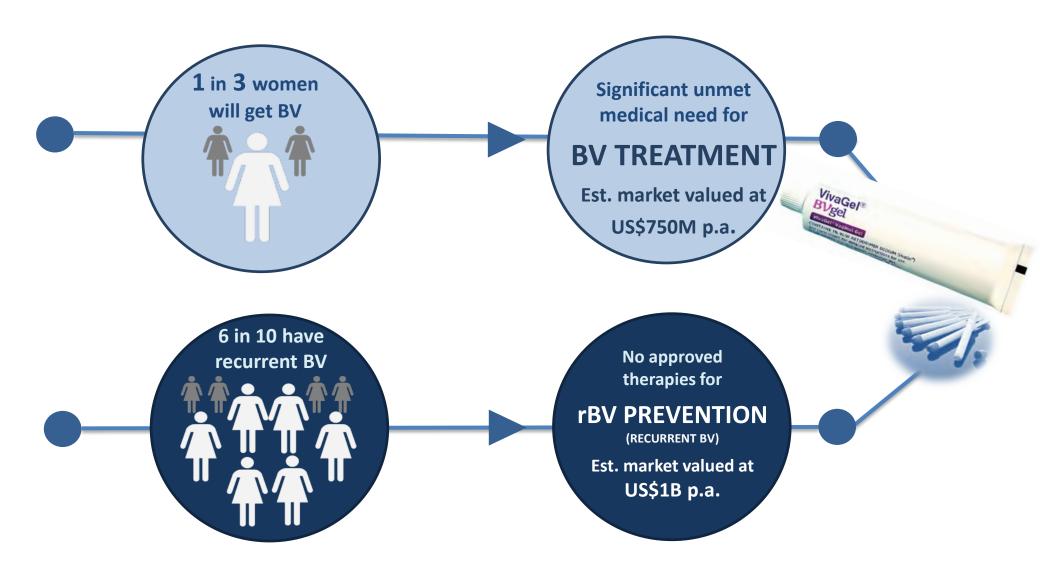
#### **BV** – Major Impact for Patients

- >2/3 of women reported BV had a major impact on their lives
- Most distressing symptom for women was odour
- BV made women feel embarrassed, self-conscious and uncomfortable
- Concerns about BV symptoms caused some women to avoid professional, social or recreational activities

Source: Independent VivaGel® BV US Market Research 2017, KOL feedback & multiple publications



### **VivaGel® BV: Two Attractive Commercial Opportunities**



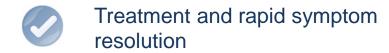


## VivaGel® BV: A breakthrough therapy for BV - a significant unmet medical need

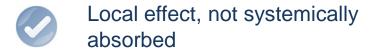
"VivaGel® BV is a wonderful product which specifically targets BV bacteria. My patients have called it a 'life-changing and miraculous treatment'."

Dr Belvia Carter, Ob-Gyn, Memphis, Tennessee. Principal investigator in VivaGel® BV Trials

#### VivaGel® BV







- Excellent tolerability
- Selective antimicrobial effect
- Suitable for long-term use

#### **Current BV Therapies**

- Inadequate efficacy or inappropriate for use in prevention of rBV
- Antibiotic resistance is problematic
- Do not stop BV recurring
- Antibiotics have unpleasant side effects and other issues that inhibit usage (e.g. bad taste, yeast infections, patients unable to consume alcohol)
  - No currently approved therapies for prevention of rBV



# Positive market research findings for VivaGel® BV - from US physicians and payers alike

"I would love to try it [VivaGel® BV] because it is not an antibiotic."

-US GYN #1

"it [VivaGel® BV] is certainly simple enough and the side effect profile is minimal" -US GYN #6

"I like the molecule [VivaGel® BV] a lot better for this [prevention of rBV]. **There is nothing really that treats that recurrent patient**".

-US Payer #2

"I think part of the reason why we are seeing more recurrence is that there has got to be some kind of resistance being built up to the antibiotics."

**-US GYN #5** 



"It seems like it [VivaGel® BV ] would replace current [off label] prophylactic regimens that I recommend."

-US NP #1

"The good news is **not having an antibiotic** hanging around the environment **is good**. The more antibiotics you have out there, the more potential for resistance."

-US Payer #3

"The biggest unmet need is to be able to prescribe a treatment that has **minimal side effects**, does not interfere with the patient's lifestyle and **resolves symptoms quickly.**"

**-US PCP #1** 

Source: Independent US VivaGel® BV Market Research 2017



#### Extensive global licensing negotiations for VivaGel® BV

VivaGel® BV licence strategy and negotiations positively impacted by:

- Fast Track status and QIDP
- Revised, favourable FDA BV guidance
- Successful phase 3 VivaGel® BV rBV results
- NDA lodgement under rolling submission with Fast Track status
- TGA and EU approval, relevant for other markets

Global and regional negotiations covering all the large markets, including in North America, Europe and Asia

- Multiple term sheet negotiations underway in parallel
- Leading US healthcare investment bank appointed to support global licensing process for VivaGel® BV
- Major global and regional companies as well as specialised Women's Health companies are involved in licensing negotiations





## Successful VivaGel® rBV phase 3 trial results (Aug 2017)

#### VivaGel® BV demonstrated statistically significant efficacy in 2 pivotal phase 3 trials



- ➤ Two randomised, double-blinded, placebo-controlled trials enrolled 1,223 women across more than 100 trial sites conducted under SPA
- ➤ VivaGel® BV consistently resulted in reduced rates of BV recurrence by the primary efficacy endpoint *and* five secondary efficacy measures



- VivaGel® BV showed sustained benefits for at least 3 months after cessation of treatment
- ➤ VivaGel® BV demonstrated excellent safety and tolerability, very low rates of candidiasis



➤ VivaGel® BV Phase 3 trial results add significant commercial value

"Our ability to prevent recurrent BV with current treatment regimes is abysmal.

There is an enormous need for a safe and effective treatment to prevent recurrence of BV in women suffering BV."

Professor J Sobel, ID Physician & KOL Dean, Wayne State Uni School of Medicine



#### VivaGel® condom

- VivaGel® condoms carry the VivaGel® brand and Starpharma receives royalties based on sales
- VivaGel<sup>®</sup> condom recently launched in Canada under LifeStyles<sup>®</sup> Dual Protect<sup>™</sup> brand
- Ansell sold its sexual wellness division to Chinese Company Humanwell; Re-branded LifeStyles® – the VivaGel® condom continues to be marketed under the Lifestyles® Dual Protect™ brand
- Humanwell's strong presence in the fast-growing Asian markets - complementary to Sky and Land licence for the Chinese Government market
- Good regulatory progress in Japan, China, Europe and other markets, with a number of approvals expected in 2018

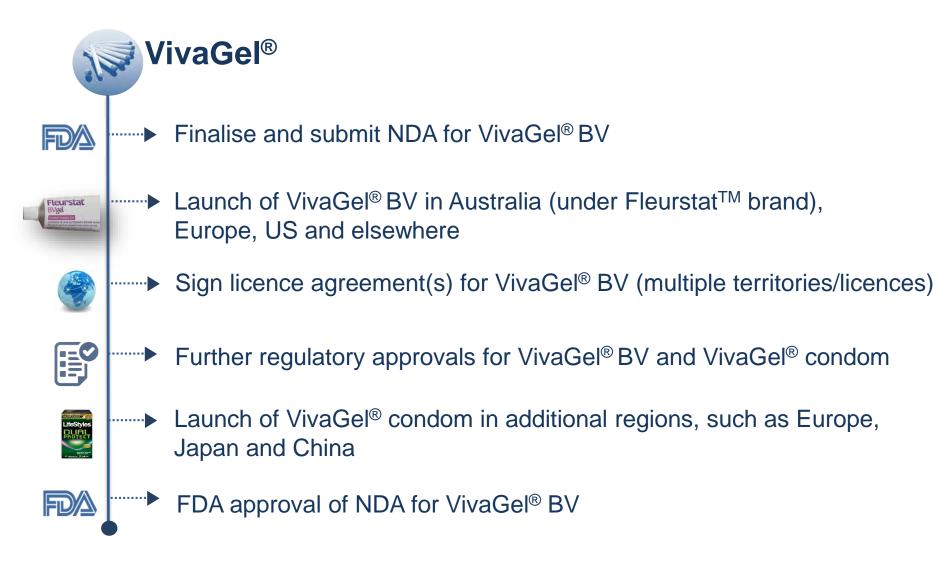








#### **Outlook**





#### **Outlook**









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