

SHAREHOLDER

# Update

OCTOBER 2015



VIVAGEL®

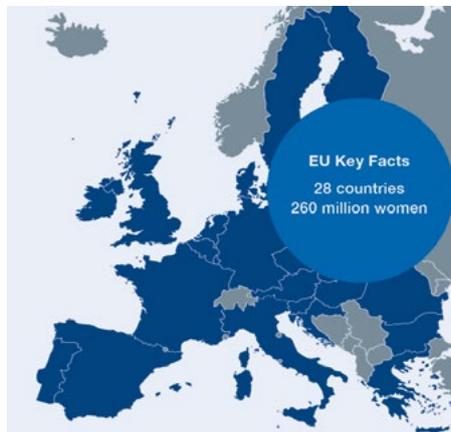
## >> EU marketing approval granted for VivaGel® BV

Starpharma recently achieved the important milestone of marketing approval in the European Union (EU) for VivaGel® BV as a stand-alone gel for the topical treatment and rapid relief of bacterial vaginosis (BV) including symptoms.

The current market for the management of BV and associated symptoms is estimated to be in excess of US\$750 million globally, with significant areas of unmet need for BV sufferers.

The EU approval allows VivaGel® BV to be marketed in the European Economic Area (EEA), which includes the 28 countries of the EU plus the European Free Trade Association (EFTA) countries, providing access to a population of more than 260 million women. The approval is also being used to support regulatory and marketing approvals for VivaGel® BV in a number of other countries that recognise the EU approval, and these activities are now underway.

Negotiations regarding marketing rights for VivaGel® BV are well advanced with a number of potential commercial partners and have been further accelerated by the EU approval. These commercial discussions involve partners with extensive experience in women's health, and cover Western and Eastern Europe, Asia Pacific, Latin America, Canada and the Middle East.



*"The EU marketing approval opens up a very important and large market for Starpharma in the treatment of bacterial vaginosis – a condition with a significant unmet medical need. The approval will also help expedite other approvals for the product in countries which recognise the EU approval, further expanding Starpharma's market reach."*

CEO Jackie Fairley.

DRUG DELIVERY

## >> Multi-product DEP® license with AstraZeneca



In September, Starpharma signed an important multi-product licensing agreement with global pharmaceutical giant, AstraZeneca, for the development of DEP® enhanced drugs from a defined family of targets.

Key terms of the deal are:

- > Milestones for the first AstraZeneca DEP® product of USD\$126 million, and US\$93 million for each subsequent DEP® product
- > In addition, all AstraZeneca DEP® products attract tiered royalties on net sales
- > AstraZeneca to fund all development and commercialisation costs
- > Starpharma's DEP® platform remains unencumbered and available for licensing in the vast majority of oncology and other applications for future deals.

*"The AstraZeneca agreement clearly illustrates the commercial potential of Starpharma's DEP® platform. We estimate that each qualifying product could be worth around US\$450 million to Starpharma over its life, and depending on the range of indications and degree of commercial success in the market, potentially significantly more."*

CEO Jackie Fairley.

In October, Starpharma received the signature payment of US\$2 million and is eligible to receive milestone payments and royalties on one or more AstraZeneca DEP® products as they progress through development and commercialisation.



## >> VivaGel® BV

Bacterial vaginosis (BV) is the most common vaginal infection worldwide. It is the most common cause of abnormal vaginal discharge and unpleasant vaginal odour in women. Up to 60% of BV sufferers have recurrent disease.

VivaGel® BV – Key Facts	
Symptomatic relief and Treatment of BV	Prevention of Recurrence (PoR) of BV
<ul style="list-style-type: none"> <li>Up to 30% of women suffer from BV</li> <li>Acute Use – daily for 7 days</li> <li>Approved in EU – more countries to follow</li> <li>Non antibiotic treatment; excellent patient feedback</li> <li>Global market estimated to be more than US\$750M</li> </ul>	<ul style="list-style-type: none"> <li>Up to 60% of BV sufferers have recurrent disease</li> <li>Longer term use – Once every 2nd day</li> <li>In phase 3 clinical trials</li> <li>No current approved options for PoR</li> <li>Global market estimated to be more than US\$1B</li> </ul>

### Symptomatic Relief and Treatment of BV

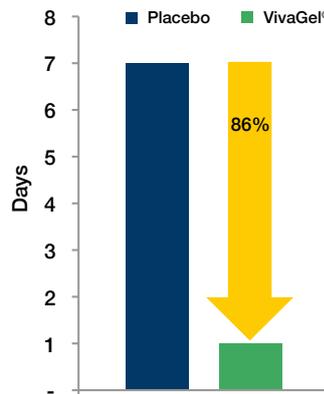
In several clinical trials, VivaGel® BV demonstrated significant benefits over placebo in the treatment of BV and its symptoms when used once daily for seven days. A key benefit of VivaGel® BV was the rapid relief of patients' symptoms associated with BV, including unpleasant vaginal odour and discharge. In addition to resolution of these

problematic symptoms, VivaGel® BV helped to normalise vaginal pH and suppress the bacteria that cause the vaginal microflora imbalance associated with BV. Feedback in formal market research from trial participants using VivaGel® BV was also extremely positive. BV sufferers using VivaGel® BV reported very high levels of overall satisfaction and ease of use.

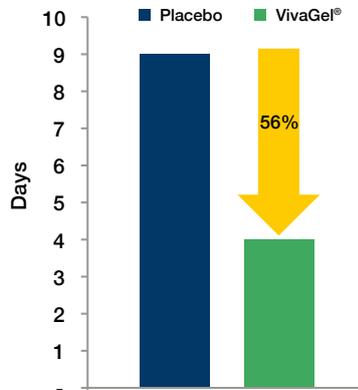
*"It was like gone almost overnight"*  
*"I would definitely use it again."*  
*"The next day I noticed a huge difference."*  
*"I would use it....I will use it indefinitely..."*

VivaGel® BV  
Trial Participants

Time to Resolution of Odour



Time to Resolution of Discharge



### Prevention of recurrence of BV

The VivaGel® phase 3 clinical trial programme for the prevention of recurrent BV continues to progress smoothly with over 100 sites actively recruiting patients and recruitment now well in excess of 50%. The two double-blind, placebo controlled, trials are being conducted across North America, Europe and Asia. The programme is being conducted in accordance

with a US FDA Special Protocol Assessment (SPA), a binding agreement with the regulator that significantly reduces regulatory risk through an agreed trial design. There has also been agreement on the trial design by the European regulatory authority.

In October, Starpharma was granted an additional patent for VivaGel® BV by the US Patent Office, providing a 7 year extension of the patent term to 2032. Further patent extension may also be available subject to the timing of regulatory approval.

Starpharma Chief Executive, Dr Jackie Fairley, commented: "The grant of this new patent is confirmation of the innovation that VivaGel® brings to the bacterial vaginosis field. The patent is one of several in the VivaGel® portfolio and further enhances the commercial value of VivaGel® BV to both partners and shareholders."

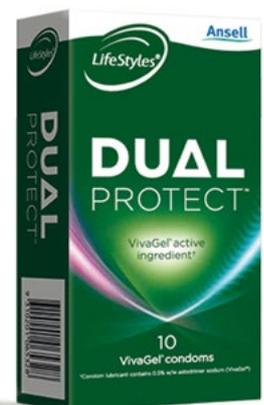
## >> VivaGel® condom

The VivaGel® condom has now been rolled out to Australian pharmacies nationally, including Chemist Warehouse, and a number of online outlets, following the official Australian launch of the condom last year under Ansell's LifeStyles® Dual Protect™ brand.

Regulatory processes are well advanced in a number of other markets and Starpharma expects that the VivaGel® condom will be approved and launched into a number of additional markets over the coming year. In Japan, Okamoto and Starpharma continue to

work closely with the regulatory authorities to reconfirm the classification of the VivaGel® condom to facilitate launch.

Starpharma has also recently received expressions of interest for the supply of VivaGel® condoms into the Chinese Government market and is currently in discussions with the relevant parties in relation to this significant commercial opportunity. The Chinese Government currently supplies condoms to its citizens, with that market currently estimated at 3 billion condoms per year.





## >> Multi-product DEP® license with AstraZeneca

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For the initial DEP® product, which is an oncology compound, development and launch milestone payments of up to US\$64 million, and sales milestone payments of up to an additional US\$60 million (total US\$124 million) plus royalties payable on net sales. Milestones of up to US\$93 million plus royalties will be payable on each subsequent DEP® product.



AstraZeneca will fund all development and commercialisation costs under the agreement, including ongoing and future collaborative work conducted by Starpharma.

The licensing deal follows a successful collaboration with AstraZeneca, through which Starpharma's DEP® drug delivery technology was applied to an important AstraZeneca oncology candidate, with very positive results.

## THE WALL STREET JOURNAL

### >> Starpharma features in Wall Street Journal

The Wall Street Journal reported on Starpharma's unique technology in both print and video media.

*"Melbourne-based Starpharma is using nanotechnology to create a unique way of delivering cancer drugs without side effects such as hair loss, nausea and bone-marrow damage."* Wall Street Journal, 5 Things to know about Australia's Biotech Push, 15 September 2015.

The video is available at: <http://www.wsj.com/video/start-ups-driving-australia-ilicon-valley/3F0BF953-6679-4E6C-8644-28127E68303F.html>



## >> Phase 1 DEP® docetaxel trial update

In the phase 1 study of Starpharma's DEP® docetaxel, a number of patients have now been dosed at the 105mg/m<sup>2</sup> dose level with no cases of neutropenia (Taxotere®'s dose limiting toxicity) or alopecia reported. In contrast, 75% of patients treated with the most commonly used dose for Taxotere® of 75mg/m<sup>2</sup> would typically experience severe neutropenia.

DEP® docetaxel has been generally well tolerated and despite the fact that this is a phase 1 trial where enrolled patients are expected to be less responsive (due to prior treatments and advanced disease), encouragingly, a significant proportion of patients treated with DEP® docetaxel have shown potential efficacy signals in a range of tumors including some which docetaxel would not normally be expected to be effective in.

**In 2012, there were an estimated 14.1 million cases of cancer worldwide (expected to increase to 24 million by 2035).**

- Docetaxel is indicated for use in breast, lung, prostate, gastric, ovarian and head and neck cancers
- These cancers accounted for almost 50% of all new cancer diagnoses in 2012
- These cancers also represent 5 of the top 10 most common cancers worldwide
- In 2010, peak sales of docetaxel were in excess of US\$3 billion

Source: World Cancer Research Fund International; Medtrack

Further dose expansion and optimisation is now underway to determine the recommended dose for phase 2. In parallel Starpharma is in active discussions with key opinion leaders locally and internationally to finalise the design and conduct of the phase 2 program. In the context of future clinical programs it has been identified that DEP® docetaxel's lack of bone marrow toxicity (neutropenia) may make it an ideal combination agent for immunotherapies and this is potentially also being explored further with various parties.



## >> AstraZeneca license FAQs:

- Q** Is there any impact on the DEP® docetaxel program?
- A** Starpharma's other programs, including the company's wholly-owned DEP® docetaxel product, are not negatively impacted by this arrangement.
- Q** Is there any impact on the DEP® platform?
- A** Starpharma retains all rights outside of a well-defined and narrow area of application which means the DEP® platform remains unencumbered and available for licensing in the vast majority of oncology and other applications for future deals with other partners.
- Q** Is this agreement only for oncology products?
- A** The compounds covered by the agreement are for a defined family of targets, which are not limited to oncology. However, the first compound is an oncology product.
- Q** How many products is the agreement for?
- A** The agreement covers any number of products within the defined family of targets. Each product attracts significant additional development and commercialisation milestones, as well as royalties.
- Q** Who will fund development and commercialisation of these compounds and products?
- A** All development and commercialisation costs of the DEP® compounds and products under the agreement will be fully funded by AstraZeneca, including ongoing and future collaborative work conducted with Starpharma.

## AGROCHEMICALS



## >> Agrochemicals

In recent months a number of new agreements have been signed or extended with major agrochemical companies for the European, Asian and North American markets. Most recently, a Priostar® collaboration was signed with a major Japanese agrochemical company. In addition, licence negotiations are underway for rights to Priostar® to enhance a number of existing agrochemical products.

Recent regulatory compliant field trials on Priostar® enhanced versions of several major herbicide and fungicide formulations showed commercially compelling product benefits, including improved effectiveness and faster onset of action. In addition, Starpharma has recently developed more environmentally friendly formulations of major herbicides and insecticides using Priostar® technology, which are now the subject of commercial discussions.

### 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



**Starpharma's Patented Priostar® offers...  
Improved formulations with high barrier to entry for competitors, with or without new actives**

## CORPORATE NEWS



## >> Starpharma in the News

Starpharma has attracted substantial media coverage recently, with a large number of top-tier articles and interviews on various aspects of the company, including the recent AstraZeneca license agreement and EU approval of VivaGel® BV.

The announcement of the AstraZeneca deal in September generated more than 40 pieces of media coverage, including *The Australian Financial Review*, *The Australian* and the *Herald Sun*. CEO Jackie Fairley was also interviewed on *Sky Business News* and ABC's *The Business*.

<http://www.theage.com.au/business/starpharma-signs-deal-with-astrazeneca-on-drug-delivery-technology-20150906-gjigig>

Herald Sun columnist John Beveridge noted that the beauty of Starpharma's DEP® technology was that “it is exceptionally good at making all sorts of medicines dissolve and that the deal highlighted it “could literally be worth \$1 billion or much more as a range of Astra Zeneca's cancer drugs are switched into dramatically improved versions.”

In June, *The Australian Financial Review* also wrote a feature piece on high-net worth investors James Dack and Mark Carnegie joining the Starpharma register, while *The Australian* published an interview with CEO Jackie Fairley in which she called for changes to Australia's superannuation system to boost Australia's knowledge economy and investment in innovation.

<http://www.afr.com/business/health/biotechnology/big-hitters-mark-carnegie-and-james-dack-back-aussie-biotech-starpharma-20150616-ghpa1s>

## FINANCIALS



## >> Starpharma full-year financial results

In August, Starpharma released its annual report and financial results for the year ended 30 June 2015. Key financial results are summarised in the table below.

Key Financial Results	AUD for financial year 2015
Total revenue and other income	\$1.7M
R&D tax incentive	\$3.5M
Net loss after tax	(\$19.0M)
Operating and investing cash outflows	(\$14.3M)
<b>Cash at 30 June 2015</b>	<b>\$30.8M</b>

## CONFERENCES



## >> Presentations and conferences

In addition to a number of industry and investor conferences, Starpharma's CEO Jackie Fairley recently presented at the OTCQX Life Sciences Virtual Investor conference which attracted over 500 investors. Dr Fairley gave an introduction to the company and an update on the AstraZeneca licensing deal and EU marketing approval for VivaGel® BV.

The presentation is available for viewing at <http://www.virtualinvestorconferences.com/agenda-oct2015.html>

**Starpharma Holdings Limited**  
(ASX:SPL; OTCQX:SPHRY)  
ABN 20 078 532 180  
4-6 Southampton Crescent  
Abbotsford  
Vic 3067  
+61 3 8532 2700

[www.starpharma.com](http://www.starpharma.com)

**Company**  
Nigel Baade  
CFO/Company Secretary  
+61 3 8532 2704  
investor.relations@starpharma.com

**Media Relations**  
Rebecca Wilson  
Buchan Consulting  
Mob: +61 417 382 391  
rwilson@buchanwe.com.au

**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.