

# SHAREHOLDER Update

MARCH 2015



DRUG DELIVERY

## » Phase 1 DEP™ docetaxel clinical trial update

Starpharma's phase 1 clinical trial of DEP™ docetaxel in patients with advanced cancers is approaching 50% recruitment, and continues to show very encouraging clinical data.

The drug remains well tolerated and no neutropenia or hair loss has been observed to date, despite continued dose escalation and some patients receiving as many as 6 cycles of treatment.

"It is very pleasing to see these continued strong results from the trial

which are consistent with our earlier good preliminary data for DEP™ docetaxel from the trial's first cycle of dosing and also the preclinical studies", Starpharma CEO Dr Jackie Fairley said.

"The beneficial features from the pharmacokinetic (PK) analyses and preclinical studies include a substantially extended duration of exposure, greatly increased extent of exposure to drug and reduced peak levels of drug."

Four sites are now involved in the trial, with Liverpool Hospital, in Sydney NSW, recently added for the completion of the dose escalation phase and in readiness for the final phase of the study which will assess the maximum tolerated dose (MTD) in an expanded patient cohort. The trial is expected to enrol approximately 25–30 cancer patients.

DRUG DELIVERY

## » DEP™ docetaxel – in the news

Starpharma's phase 1 DEP™ docetaxel trial was recently featured in an article on the study in the Herald Sun and associated newspapers.

The article highlighted that, compared with the currently marketed form of docetaxel, known as Taxotere®, Starpharma's dendrimer-enhanced docetaxel (DEP™ docetaxel) reduced side effects and better targeted tumours in animal studies.

Clinical trial principal investigator, Dr Jason Lickliter said: "The idea is that there will be a higher level of the toxic

## Herald Sun

### Chemo trial offers relief

Side effects reduced

LUCIE VAN DEN BERG  
MEDICAL REPORTER

VICTORIA'S patients are trying chemotherapy with a new technological twist that aims to boost the effectiveness of the drug and ease its debilitating side effects.

It was hoped the results would be replicated in the phase I human trial.

The CEO of the company behind the technology, Starpharma's Jackie Fairley said the drug was an improved formulation of an existing drug known as Docetaxel or Taxotere.

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## Participating trial sites



Royal Brisbane and Women's Hospital

chemotherapy drug in the tumour that will lead to better responses and there will be less of the drug in the normal tissues of the body and therefore less toxicity."

The article also described the experiences of Alison Mew, a cancer patient, who was given the currently marketed docetaxel as part of her therapy that was stopped after she suffered a variety of severe and unpleasant side effects. Based on her experiences, Ms Mew said that "any advancement to reduce chemotherapy side-effects was welcome."

See the article at: <http://www.heraldsun.com.au/news/victoria/chemotherapy-trial-offers-relief/story-fni0fit3-1227234616274>



## >> Partner News

In late 2014 Starpharma's partner, AstraZeneca, announced oncology as a key growth area. "Fuelled by a very exciting portfolio of new products, oncology is set to become AstraZeneca's sixth growth platform", AstraZeneca Chief Executive Pascal Soriot said in a recent speech.

AstraZeneca's pipeline of drugs is expected to drive strong and consistent revenue growth, delivering annual revenues in excess of US\$45 billion by 2023, which would represent a quarter of its sales.

Starpharma's agreement with AstraZeneca, for access to Starpharma's DEP™ platform technology to improve cancer drugs from AstraZeneca's development pipeline, is progressing very well, with AstraZeneca conducting extensive testing of the DEP™ candidates and providing expanded funding for Starpharma's work.

 Another of Starpharma's partners, ADAMA Agrochemicals has significantly strengthened its presence in China, one of the world's largest crop protection markets with the acquisition of businesses from China National Chemical Corporation (ChemChina), which is expected to close in 2015.

The deal gives ADAMA a major foothold in the Chinese market which is expected to become one of its key growth engines and forecast to raise ADAMA's revenues to almost US\$4 billion. "This is a first step towards the creation of the only truly integrated China-Global player in the crop protection industry", said ADAMA President and CEO Chen Lichtenstein.

Starpharma is partnering with ADAMA in its agrochemicals program where ADAMA is applying Starpharma's Priostar® dendrimer technology to create novel crop protection formulations across its extensive product portfolio.

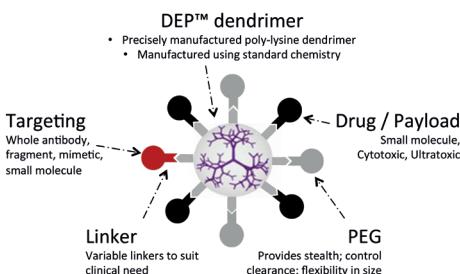
Late last year Starpharma was granted a formulation patent for Priostar® dendrimers with agrochemicals, including with glyphosate, by the State Intellectual Property Office of China, with the term of the patent expected to be until 2030.



## >> Starpharma targeting key growth areas in Oncology

In addition to its partnered programs and Starpharma's DEP™ docetaxel phase 1 trial, Starpharma has made substantial recent progress in targeted DEP™ drug conjugates – a new approach to drug conjugate design with a large market potential.

By combining the unique targeting capabilities of Starpharma's DEP™ platform with the cancer killing ability of cytotoxic drugs, Starpharma's targeted DEP™ drug conjugates allow highly sensitive discrimination between healthy and diseased tissue. The diagram below shows a schematic version of a targeted DEP™ drug conjugate.



Starpharma's targeted DEP™ drug conjugates have already shown a number of benefits over standard targeting technologies:

Can use small molecule, whole antibody, antibody fragments or antibody mimetics	✓
Bind with high affinity and specificity	✓
Flexible and tailored to suit clinical requirements	✓
Homogeneous	✓
Standard Chemistry yielding consistent, reproducible, stable molecules	✓
DEP™ dendrimer platform already in the clinic and demonstrated to be safe and well tolerated	✓

The targeted drug conjugate market has large revenue potential with 50% of the top-ten products worldwide being antibodies with 2013 sales in excess of \$US38 billion, while the top-three oncology products are all antibodies with combined sales in excess of US\$20 billion.



## >> Bacterial vaginosis: Prevention of recurrence (PoR)

Starpharma's two double-blinded, placebo controlled phase 3 trials are progressing well, with the majority of the 100 sites now recruiting. These trials are being conducted across the US, Canada, Mexico, Europe and Asia, with each trial planned to enrol around 600 women. The study was granted a Special Protocol Assessment (SPA) by the FDA in 2014 which reduces Starpharma's regulatory risk through a binding trial design. In addition there has been agreement on trial design granted by the European regulatory authority.

Bacterial vaginosis (BV) is a highly prevalent disease with more than 29% of women infected in the US (14–49 years) and up to 51% in certain demographics. A particularly troublesome form, Recurrent BV, affects 50–60% of BV sufferers with no approved therapeutic option currently available.



### TWO

Double-blinded, placebo controlled phase 3 trials in multiple sites globally

### \$US1 billion

Estimated size of recurrent bacterial vaginosis (R-BV) market

### None

Currently no approved products for the prevention of R-BV



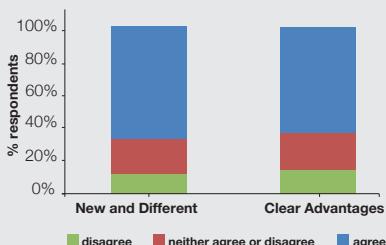
## » Bacterial vaginosis: Symptomatic relief

Regulatory submissions for VivaGel® for Symptomatic Relief of BV are now underway for a number of countries. This indication is for the short term use of VivaGel® once a day for 7 days which was shown in clinical trials to have a rapid effect on symptoms (within 1 day for odour resolution) and in market research to have high acceptance.

### VivaGel® BV Market Research:

Majority of respondents felt that VivaGel® is new and different and offers clear advantages when compared to options available.

VivaGel® BV Quantitative Research – October 2013

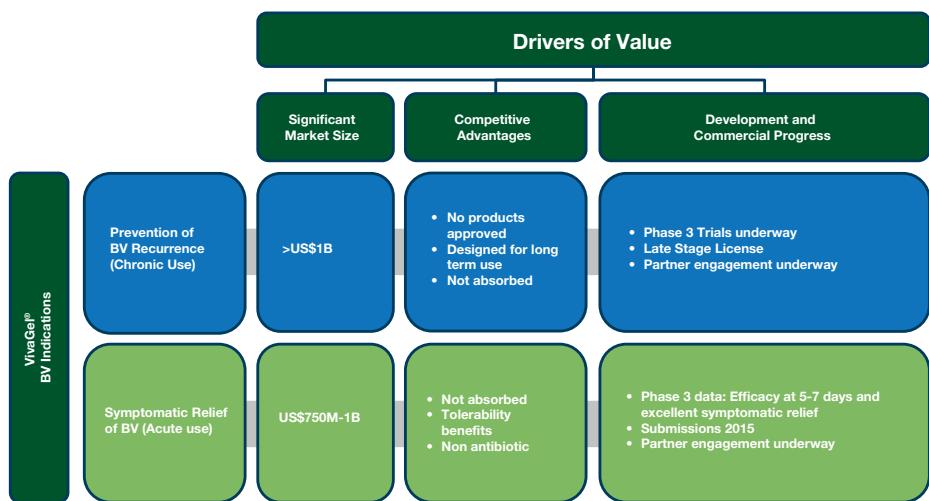


Dr Carter, a Board Certified OBGYN with a large BV practice in Memphis, Tennessee, and an investigator in the VivaGel® trials for the 7 day treatment, was so positive about the efficacy of VivaGel® that she also wanted to be part of further trials (she is now part of the phase 3 PoR clinical trial program). Feedback from her patients in the 7 day treatment trial on VivaGel® was very positive. "This is a great product", she said.

According to Dr Carter: "BV has a

significant social impact on patients and women are very concerned about their odour and often have a low quality of life." Dr Carter stated that she has many patients in her clinic today that would benefit from access to VivaGel®.

Commercial discussions with parties regarding marketing rights for VivaGel® in various regions are continuing to progress well. It is estimated that the size of the global market for BV symptom management is more than \$US750 million.



## » VivaGel® condom

The VivaGel® condom was officially launched by Starpharma's marketing partner, Ansell, under its LifeStyles® Dual Protect™ brand late last year. The condom is now available from Woolworths' supermarket stores across the country.

Continuing on from significant social media interest received upon initial approval of the condom by the Therapeutic Goods Administration, and to mark the launch of the world's first anti-viral condom, Ansell conducted a social media promotional campaign, including #shareyourfirsts on Facebook, encouraging its followers to post examples of 'firsts' to its page – such as first dates and the buying of a first apartment.

The campaign also featured videos on both Facebook and YouTube of ex-North Melbourne AFL player Ed J Lower talking about his first AFL game, model Jazz Bell talking about her first photo shoot and actor Ed Kavalee speaking about his first acting audition.

Go to: <http://www.ansellcondoms.com.au/videos/>



Dual-Protect™ Condom billboards will go up at a number of train stations in March 2015

Starpharma is anticipating the rollout of the VivaGel® condom to additional Australian retail outlets and further countries in 2015. Marketing clearance for the New Zealand market was obtained in November last year, with other regulatory approvals anticipated from filings in progress.

As well as a licence agreement with Ansell, Starpharma has a licence for the VivaGel® condom in Japan with Okamoto Industries, the market leader for condoms sold in Japan. Okamoto and Starpharma continue to work closely with the Japanese Regulatory Authorities to confirm the classification of the VivaGel® condom in Japan. In parallel, Okamoto is

actively undertaking launch preparations with a view to launching the product quickly following the outcome of the regulatory review.



Always read the label. Use only as directed. Condom lubricant contains VivaGel®. \*Anti-viral effects demonstrated in laboratory studies only

**CORPORATE NEWS**


## » Starpharma's new premises

After a long tenancy on the Alfred site, Starpharma was advised that the Baker IDI Heart & Diabetes Institute would require the space itself from 2015. Starpharma was able to secure excellent alternative premises with existing established laboratories and office space, centrally located in Abbotsford, Melbourne.

The company relocated in December and after a smooth transition, has now settled in to its new premises.


**CORPORATE NEWS**


## » Starpharma included in OTCQX's new International Index

Starpharma has recently been included in the US OTC (Over the Counter) Market Group's new OTCQX International Index.

The OTCQX singled out Starpharma in its news release along with recognised international brands and companies.

"OTCQX International Index is comprised of more than 200 International Securities traded on OTCQX. This includes large-cap global companies such as Adidas AG, Heineken NV and Volkswagen AG, as well as growing international companies such as Starpharma Holdings Limited."

Currently 4.4% of Starpharma investors are 'ADR' holders through the OTCQX platform.

**CORPORATE NEWS**


## » Interviews, Presentations and Conferences

Starpharma CEO Dr Jackie Fairley regularly meets with domestic and international investors and partners, and in January was in San Francisco attending the JPMorgan Global Healthcare Conference.

Whilst there, Dr Fairley also presented at the Biotech Showcase – an event that attracts around 1,700 investors, analysts, biopharmaceutical executives and industry professionals from around the world. At both conferences, Starpharma held partnering meetings to present an update of Starpharma's programs including the recent data from the DEP™ docetaxel clinical trial. Meetings were also held with investment funds and executives with an interest in agrochemicals and other products.

In February Starpharma's CEO, Dr Jackie Fairley was interviewed on 640WGST Talk Radio, Atlanta's Health Tech Talk Live, hosted by Ben Chodor. In this interview, Dr Fairley discussed VivaGel®, the company's development of the world's first anti-viral condom (the VivaGel® condom), Starpharma's current phase 3 clinical trials of VivaGel® for the prevention of recurrent bacterial vaginosis as well as its clinical trial of DEP™ docetaxel.

Listen to the interview at:

<https://www.youtube.com/watch?v=ieH6wsC-DfA>

In March, Dr Fairley presented at both the leading Annual ROTH Capital Partners Conference in California and the 8th ASX Spotlight Conference in New York. These conferences both provide an opportunity for Starpharma to present the business to US investors. The invitation only ROTH Conference focuses on small and mid cap companies and is attended by more than 3,000 participants including both institutional and private investors.

**FINANCIALS**


## » Starpharma half yearly financial results

The consolidated loss after tax for the half-year to 31 December 2014 was \$8.5M (December 2013: \$5.6M), reflecting costs associated with running the business including the two clinical programs underway – VivaGel® phase 3 clinical trials for the prevention of recurrent bacterial vaginosis and the phase 1 trial of DEP™ docetaxel.

Starpharma's cash balance at 31 December 2014 was \$39.3M, which includes the net \$20.5M proceeds from the institutional placement and share purchase plan. The placement attracted six new local institutions and seven new international institutions and was significantly oversubscribed.

R&D Tax Incentives of \$1.6M (December 2013: \$2.6M) have been recorded for research and development activities eligible under the Australian Government's R&D Tax Incentive program.

Key Financial Data	AUD \$ for half year FY15
Total revenue and income	\$0.7M
R&D tax incentive	\$1.6M
Net loss after tax	(\$8.5M)
Operating and investing cash outflows	(\$5.5M)
Cash at 31 December 2014	\$39.3M

Starpharma Holdings Limited (ASX:SPL; OTCQX:SPHRY) ABN 20 078 532 180 4-6 Southampton Crescent Abbotsford Vic 3067 +61 3 8532 2700	Company Nigel Baade CFO/Company Secretary +61 3 8532 2704 investor.relations@starpharma.com
<a href="http://www.starpharma.com">www.starpharma.com</a>	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.