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### IN THIS ISSUE

- Starpharma commences pivotal phase 3 VivaGel® BV treatment trials
- Starpharma continues to build momentum as a leader in the sector
- Starpharma improves efficacy of leading chemotherapy drug docetaxel with dendrimers in breast cancer model
- Nanobiotechnology to reach \$6 billion by 2017

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### >> Pivotal phase 3 clinical trials commenced for VivaGel® as a treatment for bacterial vaginosis

In late March Starpharma was pleased to announce the commencement of two concurrent phase 3 clinical trials of VivaGel® for the treatment of bacterial vaginosis (BV). These pivotal trials will take place at 30 international sites, and enrol approximately 220 participants each.

This is a major milestone both for Starpharma and the Australian biopharmaceutical industry (see "In Good Company" on page 2 for more information). The results of the trials are anticipated by the end of 2012 and shortly thereafter, Starpharma intends to submit a dossier to the US Food and Drug Administration (FDA) for approval of VivaGel® under a New Drug Application (NDA).

VivaGel® for the treatment of BV has already received a Special Protocol Assessment or SPA by the FDA. An SPA is a declaration from the FDA that a phase 3 trial's design, clinical endpoints, and statistical analyses are approvable by the FDA once completed to a pre-agreed level. This early clarity reduces the risk

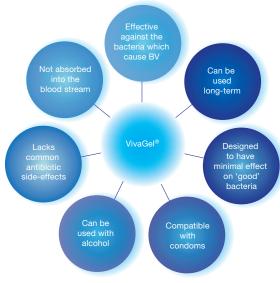
These phase 3 trials are designed to confirm the results of a similarly designed phase 2 study that was completed in 2011 and demonstrated VivaGel® was safe and effective in the treatment of BV. VivaGel® met the primary endpoint of that trial, demonstrating significant efficacy in the treatment of BV with a very high level of statistical significance. Importantly, the primary endpoint for the two new phase 3 trials is the same as the completed phase 2 study.

inherent in regulatory processes.

The diagram on the right summarises the benefits of VivaGel® over the current, antibiotic-based treatments available on the market. The market for topical BV treatments is approx. US\$300-\$350 million.

"The commencement of these studies is a landmark achievement in the development of VivaGel®. Starpharma is excited to be at this pivotal stage for VivaGel®, with its potential as both a treatment and a preventative for this highly problematic and widespread condition"

Starpharma CEO, Dr Jackie Fairley.



**VIVAGEL® FOR BV TREATMENT** 





### » Millions of women seeking better treatment for bacterial vaginosis

Starpharma's new clinical trials address a large market with strong demand

The long-term patient implications for a successful bacterial vaginosis (BV) treatment are very significant. Research shows that one in three women suffers from the embarrassing and unpleasant condition during their lives. Compounding this, many experience BV on a recurring basis, which can severely impact overall health, confidence and well-being.

BV is a difficult issue to talk about publicly; but women all over the world are voicing their frustration via women's health blogs, forums and chat rooms:

"I've had BV for three months now. I am sick and tired of reading about this infection and only getting as far as keeping it at bay. I am getting pretty desperate and I am looking for a final solution. ... I want an answer to get rid of this awful thing. No woman should have to deal with this."

Curezone forum

### >> IN GOOD COMPANY

Starpharma joins the small group of Australian companies to take a New Chemical Entity drug to phase 3.

The commencement of
Starpharma's newest trials is
a sign of the maturation of the
biopharmaceutical industry in
Australia. Upon successful
completion, Starpharma will
become one of very few
companies where a New Chemical
Entity has been discovered in

Australia, and developed all the way through to a New Drug Application (NDA).

These trials will complete the development program for VivaGel® as a treatment for BV. An NDA submission to the US FDA is planned upon completion of the trials.

The NDA is the vehicle in the United States through which companies formally apply to the FDA to approve a new pharmaceutical for sale.

### What is BV?

BV is a condition in women where the normal balance of different species of bacteria in the vagina is disrupted. It is accompanied by discharge, odour, and sometimes pain, itching, or burning. It is the most common vaginal condition in women of childbearing age.

More seriously, BV is also linked to pelvic inflammatory disease and an increased risk of sexually transmitted infections, including HIV, and preterm birth.

BV is not well understood but it is known that certain ethnic groups are more susceptible and some activities upset the balance of 'good and bad' bacteria in the vagina including a new sex partner, multiple sex partners, or douching.

### How is it treated?

Existing treatments of BV are primarily conventional antibiotics. Standard practice is to provide women with antibiotics which are moderately effective, but often have harsh side effects and fail to control recurring episodes of BV.

### How is VivaGel® different?

VivaGel® is a non-antibiotic clear topical gel that is applied to the vagina with an applicator. VivaGel® is not absorbed into the bloodstream (as antibiotics are), and as such is not associated with the side effects of antibiotics. Clinical trials of VivaGel® show a high level of patient acceptability.





### >> Starpharma continues to build momentum as a leader in the sector

On 22 March, global investment group M&G announced that it had increased its holding in Starpharma by 1% to 8.01%. One of the largest equity fund managers in the UK, M&G is the European fund management arm of international finance group Prudential plc. M&G became a substantial holder with a 6.7% stake in late November 2011 during Starpharma's oversubscribed capital raising.

Other domestic and international investors continue to acknowledge the strong performance Starpharma has achieved in recent months and are closely monitoring advancement of the Company's development programs.



The maturation of the Starpharma portfolio, its successful partnering model, and the optionality of the company's platform technology have resulted in continued strong share price performance (as shown in the accompanying graph). In the 12 months to late March 2012 Starpharma's share price has increased by 53.5%, well above the ASX 300 (-8.6%), All Ordinaries Index (-8.5%) and its industry peers.

### >> ANALYST COVERAGE

New research has been released so far this year by Nomura, Shaw Stockbroking and Bell Potter:

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## >> Starpharma improves efficacy of blockbuster cancer drug in breast cancer model

In February, Starpharma released data from an animal efficacy study which demonstrated that its dendrimer-docetaxel formulation of leading chemotherapy drug docetaxel was significantly more efficacious than standard docetaxel (Taxotere®) in a breast cancer model.

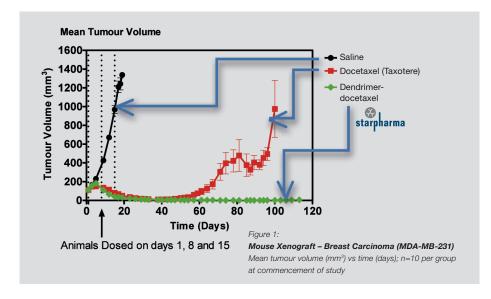
Docetaxel is a leading chemotherapy drug used to treat a wide range of tumours including breast, lung and prostate cancers.

It is marketed by Sanofi as Taxotere® and generated sales in excess of US\$3 billion in 2010.

Starpharma conducted the latest study, a breast cancer xenograft in mice, as part of its drug delivery program for docetaxel – having already demonstrated a marked improvement in the water solubility of docetaxel with its dendrimer formulation.

The results of this study show Starpharma's dendrimer-docetaxel formulation demonstrated significant enhancement of anticancer effects when compared to docetaxel (Taxotere®) alone. Furthermore, 60% of animals treated with Starpharma's preferred dendrimer-docetaxel formulation had no evidence of tumours at 94 days – whereas 100% of the Taxotere® treated mice showed significant tumour regrowth at the same timepoint.

This data is an exciting progression for Starpharma's internal drug delivery program. Reformulations of successful drugs are a lower risk and lucrative strategy for companies who can demonstrate significant improvements over the original formulation.





### International licensing expert **Peter Turvey** joins Starpharma **Board**

In March the Starpharma Board welcomed Peter Turvey as a Non-Executive Director. Peter recently



Non-Executive Director. Peter Turvey

retired from CSL (ASX:CSL) as Executive Vice President (Licensing) and Company Secretary after nearly two decades. He brings to the Starpharma Board exceptional commercial licensing skills having worked at CSL since 1992 in various roles including Group General Counsel, Company Secretary and Executive Vice President Licensing. Peter played a key role in the transformation of CSL from a government owned enterprise, through listing in 1994, to its current status as a global plasma and biopharmaceutical company. The many licensing deals he was involved with included the Gardasil (HPV vaccine) license to Merck & Co.

"Since retiring from CSL, I was keen to remain active in a leading biopharmaceutical company and was excited and impressed at the depth and breadth of the Starpharma portfolio, the company's Management Team and the significant opportunity to contribute to this business at a time where there are multiple market opportunities".

Peter Turvey

### Half year Financials

Starpharma released its half year financial results on 20 February 2012. The Company is in a strong cash position following outstanding support for its \$35 million capital raising in late 2011.

The cash balance at 31 December 2011 was \$49.0 million, compared with \$18.9 million at 30 June 2011, with net equity proceeds of \$33.8 million during the period. Net cash outflows from operations were \$3.9 million and the net loss after tax of \$4.7 million was consistent with the Company's budget estimates.

Funds are being applied to the VivaGel® BV phase 3 programs (both treatment and prevention of recurrence) and also to accelerate exploitation of the multiple product opportunities across the Company's drug delivery and agrochemicals programs.

### >> Nanobiotechnology to reach \$6 billion by 2017

Nanotechnology's fastest growing sector - nanobiotechnology - is poised for rapid growth, especially in the field of targeted drug delivery therapies in the oncology sector, according to a new report published by Global Industry Analysts, Inc. The report forecasts the global Nanobiotechnology market will reach \$6 billion by 2017. It also defines the application of nanobiotechnology to the treatment of cancer as "nanooncology", and forecasts

significant growth in this field. Areas of nanooncology therapeutics forecast to attract high levels of R&D investment include nanoparticle-based chemotherapeutic agents/drugs, monoclonal antibody nanoparticle complexes and their role in cancer drug delivery.

Starpharma's dendrimer-docetaxel formulation (refer to page 3) is an example of the Company's work in the discipline of "nanooncology".

Starpharma, and its wholly owned subsidiary Dendritic Nanotechnologies Inc. are among a handful of companies named in the report by Global Industry Analysts, Inc. as "key players in the marketplace".

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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 filture 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 on 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, managements' expectated insight little results, including additional analysis of existing clinical data, and new clinical data; 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