

## Shareholder Update: December 2008

Welcome to the latest edition of Starpharma's Investor Update, a periodic newsletter designed to keep shareholders informed of recent company developments.

This issue provides information on the signing of a full license agreement for the VivaGel<sup>®</sup>-coated condom, an update on DNT and some background on the bacterial vaginosis opportunity. We also feature an opinion article written by CEO Jackie Fairley that appeared in a special biotechnology issue of the *Ethical Investor magazine*.

### A MAJOR COMMERCIAL MILESTONE: Full license agreement signed for VivaGel<sup>®</sup> - coated condoms

Starpharma recently announced the Company's most important commercial milestone to date with the signing of a full license agreement with SSL International for the development of the VivaGel<sup>®</sup>-coated condom. SSL manufactures and markets Durex<sup>®</sup>, the world's number one condom.

Starpharma estimates that the deal will deliver the company more than A\$100 million in royalties, milestone payments and development support.

The agreement also validates the expanding potential of VivaGel<sup>®</sup> and highlights the international recognition afforded to Starpharma's technology. The announcement generated extensive media interest with coverage in *The Australian*, *The Australian Financial Review*, *The Sydney Morning Herald* and *The Age*. CEO Jackie Fairley was also interviewed live on *Sky Business News* and *Bloomberg Today*.

Condom manufacturers have long understood the commercial potential for premium condoms and innovative products. In addition, the industry and regulators have been seeking a replacement for nonoxynol-9 (N9) which for some years has been used as a spermicidal coating for premium condoms. However, N9 has recently been associated with safety concerns including increasing the risk of infection with HIV and the human papillomavirus, and so alternative coatings are actively being sought.

The potential for VivaGel<sup>®</sup> is well demonstrated by the deal with SSL. The proposition for a unique product with a proprietary spermicidal and virucidal coating is attractive to SSL. The agreement secures for SSL marketing rights to the VivaGel<sup>®</sup>-coated condom in most of the world, including Europe and the USA, while providing Starpharma with a strong partner and significant global coverage.

SSL's CEO Garry Watts in announcing the company's half-year results recently emphasised the importance of innovation and novel products: "Innovation is key to SSL's strategy to keep sales growing

and consumers interested." The VivaGel<sup>®</sup>-coated condom represents an exciting opportunity squarely in this innovative product strategy.

Leigh Taylor, Head of Innovation at SSL, added: "VivaGel<sup>®</sup> offers leading-edge technology with the potential to enhance our Durex<sup>®</sup> business."

SSL has approximately 30% of the global market for condom retail sales, estimated to be US\$3.2 billion. SSL's dominance in the condom market has been further strengthened by its recent financial performance. The company posted a 23% sales surge in the last six months, largely on the back of its Durex<sup>®</sup> brand. It is worth noting that sales in the condom market are expected to be relatively immune to the current economic downturn.

SSL's recent acquisition of a stake in the owner of Russia's leading condom brand, and its expansion into Eastern Europe and the Middle East are indicative of the company's aggressive growth strategy for its condom business. These developments, building on SSL's already dominant marketing capabilities, are good news for Starpharma and the VivaGel<sup>®</sup>-coated condom.

The co-development program for the VivaGel<sup>®</sup>-coated condom is making excellent progress and the collaboration with SSL is proving to be highly productive. Starpharma is delighted to be working with SSL and in doing so to participate in the company's aggressive growth plans, but also to benefit from SSL's capabilities and marketing strength to rapidly move the VivaGel<sup>®</sup>-coated condom through registration and into the market.

## NEWS IN BRIEF FROM STARPHARMA

### SPL7013 shows activity against all major clinically relevant HPV strains

Early this month we announced new data showing that SPL7013, the active ingredient in VivaGel<sup>®</sup>, inhibits all four strains of the human papillomavirus (HPV) targeted by the two marketed cervical cancer vaccines. These latest pre-clinical results extend those of a previous study showing that SPL7013 was active against two of the four strains targeted by the vaccines. SPL7013 has now been shown to have *in vitro* activity against HPV-16 and -18, which account for approximately 70% of cervical cancers; and HPV-6 and -11, which together account for approximately 90% of the incidence of genital warts.

In addition, the latest results demonstrate SPL7013 to be active against HPV-31. Previously SPL7013 has been demonstrated to be active against HPV-45. These two strains have been implicated in more than 4% of cervical cancers but neither is included in the existing vaccines.

The new data support our earlier findings that VivaGel<sup>®</sup> may have potential for reducing the risk of genital HPV infection, the most common sexually transmitted infection in the United States.

### VivaGel<sup>®</sup> patent granted in Japan

In October Starpharma announced that one of its key patents relating to the use of dendrimers to protect against sexually transmitted infections had been granted in Japan.

This approval means that VivaGel<sup>®</sup> and the VivaGel<sup>®</sup>-coated condom are now covered by granted patents in all major markets including Europe, the US and Japan.

### DNT update

Following acquisition of the US-based subsidiary Dendritic Nanotechnologies Inc (DNT) Starpharma's Board and management have been progressively integrating research and development activities and consolidating operational roles across the two sites.

From December, all of DNT's financial operations and administrative functions will be transferred to existing staff at the company's headquarters in Melbourne. Similarly, some of the research programs under way at DNT have been transferred to Australia. The US team will be purely focused on business development activities and a small number of scientific programs - including the US\$680,000 Department of Defense-supported water remediation project.

As a result of the transfer of functions and activities, the roles and responsibilities of the President of DNT have become redundant. These changes at the US subsidiary will save Starpharma in excess of \$500,000 per annum.

In making these changes Starpharma has kept sight of the priority of advancing its current clinical and near term commercialisation programs. The changes at DNT will not impede the progress of those programs, nor impact on the ongoing revenues derived from partnerships with Dade Behring and Qiagen based on DNT technology.

## A new indication for VivaGel<sup>®</sup>: Bacterial Vaginosis

In early July, Starpharma announced the treatment of bacterial vaginosis (BV) as a new indication for VivaGel<sup>®</sup>. This is the first application of VivaGel<sup>®</sup> as a treatment, signalling the diversity and further potential of its development program.

Trends observed in human clinical trials in women who had asymptomatic BV at the time of enrolment into the trials suggest that VivaGel<sup>®</sup> treatment could potentially restore the normal balance of bacteria in the vagina.

BV is a major cause of vaginal infection and is particularly prevalent in the US where it is reported to affect 29% of women. This product

application opens a new and potentially rapid path to market for VivaGel<sup>®</sup>. The global market for topical vaginal treatments for BV is estimated at approximately US\$300 million.

If proven effective against BV, VivaGel<sup>®</sup> will offer an alternative to current conventional antibiotic treatments with several advantages: it is compatible with condoms and is not absorbed by the body, so has a low likelihood of causing drug interactions or leading to drug resistance. Most importantly, it also offers an alternative therapeutic approach for women who are unhappy about the need for continued administration of conventional antibiotics for recurring BV.

## Water remediation technology update: US Department of Defense project progressed to Phase II

Starpharma's DNT has been working with the US Department of Defense's (DoD) Strategic Environmental Research and Development Program since 2007 to develop its Priostar® technology for use in water purification.



The initial US\$1.3m DoD contract was awarded in 2007 to DNT and the Central Michigan University Research Corporation to develop water remediation technology using DNT's Priostar® dendrimers. Recently, Starpharma was delighted to be awarded an extension of this contract to Phase II following the commitment of a further US\$680,000 by the US DoD. Starpharma retains all commercialisation rights to technology developed under the program.

Starpharma's dendrimer technology is intended to work as a sponge, soaking up toxic chemicals from groundwater. The initial target is perchlorate, but the technology will be applicable to metals such as lead, silver and zinc, as well as other contaminants such as arsenic and mercury which are found in waters worldwide.

The novel nanoscale dendritic polymer system is being developed to provide a highly attractive and environmentally acceptable alternative to current technologies used by the US DoD. The dendritic structures will have a high functional surface area relative to their volume and will include container properties to encapsulate contaminants.

It is anticipated that this technology will be easily adaptable, cost effective and will be highly sought after worldwide.

Whilst this is a non-core area for Starpharma, water purification addresses an important global issue and is a commercially relevant application of dendrimers which has the potential to yield royalty income in the future.

### About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHY) is a world leader in the development of dendrimer nanotechnology for pharmaceutical, life science and other applications. SPL has two operating companies, Starpharma Pty Ltd in Melbourne, Australia and DNT Inc. in the USA.

Products based on SPL's dendrimer technology are already on the market as diagnostic elements and laboratory reagents through licence arrangements with partners including Siemens and Merck KgA.

The company's lead pharmaceutical product is VivaGel® (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of sexually transmitted infections, including HIV and genital herpes.

### Further information

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Ethical Investor magazine, September 2008

Starpharma was featured in the biotechnology special edition of the *Ethical Investor* magazine in September. Editor, Oliver Wagg commented: "there is a compelling case for investment in companies that will play a part in the global health standards revolution".

Accordingly, CEO, Jackie Fairley was invited to submit an article profiling the work of Starpharma and in particular VivaGel® that highlighted its potential to curb significantly the increasing global prevalence of STIs. The article from *Ethical Investor* is reproduced below.



## A solution for STIs

Starpharma is developing and commercialising a new class of pharmaceuticals called dendrimers; one of the first applications is a microbicide for the prevention of sexually transmitted infections.

By JACKIE FAIRLEY



**Global rates of sexually transmitted infections (STIs) are rising at an alarming pace. At the 17<sup>th</sup> International AIDS Conference in Mexico City last month, more than 22,000 scientists, policymakers and fieldworkers from around the world gathered to lament the lack of progress made by the international community in reversing the HIV epidemic, which nears its 30 year anniversary and shows little sign of slowing.**

A recent UNAIDS report has stated 2.7 million people became newly infected in 2007, and listed Australia with countries such as China, Papua New Guinea and most of Africa as those that were seeing increases in rates of HIV infection. Such epidemic status is not just reserved for HIV however. The prevalence of other STIs, such as genital herpes, is reaching new heights with data showing the two epidemics are closely linked. In Australia one in eight women carry the virus that causes genital herpes and in America one in four women are living with the disease. While there is little doubt that therapies for HIV and herpes have improved, the reality remains that once contracted these infections are for life. The only real hope then lies with prevention.

At Starpharma (ASX: SPL), we are developing and commercialising a new class of pharmaceutical called dendrimers, and one of the first applications is VivaGel, a vaginal microbicide for the prevention of STIs, such as HIV and genital herpes. The gel is intended to be applied to the vagina before intercourse and contains the active ingredient known as SPL7013, which has been shown to prevent viral infection in rigorous pre-clinical studies.

The clinical development of VivaGel for the prevention of infection by the viruses that cause AIDS (HIV) and genital herpes (HSV-2) is well underway, and as a result of new positive data we have now added the human papillomavirus (HPV) to the list of sexually transmitted targets. We have also


added to the development program the first application of VivaGel as a potential treatment for bacterial vaginosis.

We are proud of the early traction VivaGel has gained as the only microbicide in clinical development for genital herpes. It has FDA Fast Track Status and the US National Institute of Health has provided in excess of US\$20 million funding for its ongoing development. In addition, we have also recently signed an exciting partnership with the manufacturers of the world's best selling condom brand, Durex for the commercialisation of VivaGel-coated condoms.

Offering a sense of empowerment lies at the heart of the appeal of microbicides and is the reason why they have been lauded as the 'silver bullet' to slowing the STI epidemic. For women from both developed and developing nations such as Africa and Asia, where HIV is particularly prevalent, such a product will empower them to have greater control over their sexual health and in protecting themselves against contracting STIs.

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VivaGel is advancing rapidly and is Starpharma's highest profile program. Additional applications which are being focused on by the company include the use of dendrimers to deliver existing pharmaceuticals more safely and also a program to allow the restoration of contaminated ground water.

Whilst commercialisation and return on shareholder investment remains a key factor in our decisions and focus, we nevertheless also remain motivated by the need to deliver products that will result in real and visible improvements to people's lives. 

Jackie Fairley BVSc, BSc, MBA is CEO Starpharma Holdings