

## Update Report to Shareholders: September 2006

- > Starpharma Holdings Limited (ASX:SPL, USOTC:SPHRY) today announced its full year financial result for the year ended 30 June 2006.
- > The following shareholder update supports the lodgement of the Company's Appendix 4E for the year ending June 30 2006. The Update provides an overview of the major highlights of the year.

### Significant increase in grant income

Starpharma's revenue from *other income* increased significantly over the period with the company receiving nearly A\$6.5 million. Government grants remain a valuable source of funding for Starpharma as the money is non dilutive to shareholder equity and has no negative impact on the commercial returns that the Company will receive from VivaGel™. Grant income increased by more than A\$5 million for the period, up from A\$1,409,844 to A\$6,422,066.

The two main sources of grant income came from funding provided by the United States Government National Institutes of Health (NIH) and the Australian Government's Pharmaceuticals Partnerships Program (P3).

The NIH has committed in excess of A\$26 million for the development of VivaGel<sup>™</sup> for the prevention of HIV and has also committed an undisclosed sum for the clinical development of VivaGel<sup>™</sup> for Genital Herpes.

Other income during the year included A\$554,003 from the Commonwealth Government's P3 program. P3 is a competitive entry program focused on developing medicines for global markets and encouraging international firms to foster partnerships with local companies.

During the year the company also successfully raised A\$15 million through an institutional placement and Share Purchase Plan, and this is reflected in the cash balance below.

## Microbicides gaining momentum

"If I had a magic bullet to accelerate something it would be a microbicide."

Bill Gates (The Bill & Melinda Gates Foundation) July 2006

Starpharma's lead product VivaGel™ is being developed for the prevention of HIV and Genital Herpes. The company's goal is to show that VivaGel is a safe and effective vaginal microbicide that women could use to protect themselves from these sexually transmitted infections. Much work has already been done: it is known that in test tubes and in animals the gel is highly effective at inactivating these viruses. VivaGel™ has also been tested for safety in animals and in an initial human trial with further human studies underway.

Over the last year, influential figures ranging from Bill Clinton to Bill Gates have fuelled the growing interest in the role of microbicides to prevent the spread of sexually transmitted disease. Between 15% and 20% of sexually active adults in the western world are infected with genital herpes, and it is now one of the most prevalent sexually transmitted infections in the modern world. HIV continues to be a major health burden globally, with more than 40 million people infected with the disease. The United Nations has estimated that as many as 90 million people in Africa alone may be infected with HIV over the next 20 years if the spread cannot be stopped. AIDS is difficult and expensive to treat.

Starpharma has one of the more advanced microbicide products under development globally and was granted Fast Track Status by the FDA in January of this year.

### **Financial Snapshot**

Revenue from other income

↑ Up 350% to A\$6,422,066

Loss from ordinary activities

**▶** Down 3% to (A\$7,522,789)

Cash at hand

↑ Up \$6m to A\$14,283,824



Starpharma is pioneering new and largely unchartered waters in developing VivaGel<sup>™</sup> for the prevention of sexually transmitted infections (STIs), the spread of which is continuing apace. Whilst the outcomes of all such ventures have some degree of uncertainty, Starpharma is leading the world in the development of a genital herpes preventative microbicide.

## Genital Herpes: Affecting up to one in four American women

Approximately 45 million Americans, and on the most recent figures 16% of Australian women, are infected with genital herpes (HSV-2). Genital Herpes is a recurrent, lifelong viral infection. It is very prevalent in developed countries such as the US and Europe and in the US is expected to rise to almost 40% unless effective preventative measures can be introduced.

## Clinical trial update

Starpharma recently announced the commencement of a new clinical trial, a male tolerance study of VivaGel<sup>TM</sup>. The trial is based at the Melbourne Sexual Health Centre and is assessing the safety and pharmacokinetics of VivaGel<sup>TM</sup> in 36 healthy male volunteers when applied topically once a day for seven days.

The results of the trial will benefit both the genital herpes and HIV applications of VivaGel™ and would also apply to a "male protection" application, should Starpharma decide to pursue it. Recruitment has begun with the results expected within 2-3 months of the last volunteer joining the study.

Further clinical trials are in the advanced stages of planning. A new clinical trial of Viva $Gel^{TM}$  in Kisumu, Kenya, and San Francisco, US is scheduled to commence shortly.

"The sites for the proposed trial were deliberately chosen both for their geographic, social and economic diversity and because they represent the various target markets for VivaGel™," said Dr Tom McCarthy, VP of Drug Development at Starpharma.

This trial is funded by the NIH, and is the first such trial specifically intended to support a prevention of genital herpes application for a vaginal microbicide such as  $VivaGel^{TM}$ .

The trial is being conducted under an Investigational New Drug application (IND), which was cleared by the US Food and Drug Administration (FDA) in July 2006, for VivaGel<sup>™</sup> for prevention of genital herpes.

#### VivaGel<sup>™</sup> has strong contraceptive effect in rabbits

In June, Starpharma announced the results of a study showing that SPL7013, the active ingredient in its lead product VivaGel™, exhibited a potent contraceptive effect in a rabbit model.

In the independent study undertaken at Johns Hopkins University (Baltimore, USA) two different formulations containing 3% SPL7013 (the dose level used in VivaGel™) resulted in a 75% and 95% reduction, respectively, in the number of embryos in rabbits compared to an inactive control gel. The extent of these contraceptive effects is comparable to results published for contraceptive products on the market that contain the detergent nonoxynol-9 (N9).

Studies in a number of countries, including the US, show that contraceptive activity is a very highly valued microbicide characteristic amongst women. We anticipate that if this contraceptive activity were confirmed in humans, it would increase the uptake of VivaGel<sup>TM</sup> considerably. In addition, it would allow the development of VivaGel<sup>TM</sup> for the additional claim of contraception.

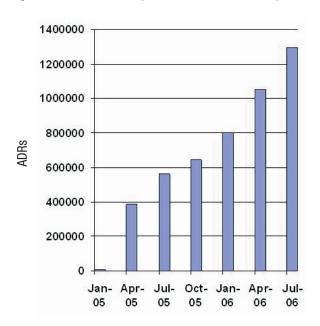
# Growing US investor support: 9.5% of issued capital

Starpharma's American Depository Receipts (ADR) Program has been strongly supported since its inception in January 2005. The number of ADRs outstanding has been growing at an average rate of 9% per month, increasing to more than 15% per month in early 2006 (see Figure 1 at right). Managed by the Bank of New York, today the Starpharma ADR program currently represents 9.5% of the company's issued capital and is traded by major brokers including Merrill Lynch, Credit Lyonnais, Natexis Bleichroeder and Pershing LLC.

The Company believes that three key elements have contributed to the increasing US following and investor interest:

- The NIH awarded Starpharma a contract in October 2005 for US\$20.3m to develop VivaGel™ against HIV,
- the FDA granted Fast Track status to expedite this development and
- there is increased awareness of both nanotechnology and sexually transmitted infections in the US.

Figure 1. Growth of ADRs (each ADR = 10 SPL shares)



## **New CEO appointed**

After 10 years at the helm of Starpharma, and one of the longest "tours of duty" for a serving CEO in biotechnology, Dr John Raff has announced his retirement and the appointment of his successor, Dr Jackie Fairley.

Dr Fairley was appointed COO in July 2005 as part of the company's CEO succession strategy. Since then she has worked with Dr Raff to prepare for the transition and to progress the corporate and clinical programs of Starpharma.

Dr Fairley's experience is particularly strong in pharmaceutical product development and corporate transactions, having worked in the pharmaceutical and biotechnology industries for over 16 years. She has held a variety of international business development and senior management roles with various companies including CSL and Faulding (now Mayne Pharma), and has successfully managed a number of pharma collaborations and developed a strong track record with institutional investors.



## In profile: Dendritic Nanotechnologies, Inc. (DNT)



- SPL has a 33% holding in the private US company DNT
- The DOW Chemical Company holds 30% equity in DNT
- DNT has revenue streams and deals with leading companies including Pfizer Inc;
  Sigma Aldrich; Dade Behring; General Dynamics Corp. and Lumera, and the US Department of Defense

Nanotechnology is the controlled manipulation of atoms into nanoscale structures that can be used in computing, medicine and manufacturing. Dendrimers are nanoscale molecular building blocks with precisely defined properties.

In mid 2002, Starpharma had the foresight to partner with Dr Donald Tomalia, a pioneer and world leader in the field of dendrimer-based nanotechnology, to form Dendritic Nanotechnologies, Inc (DNT).

Today, DNT has ownership of 33 patent families and more than 182 patents that cover a wide range of dendrimer applications including:

- Nanomaterials
- Drug delivery
- Diagnostics
- Gene transfection and gene therapy
- Water soluble materials
- Chemical catalysts
- Optical and electro active applications

Aside from the valuable equity position in DNT, Starpharma has commercialisation rights to DNT's existing and future dendrimer technologies applicable to nanodrugs.

A major coup for DNT was the acquisition in 2005 of the intellectual property of the Dow Chemical Company's dendrimer portfolio. This represents the broadest patent portfolio in the field of dendrimers, and establishes Starpharma and DNT as leading providers of market-validated nanotechnology with near term, tangible applications.

For further information http://www.dnanotech.com.



# Starpharma Holdings Limited Further information

www.starpharma.com

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