

STARPHARMA POOLED DEVELOPMENT LIMITED

DIRECTORS' REPORT

Your directors present their report on the consolidated entity consisting of Starpharma Pooled Development Limited and the entities it controlled at the end of, or during, the half-year ended 31 December 2001.

This interim financial report should be read in conjunction with the annual financial report for the period ended 30 June 2001.

Directors

The following persons were directors of Starpharma Pooled Development Limited ("the Company") during the whole of the half-year and up to the date of this report:

R J D Oliver
P M Colman
R Dobinson
L Gorr
P J Jenkins
J W Raff

Review of Operations

Starpharma's core competency and scientific base is discovery chemistry in the relatively new area of dendrimer nanotechnology. The Starpharma chemists began to focus on dendrimers ten years ago, and since that time there has been a dramatic increase in scientific and commercial interest in the area. The reason for this level of interest is that dendrimers are one of the few structurally defined building blocks for the science of nanotechnology. The application of nanoscale structures has been recognised internationally as a new scientific frontier with the potential to impact the world economy. The USA National Science Foundation has predicted that the market for nanotechnology products and services in the USA alone will reach \$US 1 trillion by 2015.

Starpharma's current position is that it is a world leader in dendrimer research and development for pharmaceutical applications. Starpharma has a series of patents and a dominant intellectual property position in the area of dendrimer pharmaceutical applications.

Starpharma's activities over the last six months have therefore been focused on protecting and enhancing its unique intellectual property position in dendrimer based pharmaceuticals and establishing the development and commercialisation infrastructure to fully capitalise on this opportunity. Starpharma has established key international relationships and an in-house development group which is leading the world in taking the first dendrimer based nanodrug through the US regulatory system for testing in humans.

The Company's investment in Dendritic Nanotechnologies Limited will expand Starpharma's direct areas of interest into non-pharmaceutical biological applications and indirectly into other fields such as photonics and electronics.

The Establishment of Dendritic Nanotechnologies Limited (DNT)

The most significant international relationship developed by the Company has been Starpharma's establishment of DNT as a joint venture company with Dr Donald A Tomalia and his team. Dr Tomalia is the US pioneer of dendrimer technology and he is a leading authority on nanotechnology. DNT is established as an Australian unlisted public company, employing Dr Tomalia's team of dendrimer experts. The laboratories of DNT are located in Michigan, which is the major US centre for chemistry and the head office of The Dow Chemical Company (the largest chemical company in the USA) is located there.

Dr Tomalia is committing the rights to over 30 patent families (covering a broad range of biological applications of dendrimers) to DNT.

DNT will specialise in the synthesis of novel dendrimer structures and the creation of new intellectual property for a range of dendrimer applications. DNT intends to license the technology to other companies for the development of various applications, with Starpharma being responsible for the development and commercialisation of pharmaceutical applications. DNT has early cash generating opportunities via the sale and licensing of unique dendrimer compounds and technology.

Starpharma is the major shareholder in DNT, and details of the investment and funding strategies for expanding DNT's operations are being finalised.

DNT provides Starpharma with a number of opportunities.

- Dr Tomalia's commitment to DNT has increased Starpharma's scientific and commercial profile in the USA.
- Starpharma will have development and commercialisation rights to existing and new intellectual property in DNT for pharmaceuticals and potentially in other specific biological applications. This will significantly broaden Starpharma's commercial involvement in areas such as drug delivery and diagnostics.
- Starpharma will benefit financially from its equity investment in DNT. The joint venture increases the opportunity for US investment (at US based capital values) in both DNT and Starpharma.

Other International Collaborations

The increasing interest world-wide in dendrimers and nanotechnology has resulted in Starpharma continuing to obtain research and funding support from organisations such as the National Institutes of Health (NIH). Starpharma and DNT intend to enter into a number of research and licensing relationships with companies that have development and commercialisation expertise in the various applications of dendrimer based nanotechnology.

Building Starpharma's Research Infrastructure

Starpharma has been growing its research team, whose scientific excellence is progressively being recognised internationally. The relocation of Starpharma to the medical and pharmaceutical environment at the new Baker Institute building in Commercial Road, Prahran, Victoria is part of the Company's strategy to integrate various scientific discovery disciplines with medical applications.

Building Starpharma's Development and Quality Assurance Infrastructure

Starpharma has established a team to manage the development and regulatory process for its lead drug programs. Starpharma has implemented a fully integrated quality assurance program within the Company and extending to its network of collaborators. Starpharma's auditing of international contractors identified some deficiencies in meeting regulatory standards and alternate arrangements have been put in place. These arrangements have resulted in increased efficiencies, reduced costs and increased control over outcomes.

An active quality assurance program is essential for both regulatory development and due diligence in the commercial licensing of technology and is therefore fundamental to the future growth of the Company. Starpharma has fully embraced quality assurance as an integral part of the research development and commercialisation activities of the company.

Lead Project – Sexually Transmitted Disease Prevention

Starpharma's lead drug candidate is a sexually transmitted disease preventative, which women would apply prophylactically. Prevention of sexually transmitted disease is a major unmet medical need, and the market for a product that is effective against a number of pathogens is very large (several billion dollars per annum).

Our lead compound, SPL7013, continues to perform well in testing against a range of sexually transmitted diseases. In ongoing work, the NIH is assessing the ability of SPL7013 to offer protection from HIV infection. Earlier studies showed that SPL7013 was a potent inhibitor of HIV virus attachment to healthy cells but was safe to strains of *Lactobacillus* that make up natural vaginal flora.

More involved assays have recently shown that cells isolated from human blood are protected by SPL7013 against infection by a strain of HIV. Current studies are investigating if SPL7013 protects cells from infection by a panel of HIV strains isolated in the clinic. Good activity against these clinical isolates of HIV will see SPL7013 advance to NIH-supported trials in monkeys.

In the herpes indication, Professor David Bernstein at the Children's Hospital Medical Center, Cincinnati has shown that a gel containing SPL7013 significantly protected guinea pigs from genital herpes infection and disease. These results build on the previously reported positive results in mice. In addition, work is continuing to expand on the encouraging activity of SPL7013 against human papilloma virus and chlamydia and SPL7013 will enter animal testing in the US soon for prevention of gonorrhoeal infection.

The Company, with the help of a team of specialist contractors, is preparing an IND submission to the United States FDA to approve human trials for the dendrimer based vaginal microbicide. It is not possible to be definitive on the IND submission date because the dendrimer is a completely new class of drug and there are no established precedents. The Company's staff are working with US regulatory authorities to establish the parameters and to ensure that all such requirements are met for a mid-year submission. Starpharma has validated the dendrimer drug substance and drug product analytical methods to GLP standards, and all current toxicity and efficacy results are positive for the drug's development.

The Company recently appointed Don Ashbrook of Global PharmAlliance to act as Starpharma's US Authorised Representative for FDA purposes, selected a Phase I clinical trial unit in the US and is finalising the early clinical trial protocols to assess the safety of SPL7013. Discussions have also taken place with the NIH on their involvement in future efficacy based human trials. Starpharma has recently retained Professor Larry Stanberry of the University of Texas Medical School to advise on our development program. Professor Stanberry has previously been associated with Starpharma during his earlier appointment at Children's Hospital Medical Center, Cincinnati.

Additional Development Projects

A number of other projects are in various stages of development:

- Genital Herpes Treatment

A topical treatment for patients previously infected with genital herpes has shown positive results in animal trials. This is an additional application for SPL7013 and development time will be reduced because of previous development of the compound for sexually transmitted disease prevention.

- **Anti-cancer Applications**

Starpharma has synthesised four classes of compounds each of which has shown potential as an angiogenesis inhibitor for anti-cancer applications. Animal studies in this area have produced conflicting results. Preliminary results from a recent animal study with compound SPL2992 have been inconclusive, despite the compound previously showing *in vitro* potential as an angiogenesis inhibitor and demonstrating activity against hepatitis B. However, because of the previous encouraging results, the NIH has offered to continue support for animal studies using the Company's dendrimer based compounds for these important applications.

Starpharma is investigating new anti-cancer opportunities in the area of targeted delivery of existing chemotherapy drugs using dendrimers as the carrier. This opportunity has become available because of the intellectual property available through DNT.

- **Respiratory Virus Treatment and Prevention**

In a collaboration with Dr Bob Sidwell of the University of Utah, Starpharma's compounds have been shown to be highly active against a wide range of respiratory viruses including Influenza, RSV, Adenovirus and a number of exotic viruses. Dr Sidwell is continuing with animal studies supported by the US National Institutes of Health which are targeting both domestic and military applications.

- **Anti-toxin Applications**

Promising results have been obtained against a range of different toxins. Based on both results and market size, Starpharma's focus is on bacterial gut based toxins for diseases such as irritable bowel syndrome and Crohn's disease. Starpharma is also synthesising dendrimers to target toxins relevant to military applications.

Summary

Starpharma has a dominant position in the major new area of dendrimer based nanotechnology. The Company is in the process of growing its research development and commercialisation infrastructure to exploit this opportunity for the benefit of shareholders.

Operating Loss

For the half-year ended 31 December 2001 the consolidated entity incurred an operating loss after income tax of \$4,013,000.

Matters Subsequent to Balance Date

On 1st March 2002 the company released the following announcement to the Australian Stock Exchange Limited:

Market Update: Dendrimer diagnostic collaboration

On September 10 2001 Starpharma announced the signing of a letter of intent with international medical diagnostics company PANBIO Limited (ASX:PBO) under which PANBIO planned to invest \$A1 million over a period of three years in the new Australian company Dendritic Nanotechnologies Limited ("DNT"). DNT was established in August 2001 by Dr Donald A. Tomalia, the pioneer of dendrimer technology, and Starpharma as a new venture to develop products using dendrimer nanotechnology.

A recent DNT strategic planning workshop attended by Starpharma, PANBIO and DNT identified major commercial opportunities for dendrimer based products. PANBIO has decided that their preferred means of accessing dendrimer technology for their diagnostic business would be by a direct collaboration between PANBIO and Starpharma rather than by a direct investment in the broader range of applications offered by DNT.

Starpharma and PANBIO have identified potential areas for collaboration such as the diagnostic application of dendrimers suited for respiratory diseases, mosquito borne diseases such as malaria, and the Herpes family of viruses. Starpharma has an experienced dendrimer research team and expertise in dendrimer based pharmaceutical product development, whilst PANBIO has a proven track record in developing diagnostic tests for a wide range of infectious diseases, many of which fit Starpharma's drug development program.

In addition to Starpharma's equity position in DNT, Starpharma scientists will work closely with Dr Tomalia's group in DNT on the creation of new dendrimer based intellectual property and products.

Starpharma will be making further announcements in relation to DNT as the company completes the establishment phase of this highly significant international venture in dendrimer based nanotechnology.

Significant Changes in The State Of Affairs

In the opinion of the directors there were no significant changes in the state of affairs of the economic entity that occurred during the half-year under review not otherwise disclosed in this report or in the financial statements.

Rounding of amounts to nearest thousand dollars

The Company is of a kind referred to in Class Order 98/0100 issued by the Australian Securities and Investments Commission, relating to the "rounding off" of amounts in the Directors' Report and the financial report. Amounts in the Directors' Report and financial report have been rounded off to the nearest thousand dollars in accordance with that Class Order.

This report is made in accordance with a resolution of the Directors.

John W Raff
Director

13th March 2002
Melbourne

STARPHARMA POOLED DEVELOPMENT LIMITED

DIRECTORS' DECLARATION

The directors declare that the financial statements and notes set out in the attached Appendix 4B (rule 4.13(b)) – Half yearly/preliminary final report:

- (a) comply with Accounting Standards, the Corporations Act 2001 and other mandatory professional reporting requirements, and
- (b) give a true and fair view of the consolidated entity's financial position as at 31 December 2001 and of its performance, as represented by the results of its operations and its cash flows, for the half-year ended on that date.

In the directors' opinion there are reasonable grounds to believe that Starpharma Pooled Development Ltd will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Directors.

John W Raff
Director

13th March 2002
Melbourne