



## Starpharma Positioned for Partnership and Collaboration

Starpharma Pooled Development Limited today announced financial results for the full year ending June 30 2002, with a net operating loss of \$7.959 million and a cash burn rate of \$7.978 million. This compares with an operating loss of \$3.906 million and a cash burn of \$2.636 million for the previous year to June 30 2001. The increased rate of expenditure is in line with previous forecasts and is a result of progression of Starpharma's microbicide program into later phase development for commercialization together with investment activities. The Company's cash reserves of \$17.434 million will provide funding of current activities for at least the next two years.

During the past year Starpharma has funded the establishment of Dendritic Nanotechnologies Ltd (DNT), an Australian company with operations in Michigan, the centre of the chemical industry in the US. Starpharma has also incurred capital cost associated with the fit-out of its new premises, which is a state of the art chemical synthesis facility within the advanced medical research precinct at the Alfred Hospital site in Prahran Victoria.

Starpharma is developing dendrimers as nanodrugs and is adding value before licensing to pharmaceutical industry partners by managing the regulatory development of the products. The Company's business development strategy is to develop some of the product opportunities through to proof of principle in human trials, and to license others at an earlier stage.

Dendrimers are one of the fundamental building blocks of nanotechnology and they continue to attract escalating interest worldwide because of their broad range of identified applications. "Starpharma is the first company to take a dendrimer-based drug through preclinical regulatory development in the U.S.A. The precedent set and the experience gained by Starpharma will significantly increase commercial opportunities for partnerships and licences by demonstrating that dendrimer-based products can be approved under the US regulatory system." said Dr. John Raff, Starpharma CEO. Starpharma's establishment of a company with US operations significantly expands the Company's opportunities to participate in the nanotechnology industry. The US National Science Foundation estimates the nanotechnology market will be worth US\$2 trillion by 2015.

Highlights for Starpharma in the past year include:

- **Establishment of Dendritic Nanotechnologies Limited (DNT)** – An Australian company with U.S. based operations formed with a U.S. pioneer of dendrimer nanotechnology, Dr Donald Tomalia. The completion involved the granting by Dr Tomalia of intellectual property licences to DNT for the rights to 33 patent families involving 182 granted patents worldwide, related to dendrimers and dendritic polymers. Starpharma and DNT will enter commercial and scientific collaborations to develop partnerships to commercialize dendrimer nanotechnologies. This initiative has the potential to expand and strengthen Starpharma's position in dendrimer based pharmaceuticals and will also expose the Company to a diverse range of other dendrimer based product opportunities.
- **Issue of U.S. patent number 6426067** – The granting of this patent titled "Angiogenic Inhibitory Compounds" provides Starpharma with broad patent rights related to

dendrimer-based products that inhibit angiogenesis (blood vessel growth), a key process in cancer tumour growth and spread (metastasis). This patent is exclusively licensed to Starpharma by the Biomolecular Research Institute and complements other patents in the dendrimer pharmaceutical area.

- **Lead product development** – Starpharma is preparing an Investigational New Drug application (IND) for its topical microbicide gel product (SPL7013) for submission to the U.S. Food and Drug Administration (FDA). Allowing of the IND by the FDA will trigger the commencement of the first human clinical trials of a nanoscale dendrimer drug product, which are expected to commence in early 2003. The challenges of pioneering the first dendrimer based product through the US regulatory system and having to create precedents at each step in the process have made the time lines difficult to predict accurately. All test results required for the IND submission have been positive and Starpharma is continuing to interact with the regulatory authorities with the intention of submitting our IND in December 2002. Phase I clinical trials are scheduled to commence in Australia in early 2003.
- **Further U.S. NIH Support for Starpharma's lead product development** – in the form of fully funded trials to assess the topical microbicide gel's ability to prevent HIV/SIV and Chlamydia infection in macaque monkeys. The trials will provide valuable additional information that will assist with the approval and potential external funding of large scale Phase II and III human clinical population trials.
- **Promising research results** – Starpharma continues to demonstrate that dendrimers are highly active compounds in a wide range of disease states. Once we have created the precedent for regulatory approval of dendrimer based drugs Starpharma will seek development partnerships and licence arrangements with pharmaceutical companies over the broad range of diseases where active compounds have been identified.
- **Appointment of new Head Chemist** – Starpharma employed Guy Krippner, an experienced synthetic medicinal chemist to head its drug discovery program. Starpharma's in-house capabilities now span all areas of its business strategy, from drug development to product commercialisation (synthetic medicinal chemistry, analytical, biology, quality assurance, regulatory affairs, and IP and commercialisation management).

In summary, Starpharma has a leading position in the development of dendrimer-based nanodrugs. Starpharma is now positioned to progress partnering and licensing arrangements to incorporate dendrimer technology in new products, and to use dendrimer technology to enhance existing drug opportunities.

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