starpharma

SHAREHOLDER Update

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VivaGel® BV trials on track for completion in 2012

Starpharma is nearing its most significant milestone to date; the completion of two concurrent Phase 3 pivotal trials investigating VivaGel® as a treatment for bacterial vaginosis (BV). The Company recently reported that patient recruitment in these trials was proceeding rapidly, with the first trial already at 100 percent enrolment and the second more than 70 percent enrolled. In addition, recruitment is also complete for the Phase 2 prevention of BV recurrence trial. The Phase 3 treatment trials and the Phase 2 prevention trial are all expected to conclude later this year.

It is a real achievement to enrol such large numbers so quickly (the trials commenced in March 2012), and it's a good indicator for investors that the trial results should be delivered, as planned, prior to the end of 2012. The rapid enrolment also validates the demand for a BV product.

The completion of Phase 3 trials will pave the way for Starpharma to submit a New Drug Application (NDA) for VivaGel® as a treatment for BV (refer to page 2).

"Once we've achieved this milestone we can prepare and submit an NDA to the US Food and Drug Administration (FDA) in parallel with licensing discussions for the product, which will be a very exciting event for the Company," said Dr Jackie Fairley, Starpharma CEO.

The FDA has already provided formal agreement in the form of a Special Protocol Assessment (SPA) declaring that Starpharma's planned Phase 3 trial design, clinical endpoints, and statistical analyses are acceptable for FDA approval once completed.

Shaw Stockbroking Research Analyst Matthijs Smith commented on the promising progression for these Phase 3 studies in a research note in early June 2012:

"Given the data from the Phase 2 trial, which is an identical design to the two current Phase 3 trials, achieved an efficacy and safety read-out that would support an approvable product by the FDA, we believe this trial has a higher than usual likelihood of success."

The global market for topical treatments for BV is estimated at US$300–$350 million. Starpharma is also conducting a Phase 2 trial to assess the ability of VivaGel® to prevent the recurrence of BV; this trial has recently reached its full enrolment of 200 patients and will also conclude in 2012.

Studies show that that as many as 50–60 percent of BV sufferers will have recurring BV episodes. Currently the only approved treatment for these patients is repeated courses of antibiotics, which have a wide profile of side effects. VivaGel® for the prevention of BV would represent a new and greatly needed management tool for this troublesome infection.

"Preventing the recurrence of BV is an important potential application for VivaGel®, as it will meet a clinical need that no other product can currently deliver. This presents a significant commercial opportunity for Starpharma and VivaGel®. If successful, it will be a great Australian innovation that will make a significant difference in the area of women's health."

Starpharma CEO, Dr Jackie Fairley.

ADVANTAGES OF VIVAGEL® FOR BV TREATMENT	
EFFECTIVE AGAINST THE BACTERIA WHICH CAUSE BV	✓
NOT ABSORBED INTO THE BLOOD STREAM	✓
LACKS COMMON ANTIBIOTIC SIDE-EFFECTS	✓
CAN BE USED WITH ALCOHOL	✓
COMPATIBLE WITH CONDOMS	✓
DESIGNED TO HAVE MINIMAL EFFECT ON 'GOOD' BACTERIA	✓
CAN BE USED LONG TERM	✓

NDA ready – activities in place to support the BV approval submission

An NDA submission for VivaGel® for BV treatment is planned following the completion of the Phase 3 trial, and activities to support this submission are already well advanced. To prepare for product launch and marketing volumes, Starpharma has already completed full scale-up of the VivaGel® active ingredient, SPL7013, to the tens of kilograms scale under full good manufacturing practices (cGMP) at an FDA and EU-certified manufacturer that supplies marketed pharmaceutical actives globally.

Scale up of the finished product to the multiple hundreds of kilograms scale has also been achieved, and planning of final process validation, to follow after submission of an NDA, is well advanced. In addition, the nonclinical toxicology program for VivaGel® to support the NDA submission is already complete.

These achievements and activities are all aimed at expediting the approval and launch process to facilitate early market entry for the product.

TECHNOLOGY

Leading the way for Australian innovations

More than 80,000 researchers around the world are working to bring tomorrow's medical solutions to reality; but true innovation is a rarity and more than invention alone. True innovation involves matching an invention with an unmet commercial and end-user need.

This principle is at the heart of Starpharma's approach to commercialisation of its proprietary dendrimer technology.[1] One of Starpharma's approaches is to use its dendrimers to improve the delivery of chemotherapy drug docetaxel. Although docetaxel (TaxoTere®) has demonstrated its effectiveness as a cancer treatment, its commercial formulations have certain toxicities leading to severe side effects in patients. When formulated with Starpharma's dendrimers in preclinical studies, the efficacy and solubility of docetaxel was significantly increased. This is an example of true innovation.

As Starpharma approaches the completion of Phase 3 trials and submission of an NDA for its lead product VivaGel® as a treatment for BV, it will join an elite group of Australian companies that have been able to identify promising invention, and through careful management and hard work, deliver real innovation and realise commercial success.

If successful, Starpharma will join a small group of Australian companies that have developed and commercialised a new chemical entity drug (i.e. a completely new molecule) discovered on Australian shores. Recent successes are fuelling a wave of interest in the Australian life sciences sector, with investment interest coming first to those companies that have clearly marketed their value proposition.

"The next cycle in the biotech industry will deliver very good returns to investors who pick companies that have mitigated risk through partnering or judicious exploitation of platform technologies."

Editor of Bioshares, David Blake.

1 Dendrimers are a type of synthetic nanoscale polymer that is highly regular in size and structure with unique properties that provide advantages in a range of applications.

DRUG DELIVERY

Starpharma's drug delivery program progresses into exciting new areas

Starpharma's drug delivery program is making excellent progress with a clinical trial for its docetaxel-dendrimer formulation expected to commence in 2013.

In parallel, Starpharma is exploring how its technology can be applied to improve the delivery of a number of other major therapeutics, including the areas of antibodies and hormones.

The drug delivery program opens up a wide range of commercially viable opportunities: Starpharma conducted a review of the world's 200 top-selling pharmaceuticals and found that more than 50 percent would be amenable to dendrimer conjugation.

With many leading drugs either off-patent or nearing the end of patent lifetimes, Starpharma's technology provides an avenue for companies to develop new and improved formulations which can be the basis for new patents. This potentially rich source of new products is very attractive to companies seeking to expand and manage the life-cycle of their portfolios. This strategy is also attractive as it carries lower development risk than developing completely new products.

The table featured in this article reviews some of the improvements Starpharma dendrimers can deliver to drugs. Significantly, the first three improvements have already been demonstrated in the docetaxel program. Starpharma also recently demonstrated the ability of dendrimers to conjugate to certain therapeutic antibodies, thus opening up the possibility of entering the very exciting field of antibody–drug conjugates. Antibodies belong to a class of drugs called biologics, which include some of the leading, most targeted and effective drugs on the market today, such as Roche's highly publicised Herceptin® for the treatment of breast cancer. The commercial potential for a technology that enhances antibody activity and functionality is theoretically enormous.

Vice President of Research, Dr David Owen, recently presented an overview of Starpharma's pharmaceutical program at the *9th International Symposium on Polymer Therapeutics* held in Valencia, Spain.

"We are excited by the continued advancement of our dendrimer drug delivery program both with our internal and pharma-partnered molecules. We have shown our technology to be compatible with many important cancer drug types including the important platinum and gemcitabine compounds. We have also been able to conjugate our dendrimers to antibodies thus opening up the possibility of entering the very exciting field of antibody–drug conjugates," said Dr Owen.

FEATURE	POTENTIAL BENEFITS FOR PATIENTS AND/OR MANUFACTURERS
IMPROVED DRUG EFFICACY	MORE EFFECTIVE TREATMENTS OR LOWER DOSES
REDUCED TOXICITY OF ACTIVES	REDUCED SIDE–EFFECTS
IMPROVED DRUG SOLUBILISATION	LESS TOXIC FORMULATIONS (ALLOWING REMOVAL OF TOXIC EXCIPIENTS)
IMPROVED PHARMACOKINETICS	LESS FREQUENT DOSING AND LESS SEVERE SIDE EFFECTS
TARGETED DRUG DELIVERY	MORE EFFECTIVE TREATMENTS WITH REDUCED SIDE EFFECTS

AGROCHEMICALS

›› Crop Protection Agreement Signed with Nufarm

Starpharma and Nufarm have signed an agreement to develop innovative crop protection formulations for Nufarm's product portfolio using Starpharma's Priostar® dendrimer technology. Nufarm is one of the world's leading crop protection companies with Group Sales for FY2011 exceeding $2 billion. Nufarm produces products to help farmers protect their crops against damage caused by weeds, pests and disease.

This agreement marks the latest development in a rapidly advancing agrochemical program.

In addition to Nufarm, this program already has projects in partnership with major, currently undisclosed industry players. The lead candidate in Starpharma's internal agrochemical program is an enhanced reformulation of the best-selling herbicide glyphosate (Roundup®), which has annual sales in excess of US$5 billion. In the same way that docetaxel's off-patent status marks it as a high-value target for improvement, glyphosate is off-patent and represents the $40 billion agrochemical market's largest opportunity for an enhanced formulation. The Company has already reported results of significant enhancement of effect of glyphosate in studies using its proprietary Priostar® technology.

In addition, Starpharma is now applying its dendrimer technology to a number of other off-patent agrochemical agents with the potential for reduction or complete removal of environmentally damaging solvents.

Some agrochemical products contain up to 70% hydrocarbon solvents. Typically growers and regulators prefer formulations without these solvents, which are toxic to handle, highly flammable, expensive to transport and leave a residue when sprayed on crops. A reduction in these solvents would be welcome from social, environmental and economic perspectives, and regulators are increasingly working with agrochemical companies to address these issues.

The potential benefits of dendrimer reformulated agrochemicals include:

- Solubility enhancement for more concentrated formulations, reducing transport costs and solvent residues;
- Improved activity;
- Modification of soil penetration properties; and
- Increased adhesion reducing losses due to rain run-off and the need for multiple applications.

To further facilitate its expanded agrochemical program, Starpharma has recently appointed an additional commercial executive – Scott Carpenter – as Director of Business Development, to further drive the commercialisation of Starpharma's technology in the agrochemical sector. Scott has extensive international experience working in product development and commercialisation within the agrochemicals sector and has worked at Bayer and Department of Primary Industries Victoria.

Starpharma's agrochemical program has the potential to add further value to the agrochemical industry's largest products making this an exciting area with commercial priority within Starpharma's core development programs.

INVESTMENT NEWS

›› Market recognition of Starpharma

Starpharma is increasingly recognised for its strong market performance, despite recent general market weakness.

Most recently Starpharma was named as the "Top Tech Stock" in BRW magazine by respected markets commentator Tony Featherstone which featured on the front page of BRW on 28 June.

The Company's market capitalisation hit $500 million in April 2012, and compound annual returns for the past five years are in excess of 30 percent.

Starpharma's ability to deliver value to shareholders has been the result of a deliberate strategy to commercially exploit a variety of applications of its technology and in doing so, to create

value along the many steps of product development.

"One of the challenges for innovation developers is giving investors a metric for assessing value. Although there are many factors that impact on Starpharma's capital growth, our strategy of leveraging our platform technology to develop a portfolio of applications partnered with top-tier companies has allowed us to deliver meaningful inflection points and to provide much greater optionality. With new major value inflection points now on the horizon – such as the completion of Phase 3 trials – we hope to see our investors continue to share in Starpharma's capital growth," said Dr Fairley.

Starpharma in the media

Starpharma continues to capture the attention of respected journalists providing endorsement of Starpharma's status as a leading biotechnology company. In addition to BRW (above) recent coverage highlights include:

- Dr Jackie Fairley's interview with Ticky Fullerton on ABC TV's "The Business" (May 30) http://www.abc.net.au/news/2012-05-30/starpharma-rides-innovation-to-success/4040848
- Live interview on Sky News, with Dr Jackie Fairley, during the Bell Potter Life Sciences conference (May 23).

Investors are encouraged to take a look at the 'News' and 'In the Media' tabs on the Starpharma website (http://www.starpharma.com/news-room) to keep up to date with the latest media coverage.

›› Starpharma people

With the issue of diversity gaining increasing attention in corporate Australia, it is interesting to focus on the team responsible for the successes of Starpharma so far– the employees, management team and board.

There are many ways to consider the differences within groups of people – the obvious ones being gender, national origin, culture, language, and age. Starpharma has an interesting mix of people, with 50 percent of staff born outside of Australia, representing 13 countries ranging from El Salvador to Eritrea, Switzerland to Sudan, and China to Romania. More than half (58 percent) of employees are female, and 64 percent hold a PhD or equivalent qualification. More than 10 percent of its 36 employees also hold MBAs.

At the board level Starpharma has two female directors, which translates to 28 percent female representation at Board level, placing Starpharma ahead of most ASX200 companies (only five ASX200 companies pass the 25 percent mark).

Quarterly cash flow to 30 June 2012

$42.9m cash at hand
$9.9m cash burn

The full 4C quarterly cash flow report is available on the news tab at http://www.starpharma.com/news-room

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