



Biotech Daily

Marc Sinatra's Bioguide

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STARPHARMA: MUCH MORE THAN VIVAGEL

Overview: Dr Jackie Fairley is a very talented person, as David Langsam's May 7, 2008 interview with the Starpharma CEO made clear. In the last year, under her leadership, Starpharma has inked deals with the US Department of Defense, Unilever, two condom companies (including the makers of Durex) and dermatological pharmaceutical company Stiefel Laboratories.

These and other deals have transformed Starpharma from a one trick pony with their vaginal microbicide, Vivagel, to a true, revenue-generating, platform technology company with a very strong intellectual property portfolio in the area of dendrimers.

With so much going on at Starpharma, what will drive their share price?

Financials: Market cap: \$58 million; cash: \$8.9 million; last quarter cash burn: \$1.2 million.

Directors: Non-executive chairman, Peter Bartels; non-executive deputy chairman, Dr John Raff; CEO, Dr Jackie Fairley; non-executive directors, Ross Dobinson, Richard Hazleton and Dr Peter Jenkins.

Starpharma's board could be improved by the inclusion of senior people with skills in finance, marketing and regulation especially one with international device and pharmaceutical development experience.

Marketed Products: Starpharma's subsidiary company Dendritic Nanotechnologies provides IP or dendrimers for the following products:

- 1) Stratus CS: Dade Behring's cardiac analyser uses Starpharma dendrimers to anchor antibodies in the correct orientation;
- 2) Superfect: Transfection kit sold by Qiagen that uses Starpharma dendrimers to carry nucleic acids into cells;
- 3) Priostar: New lower cost generation of dendrimer building blocks reputed to have improved thermal and hydrolytic properties;
- 4) Priofect: EMD Biosciences-Merck KGaA's Nanojuice transfection kit uses Priostar dendrimers as per Superfect; and
- 5) Starburst: Older style polyamidoamine based dendrimers.

Products in Development:

- 1) Vivagel vaginal microbicide: product for the prevention of sexually transmitted infections, including HIV, herpes (HSV-2) and human papillomavirus (HPV). It prevents viruses entering cells by binding to them. Vivagel has FDA fast track status for HIV. Data indicates Vivagel may also be spermicidal. Animal studies support efficacy for HIV and HSV-2. Three phase I trials (two in women, one in men) have shown Vivagel to be safe. A further phase I study in sexually active women is ongoing and a phase III study has been designed. Starpharma expects to launch Vivagel in 2010.
- 2) Vivagel condom coating: added protection product being developed with two condom manufacturers and expected to take the easier FDA 510(k) device route to market.
- 3) Drug delivery: Starpharma has several early stage projects aimed at improving drug delivery through improved pharmacokinetics, solubilization, targeting and drug loading.
- 4) Magnetic resonance imaging: projects involve concentrating imaging agents on dendrimers with or without a targeting agent to improve diagnosis of pathology.
- 5) Food imaging: co-development project with Unilever to develop a research tool to analyze the microscopic structure of foods.

Significant Product Markets: According UNAIDS, there were 33.2 million people in the world with HIV in 2007, with 1.3 million sufferers in the US. HSV-2 affects 40-60 million Americans and is a major contributing factor to HIV infection. Other microbicides are in late stage development, but none are being developed for such broad applications as Vivagel.

The most independent estimate of the market size for a vaginal microbicide is \$US900 million by 2011 from the Rockefeller Foundation, although the broad applicability of Vivagel may substantially increase this market.

Vivagel has clear advantages over nonoxynol-9 as a condom coating. Worldwide and US condom sales in 2005 were \$US3.2 billion and \$US398 million, respectively. It is unclear what percentage of sales were for nonoxynol-9 coated condoms.

Although Starpharma is in the early stages of its drug delivery program, it is worth noting that in 2007, consulting firm Cientifica believes that nanotechnology-based drug delivery will rise to \$US26 billion by 2012 from its current \$US3.4 billion.

Opinion: The evolution of Starpharma over the last few years has been impressive and it looks like a much more robust company now. The main danger it faces is that, with so many projects, it could lose focus and end up doing none of them well. With the current management team in place, however, I think this is highly unlikely.

Starpharma's share price will be driven primarily by Vivagel in the nearer term, with three risk factors that investors need to consider.

The first is that we don't have feedback regarding the acceptability of Vivagel during actual sexual encounters.

The second is that participants in its phase III trial will be advised to use condoms as well, making it more difficult to demonstrate any protective effect of Vivagel.

Finally, getting Vivagel registered in a significant market by the end of 2010 will require Starpharma's best efforts since similar phase III trials have taken three years. Unexpected changes in these areas will impact significantly on Starpharma's share price

Due to their diversified lower risk, Starpharma's other projects will reduce volatility and set a share price floor as they progress. Two projects stand out. The Vivagel condom coating projects are absolute no brainers. The Stiefel Laboratories drug delivery project is important because it is the first significant drug delivery deal for Starpharma's dendrimers and it starts to validate the theoretical advantages of dendrimers for drug delivery.

Given the complex nature of Starpharma's projects, I have valued it by comparing it to 12 other similar (at least, in part) ASX-listed life science companies and then adjusting for current market sentiment.

In doing so, I arrived at a value of 54 cents a share.

Starpharma fell 2.5 cents or 7.14 percent to 32.5 cents.

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