



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Starpharma

By TIM BOREHAM

ASX code: SPL

Share price: \$1.06

Shares on issue: 371,694,347

Market cap: \$394.0 million

Chief executive officer: Dr Jacinth (Jackie) Fairley

Board: Rob Thomas (chairman), Dr Fairley, Richard Hazleton, Peter Turvey, Zita Peach

Financials (December half): revenue \$649,000 (down 46%), loss of \$7.3 million (previously \$6.2 million loss), cash \$44.4 million

Major shareholders: Allan Gray 13.3%, M+G Investment Funds 13.1%, FIL Ltd 5.04%.

Starpharma's Abbotsford HQ in inner Melbourne used to serve as the labs and tasting rooms for Carlton and United Breweries. But these days the talk is more about eradicating BV (bacterial vaginosis) than improving the taste of VB (Victoria Bitter).

Having graced the ASX board for more than two decades, Starpharma has demonstrated both the euphoric highs and depressing lows of drug development, often in quick succession. But now the company looks to be on the cusp of commercialization of its drug platform, based on its core dendrimer technology.

Within weeks, Starpharma and its marketing partner Aspen Australia will launch Vivagel in Australia, a novel treatment for the common odiferous ailment BV.

To be sold under the brand name Fleurstat, the over-the-counter gel is an alternative to prescribed antibiotic, the current standard of care. The product both treats and prevents BV, which affects up to 30 percent of women.

“It’s an Australian discovered product developed by an Australian company and launched for the first time in Australia,” says Starpharma CEO Jackie Fairley.

Globally, Starpharma assesses the market size for treatment at \$US750 million, with prevention accounting for another \$US1 billion.

“There are currently no approved products in the US for prevention of recurrent BV, and feedback from clinicians and patients indicate a strong interest in new BV therapies,” Dr Fairley says. “These patients will finally have an effective, non-antibiotic BV treatment and an approved product for recurrent BV.”

Vivagel is approved in Europe, where it is expected to be rolled out in the current quarter, in partnership with distributor Mundipharma. Given the US accounts for about half of the paying market, investors are eagerly awaiting further news from the US Food and Drug Administration, which in late December demanded more confirmatory data (see below).

A quick recap

Having sent its animal health division off to the farm in 2016, Starpharma now revolves around the use of its dendrimer technology to tackle bacterial vaginosis, “the most common vaginal infection in the world and twice as common as thrush”.

Detected by a simple ‘whiff test’, the disorder may afflict about 46 million women in the US alone - or one in every three. Dr Fairley says that for genetic reasons, it’s more prevalent in African-Americans and Hispanics.

The original SPL-7013 dendrimer nanotechnology gel was developed for HIV and herpes simplex virus 2 (HSV-2) with attempts to have the World Health Organisation distribute it in Africa and to prevent sexually-transmitted infections in Papua New Guinea.

It was then developed as a coating for condoms. Starpharma is in bed (so to speak) with dinger maker Ansell and Japan’s Okamoto. Two years ago, Ansell (a listed ASX company) sold its condom arm to China’s Humanwell Healthcare and venture capital fund Citic for \$US600 million. To date, the enhanced prophylactics have been sold in Australia and Canada.

Dendrimers, by the way, are nanoscale polymers that have wide uses in the pharmaceutical sector.

Banishing the antibiotics

Dr Fairley says Vivagel presents several advantages to patients, including resolution of bacterial vaginosis within a day, rather than typically three days for antibiotics.

As well as posing tolerance issues, the antibiotics are quite toxic and can cause tummy upsets and secondary thrush. And - horror of horrors - patients cannot drink alcohol.

Having been diagnosed by a GP for bacterial vaginosis on the initial occurrence, patients can usually go straight to the chemists next time around for the Vivagel.

Bacterial vaginosis is a highly recurring condition and is possibly sexually transmitted, although no-one sure. It's also been linked to changes in acid-alkaline balances linked to menstrual cycles.

Like a thirst for VB, you can get it any old how ...

Dr Fairley describes treatment and prevention as two "distinct market opportunities". Expected to sell for \$35 to \$40 a pack, Fleurstat is a seven-day daily course to treat acute bacterial vaginosis. But patients can also go on a "maintenance therapy" that involves in applying the treatment every second day.

Will Vivagel pass the FDA whiff test?

With investors focused on festive matters, on December 20 last year Starpharma announced a licencing tie-up with US women's health specialist ITF Pharma to market Vivagel in the US. ITF Pharma is a subsidiary of Spain's Milan-based Italfarmaco SpA.

The deal includes \$US101 million (\$142 million) in milestones and escalating, double digit royalties. Of the milestones, \$US20 million is payable on US regulatory approval.

The joy was short lived: on December 27 the company revealed the FDA had asked for "confirmatory clinical data" prior to approval, which was expected to be a dead cert.

Company reps next week will be winging their way to the FDA's Maryland HQ to glean what exactly the agency wants. It's hoped that re-analyzed existing data is on the agency's wish list, rather than a fresh clinical trial.

A "surprised and disappointed" Dr Fairley says she can't add much insight ahead of the FDA meeting. "The FDA does not engage in routine dialogue. It's a very structured process."

ITF is responsible for all commercial aspects, with the deal lasting for the longer of 10 years or patent expiry in 2030. But Starpharma remains responsible for securing regulatory approval.

With a planned sales force of 60 reps, ITF was to have been selling by mid-2019 but now the US launch looks like being next year.

Don't forget oncology

Starpharma also has an early to mid-stage oncology program, both off its own bat and in alliance with Astrazeneca.

The company has three dendrimer enhanced products (DEPs) in development to treat solid tumors in combination with three existing drugs. These are docetaxel (breast, head and gastric cancers), cabazitaxel (prostate cancer) and irinotecan (colorectal cancer).

DEP delivery is touted to result in better drug targeting and pharmaco-kinetics and reduced side effects (such as bone marrow toxicity and hair loss).

DEP docetaxel is in phase II trials after “excellent” initial results, with recruitment at four UK clinical sites underway.

Cabazitaxel is in phase I/II trials, while irinotecan is due to enter the clinic by July this year.

The tie-up with AstraZenca involves the drug giant funding three external DEP programs. Starpharma is eligible to receive development, launch and sales milestones of \$US124 million for the first AstraZeneca DEP product and \$US93.3 million for each subsequent qualifying product.

Starpharma is also eligible for tiered royalties on net sales.

Should any of the programs mature, Starpharma will seek partnering deals for any phase III efforts.

Financials and performance

In the December (first) half, Starpharma lost \$7.3 million on revenue (mainly interest) of \$649,000.

Starpharma reported revenue of \$4.95 million in the 2017-'18 year, up 38 percent. This included \$1.072 million of interest income and \$3.8 million of “royalty, customer and licence revenue”.

The company also lost \$7.3 million.

Bolstered by the proceeds of the animal health deal, Starpharma held cash of \$44.4 million at the end of December and post-balance date received a \$4 million Federal R&D Tax Incentive.

Share price-wise, Starpharma had a roller-coaster ride in late December and early January after the announcements pertaining to the ITF deal and then the FDA concerns. The latter saw the shares dumped from \$1.44 to 99 cents (31 percent).

The share movements were also complicated by a December 28 release showing Dr Fairley and fellow directors Rob Thomas and Peter Turvey bought a collective \$105,000 of shares at 96 cents each, prompting a ‘please explain’ from the ASX on January 3.

The ASX queried the timing of the US news, as well as a subsequent January 2 announcement that the Japanese regulator had approved the use of Vivagel condoms. The bourse also politely inquired as to whether the share trades conformed to the company’s securities trading policy.

In response, Starpharma said the board was unaware of the Japanese news, which was delivered to the company at 4.12pm on December 28. Because the missive was in Japanese, the company did not know of its significance until January 1, after it was deciphered (presumably not by using Google Translate).

The company said the announcement wasn't especially material because the \$US500 million a year Japanese condom market is one of the world's biggest, but declining.

Earlier, though, the company lauded the "significant value of the Japanese condom market and our partner's leading market position".

Starpharma shares peaked at \$1.80 in May 2012, with a 12-month high of \$1.62 attained on November 6 last year.

Over the last five years the shares have returned 17 percent.

Dr Boreham's diagnosis:

Starpharma's share performance has followed the typical trend of ascribing more value to a licencing deal before, rather than after, the fact.

Dr Fairley says while the shares didn't react to the ITF deal, she had great feedback from institutional investors: "When you look at comparable deals, I think that was a pretty good deal."

Some Starpharma watchers also note the Vivagel non-US sales channels are over the counter rather than the higher-margin prescription market.

In a 40-page report in January, Macquarie Equities valued Starpharma at \$2 a share, including \$1.13 per share for Vivagel and 85 cents a share for oncology. The valuation assumes the US product won't be launched until late in 2021-'22.

While the cancer drugs remain a longer-term prospect, 2019 could be the year the company puts the star into Starpharma - at least on the Vivagel side.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His practical knowledge of VB far exceeds that of BV.