



# Biotech Daily

Friday March 20, 2020

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market closed up 0.7 percent on Friday March 20, 2020, with the ASX200 up 33.7 points to 4,816.6 points. Twenty-six of the Biotech Daily Top 40 stocks were up, 12 fell, one traded unchanged and one was untraded. All three Big Caps fell.

Optiscan was the best on a 'corporate update' including increased revenue, up 1.1 cents or 73.3 percent to 2.6 cents, with 1.5 million shares traded. Alterity climbed 41.7 percent; Opthea rose 23.2 percent; Pro Medicus was up 16.0 percent; Amplia, Avita, Impedimed and LBT improved more than 11 percent; Orthocell and Osprey were up more than eight percent; Dimerix rose 7.4 percent; Paradigm was up 6.9 percent; Actinogen, Antisense, and Imugene were up 5.88 percent; Kazia, Oncosil, Prescient and Resonance were up four percent or more; Mesoblast and Polynovo were up more than three percent; Clinuvel, Cynata, Starpharma and Volpara rose two percent or more; with Telix up 1.2 percent.

Resmed led the falls, down \$2.58 or 10.4 percent to \$22.24 with 3.8 million shares traded. Cyclopharm lost 8.1 percent; Uscom fell 7.1 percent; Cochlear, Ellex and Universal Biosensors were down more than six percent; CSL fell 4.6 percent; Nanosonics and Pharmaxis were down more than three percent; Compumedics and Proteomics shed more than two percent; Immutep, Medical Developments and Next Science were down more than one percent; with Genetic Signatures down 0.45 percent.

## [DR BOREHAM'S CRUCIBLE: STARPHARMA](#)

**By TIM BOREHAM**

**ASX code:** SPL

**Share price:** 78 cents; **Market cap:** \$290.5 million; **Shares on issue:** 372,542,288

**Chief executive officer:** Dr Jacinth (Jackie) Fairley

**Board:** Rob Thomas (chairman), Dr Fairley, Richard Hazleton (retiring at this year's AGM), Peter Turvey, Zita Peach, David McIntyre

**Financials (December half 2019):** revenue \$5.7 million, loss \$5.9 million, net cash burn \$5.4 million, cash balance \$35.9 million.

**Major shareholders:** Allan Gray 14.4%, M+G Investment Funds 12.15%, UIL (Utilico Emerging Markets) 5.1%

As the drug developer would attest, a flurry of productive activity often results in sadly scant rewards.

Starpharma's latest quarterly statement lists a dozen achievements for the period, including recruitment and progression of its cancer trials and further launches of its core Vivagel product for bacterial vaginosis (BV).

Then there's the pending launch in Europe of its Vivagel-coated condom as a barrier to HIV, herpes and human papillomavirus. They're to be sold as Absolute DUAL PROTECTION – to be sure, to be sure (and then put it in capitals to be sure, again).

In April 2019, Starpharma and its marketing partner Aspen Australia launched Vivagel here and in New Zealand, sold under the fragrant name of Fleurstat.

Launches in Europe and Britain quickly ensued; and now the product is approved and licensed in 160 countries.

"It's an Australian discovered product developed by an Australian company and launched for the first time in Australia," Starpharma CEO Jackie Fairley said at the time.

But it's early days, with December quarter receipts coming in at a modest \$936,000. This revenue reflects both initial Australian and Europe sales of Vivagel and the launch of the Vivagel franger in Japan.

### **Viva Vivagel**

Vivagel is an alternative to the out-of-favor, prescription-only antibiotics (not to mention a plethora of unproven potions from douches to fragrances) commonly used to treat the odiferous bacterial condition. The company says Vivagel both treats and prevents BV.

“The product is over-the-counter, although it may not be in a small number of countries including the US,” Dr Fairley says.

Last June, Vivagel was launched in Europe, where it is distributed by Mundipharma under the (somewhat antiseptic) moniker Betadine BV.

In the UK the gel is sold under the Betafem brand. The product was launched there last November, also in league with Mundipharma. Further launches are planned in central and Eastern Europe “in coming months”.

In August last year, Starpharma won approval in its first Asian country, the name of which was not disclosed for competitive reasons.

“There's a tension between our disclosure obligations and our desire to keep the market updated but we have to respect the commercial dynamics for our partners,” Dr Fairley says.

Given the company expects this consent to trigger further regulatory approvals in the region, who said the Domino Theory was bunk?

Asia is a key target market, given there are 1.5 billion women in the region. But the US accounts for half of the current BV market, with 125 million women - or one in three - afflicted.

## **A quick recap**

Starpharma listed in September 2000 as a Keating-era pooled development fund (it later shed this structure). Formerly a practicing vet, Dr Fairley assumed the Starpharma top job in July 2006, having been chief operating officer for a year. Previously she held senior roles at CSL and Faulding (now Mayne Pharma).

Starpharma sold its agricultural chemical division to Canadian agri-giant Agrium for \$35 million 2017, in favor of focusing on the dendrimer platform. In hindsight, the timing was exquisite because Starpharma's technology related to an improved version of glyphosate - a herbicide now mired in controversy.

On the condom side, Starpharma used to sell to the ASX-listed Ansell, before Ansell sold its 'sexual health' arm to Chinese interests in 2016. But Starpharma still has the market covered with Japan's Okamoto Industries.

Starpharma's HQ, by the way is in inner Melbourne Abbotsford, with its digs overlooking Carlton and United Breweries. At knock off time workers can be seen scampering to their cars with a slab of free VB, but hopefully not BV.

## **Banishing the antibiotics**

Detected by a self-explanatory whiff test, BV is a common bacterial condition. It's the world's most common vaginal condition and twice as common as thrush.

The company claims that Vivagel resolves BV within a day, rather than typically three days for antibiotics. Antibiotics can also cause tummy upsets and other issues.

Having been diagnosed by a doctor for BV on the initial occurrence, patients can usually go straight to the chemist next time around and leave the harried medicos alone.

Fleurstat was expected to sell for \$35 to \$40 a pack - enough for a seven-day course - and sure enough Chemist Warehouse is now selling it for \$38.99 a pack.

No reports of hoarding just yet.

## **Vivagel and the US**

In the US, Starpharma is in bed with women's health specialist ITF Pharma, a subsidiary of the Milan-based Italfarmaco SpA.

Struck in December 2018, the deal includes \$US101 million (\$A176.3 million) in milestones and escalating, double digit royalties. Of the milestones, \$US20 million is payable on US Food and Drug Administration approval.

The only trouble is days after the deal was struck, the FDA refused approval, demanding "confirmatory clinical data". Starpharma thought it might be able to get away with re-analyzing existing clinical data, but the fuddy-duddies from Maryland held firm.

Starpharma says it's pursuing a dual strategy of preparing for a possible BV trial, but also seeking a formal review of some of the FDA's initial conclusions.

"There's nothing to report beyond that. It's an ongoing process," Dr Fairley says. "We have a dual strategy of preparing for a possible clinical trial and an administrative review."

The trial size is likely to be "several hundred" patients.

## **Drug giant says yep to DEP**

Starpharma's sprawling oncology program revolves around its dendrimer enhanced product (DEP) platform. Dendrimers are nanoscale polymers that have wide uses in the pharmaceutical sector.

Dendrimer enhanced product (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).

The company is pursuing clinical work off its own bat and also in cahoots with Astrazeneca, which involves the drug giant funding two (and possibly more) programs.

First off the rank is AZD-0466, a reformulation of a "best in class" Astrazeneca candidate for solid and blood cancers. The molecule, AZD4320 targets the Bcl2 and Bcl/xL inhibitor (proteins that regulate cell death).

The trial is across four to five US sites, with the drug giant having dosed its first patient in December, triggering a \$US3 million payment to Starpharma.

Meanwhile, Starpharma is pursuing its own DEP programs that combine the dendrimer with three existing drugs: docetaxel (breast, head and gastric cancers), cabazitaxel (prostate cancer and others) and irinotecan (colorectal cancer).

The most advanced program, DEP-docetaxel enhances Sanofi-Aventis's Taxotere and patients are being recruited into the phase II docetaxel trial, which targets non-small cell lung cancer and prostate cancer, in particular.

The cabazitaxel program adds the DEP magic to Jevtana, another Sanofi-Aventis drug. Having passed the basic safety hurdles, the drug candidate is entering a phase I/II study targeting prostate, ovarian and pancreatic cancer, as well as cholangio-carcinoma (bile duct cancer).

"Our derivative version is a monoclonal monotherapy. We see some interesting efficacy with not only prostate cancer - which it is approved for - but other tumor types," Dr Fairley says.

The irinotecan program tricks up Pfizer's branded drug Camptosar. Carried out at three sites in the UK, a current phase I/II trial is in dose escalation phase. The company also claims to have delivered "excellent" phase I results with new pancreatic cancer candidate DEP-gemcitabine. Patient recruitment is underway.

## **Financials and performance**

In the year to June 30 2019, Starpharma recorded revenue of \$2.7 million, down 44.6 percent and a loss of \$14.25 million. The revenue fall is partly explained because in the previous year the company pocketed milestones of \$2.9 million pertaining to Vivagel activity in Europe, Asia, South America, the Middle East and Africa.

December quarter "receipts" of \$936,000 compared with \$1.13 million through the door in the September quarter. The company also received a \$4.9 million research and development incentive refund received in December 2019.

Starpharma is well cashed up, with \$35.8 million in the bank (thanks to the agrichemical deal). The \$US3 million Astrazeneca milestone (for AZD0466) was banked post balance date.

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.

"There will be a number of other potential revenue sources," Dr Fairley says.

Starpharma shares over the last 12 months have wavered between \$1.39 in late June and 80 cents as of March 19.

The FDA hiccup in December 2019 saw the shares dumped from \$1.44 to 99 cents (31 percent) in one day. Over 10 years they have varied between 18 cents (March 2009) and \$1.80 (May 2012).

### **In case you were wondering ...**

Yes, Starpharma's active ingredient is a potent antiviral agent and the company plays in the anti-infectives sector.

But the company won't pretend to be tackling the coronavirus menace. "It's not an area we've looked at," Dr Fairley says.

Dr Fairley recalls doing roadshows in Asia when severe acute respiratory syndrome (SARS) was around "and everyone was telling me the sky was going to fall in".

SARS kind of fizzled out. Covid-19, sadly, is showing no such signs of capitulation. "The epidemiology of these things is very hard to predict," Dr Fairley says.

### **Dr Boreham's diagnosis:**

Dr Fairley estimates the size of the BV treatment market at \$US750 million (\$1,309.5 million) a year, while prevention is worth at least as much again. The benefit of the latter is the patients have to keep using the product once every two days until the affliction goes away.

"It's fair to say it's still in its early stage and there will be lumpy growth," Dr Fairley says. "[The payments] entail not just royalties but supply components and it's hard to predict the timing of the orders."

Starpharma shares peaked at \$1.80 in May 2012, which goes to show that the speculative ride is more fun than the drudging reality of fronting regulators and corralling distributors.

Starpharma's \$285 million market cap is still nothing to sneeze at, but we need a little more to rocket the stock to billion-dollar territory. Three brokers cover the stock, Bell Potter, Macquarie and CLSA. Pre Covid-19, the former two valued the stock at \$2 and CLSA guessed at \$1.60 a share.

US approval for Vivagel could provide such ignition, but more likely the fire will come from any lucrative oncology partnering deal.

Of course, in the current climate any positive news from a speculative play is likely to be ignored unless "Covid cure" is in the headlines.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. At his next social function - post isolation of course - he hopes to be offered a Corona or VB, not Coronavirus or BV.***

### IMMUTEP

Immutep says China partner EOC Pharma has completed patient recruitment of a 12-patient, single-centre, open label, phase I study of IMP321 for metastatic breast cancer. Immutep said the last patient was enrolled and safely dosed at the Fudan University Shanghai Cancer Centre in February 2020.

The company said EOC would evaluate 6mg and 30mg doses of IMP321 in combination with chemotherapy agent paclitaxel over six months on metastatic breast cancer patients to determine safety, tolerability, efficacy and dosage for a potential phase II study.

Immutep said interim safety data from the fixed dose-escalation study showed no serious adverse events and no dose limiting toxicity events were reported.

The company said it expected to report data during 2020 and to complete the study by December 31, 2020.

Immutep fell half a cent or 1.7 percent to 28.5 cents.

### REGENEUS

Regeneus says it has received JPY100,000,000 (\$A1,556,100) milestone payment from Tokyo's Kyocera Corp for rights to Progenza for knee osteoarthritis.

Earlier this month, Regeneus said Kyocera would pay the non-refundable JPY100,000,000 upfront for exclusive negotiation rights to Progenza in Japan and a further JPY100,000,000 following completion of due diligence, expected within 45 days of receiving documentation and refundable if due diligence was not met (BD: Mar 2, 2020).

Today, the company said Kyocera had begun due diligence for Progenza, which had progressed positively, and Kyocera would have until August 2020 for exclusive rights to negotiate for a commercial licence of Progenza in Japan.

Regeneus was up 1.4 cents or 27.45 percent to 6.5 cents.

### RESONANCE HEALTH

Resonance says it has raised \$2,750,000 through a "controlled placement facility" and would issue 12,640,000 shares to Acuity Capital at 21.8 cents a share.

Resonance said the facility was "one of a suite of tools available to the company to raise funds ... [and] provided a flexible and efficient capital management option.

The company said the 21.8 cents issue price was a 63.3 percent premium to the 15-day volume weighted average price to March 18, 2020.

Resonance was up half a cent or 4.8 percent to 11 cents.

### IMPEDIMED

Impedimed says it has expanded its partnership with the Dallas, Texas-based Baylor Scott & White Institute for Rehabilitation from five to 25 Sozo digital health units.

Impedimed said its Sozo device measured, monitored and managed fluid status and tissue composition using bioimpedance spectroscopy.

The company said the digital health platform would be used to implement the Institute's lymphoedema prevention program for cancer patients, using the 'test, trigger, treat' protocol for early detection and intervention of cancer-related lymphoedema.

Impedimed was up half a cent or 11.6 percent to 4.8 cents with 4.2 million shares traded.

## POLYNOVO

Vanguard Group says it has become a substantial shareholder in Polynovo with 33,228,603 shares or 5.026 percent of the company.

The Valley Forge, Pennsylvania-based Vanguard said that it bought and sold shares between November 18, 2019 and March 17, 2020, with a single largest purchase of 475,307 shares on November 26, 2019 for \$884,071 or \$1.86 a share.

Polynovo was up 5.5 cents or 3.7 percent to \$1.54 with 7.7 million shares traded.

## RHINOMED

Rhinomed chairman Ron Dewhurst says his company Kroy Wen Pty Ltd has become a substantial shareholder in Rhinomed with 8,700,000 shares or 5.14 percent.

Mr Dewhurst said that between March 16 and 18, 2020 Kroy Wen bought 500,000 shares for 10 cents a share.

Mr Dewhurst and Kroy Wen (New York, reversed) was previously a substantial shareholder in Rhinomed but was diluted in last year's \$6 million placement at 22 cents a share (BD: Sep 23, Oct 2, 2019).

Rhinomed was untraded at nine cents.

## CELLMID

Cellmid has requested a trading halt "pending the outcome of ongoing negotiations in relation to a potential material contract".

Trading will resume on March 24, 2020 or on an earlier announcement.

Cellmid last traded at 9.9 cents.

## NEUREN PHARMACEUTICALS

Neuren has requested a trading halt "regarding ongoing clinical trials following the issue of [US Food and Drug Administration] guidance on the conduct of clinical trials of medical products during the Covid-19 pandemic".

Trading will resume on March 24, 2020 or on an earlier announcement.

Neuren last traded at \$1.11.

## RHINOMED

Rhinomed says that chief financial officer Sean Slattery will replace company secretary Phillip Hains, effective from today.

Rhinomed said Mr Slattery was appointed chief financial officer in 2018 had more than 20 years' experience as a director, company secretary and chief executive officer in private and ASX listed companies (BD: Nov 20, 2018).

## TOTAL BRAIN

Total Brain says it has appointed Simon Poidevin as chief executive officer for Australasia, effective from March 23, 2020.

Total Brain told Biotech Daily Mr Poidevin he would be responsible for sales, business development and investor relations for Australia and New Zealand.

Total Brain was up three cents or 9.7 percent to 34 cents.



## MAYNE PHARMA GROUP

Mayne Pharma says chief financial officer and company secretary Nick Freeman has resigned, with Peter Paltoglou appointed as interim chief financial officer.

Mayne said that lawyer Laura Loftus had been appointed as company secretary effective from March 26, 2020.

The company said Mr Freeman resigned “for family reasons to pursue another opportunity”.

Mayne said Mr Freeman would remain with the company until mid-June 2020 and it had begun a search for a new chief financial officer.

The company said that it would relocate the chief financial officer position from Adelaide to Raleigh, North Carolina.

Mayne said Mr Paltoglou was its chief development officer, had more than 20 years’ experience in capital markets, corporate strategy and mergers and acquisitions, and was previously the managing director of investor banking at Credit Suisse Emerging Companies in Australia.

Mayne was up 4.5 cents or 23.1 percent to 24 cents with 25.1 million shares traded.

## IMPEDIMED

Impedimed says chief financial officer Morten Vigeland has resigned, with head of finance Timothy Cruickshank appointed interim chief financial officer.

Impedimed said Mr Vigeland had been a part of the senior management team for seven years and was leaving the company “for personal reasons”.

Impedimed chief executive officer Richard Carreon said that Mr Vigeland had been the chief financial officer since 2013 and was “a valued member of the management team”.

“We are grateful for his guidance and strategic leadership during a transformative stage of the company moving from clinical to commercialization and for his huge contribution to the success of the business,” Mr Carreon said.

The company said Mr Cruickshank had been part of the finance team for 12 years, including four years as the vice president of finance.