Biotech Daily

Friday April 5, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.83 percent on Friday April 5, 2019, with the ASX200 down 51.5 points to 6,181.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and three were untraded. All three Big Caps fell.

Genetic Signatures was the best, up seven cents or 6.9 percent to $1.08, with 41,230 shares traded.

Oncosil climbed 5.7 percent; Patrys improved 4.55 percent; Orthocell was up 3.7 percent; LBT, Polynovo, Universal Biosensors and Volpara rose more than two percent; Avita, Dimerix, Ellex and Neuren were up more than one percent; with Medical Developments, up 0.9 percent.

Benitec led the falls, down one cent or 7.1 percent to 13 cents, with 5,000 shares traded.

Imugene and Optiscan lost five percent or more; Clinuvel, Cynata, Opthea, Prescient and Starpharma fell more than four percent; Immutep, Kazia, Osprey and Pro Medicus were down more than three percent; Antisense, Cochlear, Impedimed, Mesoblast, Nanosonics and Resmed shed more than two percent; Actinogen and CSL were down more than one percent; with Telix down 0.6 percent.

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.

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 it taken up by the World Health Organisation for 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 Food and Drug Administration 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.

AVITA MEDICAL

Avita says economic data projects its Recell system for severe burns could save the Arizona Burn Centre up to $US28 million ($A39.3 million) a year.

Avita said its Recell spray-on-skin system used a small amount of the patients' skin to prepare the spray-on-skin, which could be prepared in 30 minutes, to treat severe burns.

The company said that skin could be re-harvested from the donor site within seven days of the treatment.

Avita said that a presentation, titled 'Budget impact of autologous cell harvesting device (ACHD) use versus standard of care (SOC) for treatment of severe burns: A case study for the Arizona Burn Center', presented at the American Burns Association meeting in Las Vegas, April 2 to 5, 2019, showed that the largest driver of cost reductions was the length of stay of patients comprising 70 percent of the savings.

The company said that using Recell patients had about 67 percent fewer autografting procedures, and reduced operating room time contributing a 13 percent cost reduction.

Avita said that other benefits included reduction in size of donor sites and the need for rehabilitation.

An article published earlier this year by UK researchers in the journal Applied Health Economics and Health Policy questioned the benefit of using the Recell system.

An abstract is available at: https://www.ncbi.nlm.nih.gov/pubmed/30635844.

The article said the National Institute for Health and Care Excellence (NICE) Medical Technologies Evaluation Programme evaluated Recell, questioning the benefits claimed in an economic model and a clinical evidence submission.

The article, titled 'Recell Spray-On Skin System for Treating Skin Loss, Scarring and Depigmentation after Burn Injury: A NICE Medical Technology Guidance' said that the manufacturer submitted clinical evidence comparing Recell to conventional dressings in shallow burns and meshed grafts in deeper burns.

The article said "the evidence did not fit the defined groups, but suggested that Recell was clinically comparable to skin grafts for partial thickness burns; however, Recell is not used in this way in the UK".

"The manufacturer submitted an economic model in which Recell treatment of partial thickness burns reduced the requirement for later skin grafts … [which] indicated that Recell alone was cost saving in comparison to conventional dressings," the article said.

"The [External Assessment Centre] indicated that this model was clinically inappropriate, but data were not available to populate a new model," the researchers said.

"NICE Medical Technologies Guidance 21 recommended that additional research was needed to address the uncertainties regarding the potential benefits of Recell," the article concluded.

Biotech Daily asked Avita for comment but at the time of publication, had not received a reply.

In its announcement, Avita quoted the Arizona Burn Center's Dr Kevin Foster saying that "based on the characteristics of our burn center and the patients we treated in 2018, use of the Recell system is estimated to produce significant cost savings of about 16 percent of our total center costs, or approximately $US28 million per year".

"Key drivers of projected cost savings were decreased length of hospital stay, fewer autograft surgeries, reduced donor site size and associated wound care, and reduced rehabilitation needs," Dr Foster said.

The company said that a separate study showed that Recell in combination with widely meshed autografts for patients with more than 50 percent burns "healed as quickly as patients with smaller burn injuries with the same treatment".

Avita was up half a cent or 1.6 percent to 32.5 cents with 13.2 million shares traded.

PRANA BIOTECHNOLOGY

Prana says shareholders have approved all resolutions to its Life Biosciences takeover and name change extraordinary general meeting but with up to 22.0 percent dissent.
Prana said the meeting passed all resolutions allowing the Boston-based Life Biosciences to invest up to $41.8 million for 63 percent of the company, change the company name to Alterity Therapeutics and appoint Life co-founders Dr David Sinclair and Tristan Edwards as directors (BD: Mar 6, 2019).
The company said the greatest percentage dissent, 22.00 percent, was against the ratification of a prior issue of shares to a party unrelated to Life Biosciences.
Prana said the greatest number of opposition votes were against the name change resolution, which required a 75 percent majority, with 12,463,395 votes (13.72%) against, 75,754,713 votes (83.40%) in favor with 2,614,310 votes (2.88%) at the proxy's discretion.
The company's most recent Appendix 3B new issue announcement said it had 567,500,950 shares on offer meaning the votes against the name change amounted to 2.2 percent of the company, not sufficient to call extraordinary general meetings.
Prana was unchanged at 4.4 cents.

ATOMO DIAGNOSTICS

Sydney's Atomo says its HIV Self Test is available to the public.
Atomo said the test was the "only diagnostic self-test for HIV that has been formally reviewed and approved by the Therapeutic Goods Administration" (BD: Dec 4, 2018).
Today, Atomo said that the test could be bought directly from Atomo via its dedicated website: www.atomohivtest.com and from selected clinics in Australia.
The company said the hand-held device needed a drop of blood from the fingertip and provided an accurate result in 15 minutes.
Atomo chief executive officer John Kelly said that "as the first HIV self-test to be approved for sale in Australia, this is an important moment in Australia's fight against HIV/AIDs".
Atomo is a private company.

CRESO PHARMA

Creso has told the ASX that its market sensitive commercial progress announcement would not have a material effect on its securities because it was not new information.
The ASX said the announcement entitled 'Market update: Creso reports significant commercial progress across premium product categories' was released on its announcement platform at 9:04am on April 2, 2019 and asked the company if it was information that a reasonable person would expect to have a material effect on the price or value of its securities.
The ASX noted that between March 28 and April 2, 2019 Creso's share price increased 32.3 percent from 32.5 cents to 43 cents.
Creso said in the announcement that Cannaqix10 and Cannaqix50 were growing steadily, it was continuing to expand Anibidiol Relax and Anibidiol Plus into 14 countries, Cannaqix Nite, Cannapeal, Cannapeal Nite and Cannadol Revitalise were ready for launch, and it was preparing to launch products from Creso Mernova Medicinal.
The company said it did not believe the information would be material because the information was previously published in its February 28 Appendix 4E preliminary financial report.
Creso fell two cents or 4.4 percent to 43.5 cents.

ELLEX MEDICAL LASERS

Ellex has requested a trading halt “pending an announcement by Ellex in relation to a leadership change requiring disclosure under Listing Rule 3.16”.
Trading will resume on April 9, 2019 or on an earlier announcement.
Ellex last traded up one cent or 1.7 percent to 61 cents.

THC GLOBAL GROUP

THC says it has a “mutually exclusive partnership” with Malaysian agricultural technology company Heleogenics to legalize and market medical marijuana in Asia.
THC said it would work with the Kuala Lumpur, Malaysia-based Heleogenics Sdn Bhd in discussions with the Malaysian Government to legalize medical marijuana.
The company said its activity in Asia would include research and development, patient access, doctor and patient engagement, off-take agreements, sales, intellectual property and commercialization.
THC said it would expand into other Asian and Middle Eastern markets with Heleogenics.
THC was up 1.5 cents or 2.7 percent to 57 cents.

MEMPHASYS

Memphasys says the Melbourne-based Monash IVF (in-vitro fertilization) has been issued 4,000,000 shares at two cents a share in lieu of consulting fees.
Memphasys said it was in a collaboration with Monash IVF to develop its Felix sperm separation device (BD: Sep 18, 2018).
The company said Monash IVF held the rights for use of the Felix device for 12 months following commercial availability.
Memphasys was up half a cent or 22.7 percent to 2.7 cents with 1.5 million shares traded.

MEMPHASYS

Peters Investments says it has increased its holding in Memphasys from 66,666,667 shares (18.32%) to 116,666,667 shares (21.36%).
The Cottlesloe, Western Australia-based Peters Investments said it acquired the 50,000,000 shares on March 28, 2019 in a take-up of rights issue for $1,000,000 or two cents a share (BD: Mar 27, 2019).