



# Biotech Daily

Tuesday June 4, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: BENITEC UP 14%; USCOM DOWN 9%**
- \* **APPLICATIONS OPEN FOR \$316k VICTORIA PRIZES, FELLOWSHIPS**
- \* **PARADIGM PPS BEATS SALINE FOR ROSS RIVER VIRUS JOINT PAIN**
- \* **STARPHARMA: 'OKAMOTO LAUNCHES 003 VIVAGEL CONDOM IN JAPAN'**
- \* **IMUGENE: 'HIGH DOSE HER-VAXX SHRINKS TUMORS'**
- \* **VISIONEERING REQUESTS 'TRANSACTION, CAPITAL RAISING' HALT**
- \* **ELIXINOL REQUESTS CAPITAL RAISING TRADING HALT**
- \* **GI DYNAMICS 'CONSIDERS DELISTING FROM THE ASX'**
- \* **SUDA SIGNS US, HONG KONG COMPANIES FOR EXPANSION**
- \* **PHARMAUST: CATALENT MAKES DOG CANCER TRIAL MONEPANTEL**
- \* **MGC RECEIVES BULK MARIJUANA, REVENUE**
- \* **ADMEDUS REQUESTS 4th FUNDING SUSPENSION EXTENSION**
- \* **ADRIAN TREVISAN SELLS ALL 19m NEUROTECH SHARES**

## MARKET REPORT

The Australian stock market was up 0.19 percent on Tuesday June 4, 2019, with the ASX200 up 11.9 points to 6,332.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and six were untraded. All three Big Caps fell.

Benitec was the best, up 1.5 cents or 13.6 percent to 12.5 cents, with 586,274 shares traded. Alterity (Prana) climbed 5.9 percent; Cynata, Orthocell, Osprey and Telix improved more than four percent; Compumedics, Mesoblast and Polynovo were up three percent or more; Antisense rose two percent; Ellex, Oncosil and Paradigm were up more than one percent; with Medical Developments and Opthea up by less than one percent.

Uscom led the falls, down 1.5 cents or 9.1 percent to 15 cents, with 6,909 shares traded. Avita and Clinuvel lost more than six percent; Nanosonics and Proteomics slipped more than five percent; Actinogen and Kazia fell more than four percent; Impedimed and Pharmaxis were down more than three percent; Cochlear, Dimerix, Optiscan and Prescient shed more than two percent; with CSL, Resmed and Starpharma down by less than one percent.

## VICTORIA GOVERNMENT

The Victoria Government says applications have opened for the Victoria Prize for Science and Innovation and the Victoria Fellowships.

A media release from the Minister for Jobs, Innovation and Trade Martin Pakula said the Victoria Prize and Fellowships “celebrate our top scientists as well as early-career researchers and provide real support for their important work”.

The Government said the Victoria Prize for Science and Innovation was awarded “to outstanding scientists who have significantly advanced knowledge in their field” with grants of \$50,000 each for physical sciences and life sciences to fund research and development in Victoria.

The Victoria Government said that it was offering 12 Victoria Fellowships of up to \$18,000 each for early-career researchers to support a short-term overseas study mission.

The media release said that study missions to France were also eligible for the Australian French Association for Science and Technology Associate Award, valued up to \$3,500.

To nominate for the Victoria Prize, go to [www.veski.org.au/vicprize](http://www.veski.org.au/vicprize) and for information on how to apply for a Victoria Fellowship, go to [www.veski.org.au/vicfellow](http://www.veski.org.au/vicfellow).

## PARADIGM BIOPHARMACEUTICALS

Paradigm says an 18-patient, phase IIa, pilot trial shows that injected pentosan polysulfate sodium is superior to saline for the joint pain symptoms of Ross River virus.

Paradigm said the randomized, double-blinded, placebo-controlled trial “met its primary end-point of safety ... with no clinically significant differences between [injected pentosan polysulfate sodium] and placebo groups” and no serious adverse events.

Paradigm said the trial met the secondary endpoint of reduced arthralgia, or joint pain and stiffness, with eight of the 11 active patients, compared to one of the seven placebo group, showing “near remission of symptoms” three months after the trial.

The company said no current treatment had been shown to shorten the duration or alter the course of Ross River virus.

Paradigm said the trial recruited subjects who had progressed from acute to chronic Ross River virus, three to 12 months post-infection, and had “debilitating musculoskeletal pain for which there [was] no adequate standard of care treatments”.

The company said that assessments of disease symptoms were conducted from day-15 to day-81 post-treatment, including changes in quality-of-life scores, patient questionnaires and hand grip strength as a measure of joint function.

Paradigm said that hand grip strength showed “statistically significant differences from baseline at all time points in the PPS-treated group” with the placebo group showing a nine percent weakening at day-15 which was statistically lower than the PPS group, and the placebo group changes did not demonstrate statistically significant improvement.

Paradigm said that improvement in hand grip strength in the PPS group was “clinically significant at all time points”.

A chart in the media release showed that placebo group hand-grip strength increased after day-15 and at day-81 equalled the improvement in the PPS group at day-39.

Paradigm said the improvement from baseline for the PPS group was statistically significant but the saline placebo improvement was not.

Paradigm chief executive officer Paul Rennie said the “small pilot [Ross River virus] study has yielded very promising safety data and key efficacy outcomes in the reduction of disease symptoms in this debilitating chronic phase of the disease”.

Paradigm was up 2.5 cents or 1.7 percent to \$1.475.

## STARPHARMA

Starpharma says the Tokyo-based Okamoto Industries has launched its Vivagel condom under the Zero Zero Three brand.

Starpharma said it was “the first condom with antiviral coating in Japan”, it would carry the Vivagel brand and the company would be eligible to receive royalties on sales as well as payment for supply of the active ingredient, astodimer sodium or SPL7013.

The company said that SPL7013 had been “proven in laboratory studies to inactivate up to 99.9 percent of HIV, [herpes simplex virus and human papillomavirus]”.

Starpharma chief executive officer Dr Jackie Fairley said the launch was “an important milestone for the product” and the company was “delighted to see the Vivagel condom launched in Japan”.

The company said Okamoto distributed products in Korea, Taiwan, Thailand, Singapore and China.

Starpharma fell one cent or 0.75 percent to \$1.33.

## IMUGENE

Imugene says by day-182 of its 14 patient, phase Ib trial of HER-Vaxx for gastric cancer the tumors of 50 microgram high-dose patients had shrunk or stabilized.

Last year, Imugene said the trial met its primary endpoints of safety, tolerability, and immunogenicity, or the ability to induce a bodily fluid or cell-mediated immune response (BD: Dec 17, 2018).

In April, the company said the trial showed one complete response and five partial responses and that all those treated at the highest dose of 50µgm had a partial response with two demonstrating a greater than 40 percent reduction in tumor size, along with higher antibody levels (BD: Apr 2, 2019.)

Today, Imugene said that data presented at the American Society of Clinical Oncology meeting in Chicago, showed that tumors in all patients either “shrunk further or stabilized” with one patient’s tumor reduced by 70 percent since joining the trial.

The company said that patients had continued to receive HER-Vaxx every three months “to maintain high levels of cancer targeting antibodies”.

In March, Imugene began a 68 patient, open-label, randomized, multi-centre phase II trial to continue to study the highest dose of HER-Vaxx (BD: Mar 14, 2019).

The company said the phase Ib trial was ongoing and all patients on the highest dose had received their day-266 doses, with results to be presented in July 2019.

Imugene was unchanged at 1.7 cents with 10.7 million shares traded.

## VISIONEERING TECHNOLOGIES

Elixinol has requested a trading halt pending an announcement “in connection with a proposed transaction and capital raising”.

Trading will resume on June 6, 2019 or on an earlier announcement.

Visioneering last traded at 6.5 cents.

## ELIXINOL GLOBAL

Elixinol has requested a trading halt “pending the announcement to the market in relation to the outcome of a proposed capital raising”.

Trading will resume on June 6, 2019 or on an earlier announcement.

Elixinol last traded at \$4.27.

## GI DYNAMICS

GI Dynamics says it is considering delisting from the ASX due to the cost of compliance and inability to raise funds for its Endobarrier for obesity and type 2 diabetes.

GI Dynamics said that once a decision had been made it would issue materials for an annual general meeting expected to be held by the end of June 2019.

The company it had in-principle advice from the ASX in relation to the potential removal from the Official List, and would agree, subject to conditions.

GI Dynamics said it might seek delisting if it was “unable to secure binding commitments for significant funding within the next two months that are conditional on the company remaining listed on the Official List”.

The company said that it incurred significant costs in complying with the filing and reporting requirements, including lawyer and accountants’ fees, printing, mailing and other costs which were on-going, comprising a significant part of corporate overhead expenses, and were difficult to reduce, and estimated to be more than \$300,000 a year.

GI Dynamics said it was “not able to utilize many of the benefits that are associated with a listing” and the current share price made using the listing as a platform to raise capital or to provide acquisition consideration extremely dilutive to our stockholders.

The company said it was not conducting trials in Australia, with studies expected in the US and India, the majority of recent investment came from the UK and the US and “as a result, it is difficult to attract Australian investors and many foreign investors are also not attracted to investing in an ASX listed entity with no business presence in Australia”.

The company said it needed to raise funds for the US pivotal trial of Endobarrier and the India trial with Apollo Sugar and the failure to raise funds might impact on its ability to comply with obligations to the Crystal Amber Fund, including a payment due in July 2019.

GI Dynamics said that as an ASX-listed company, it was required “to disclose a considerable amount of business information to the public, some of which would be considered proprietary and would not be disclosed by a non-listed company”.

“As a result, our actual or potential competitors, customers, lenders and vendors all have ready access to this information which could potentially help them to compete against us or make it more difficult for us to negotiate favorable terms with them,” the company said.

GI Dynamics said that a “material portion of ... management time is dedicated to ASX listing related matters, which could be directed elsewhere if the company were unlisted.

In 2011, GI Dynamics raised \$80 million of a hoped-for \$95 million at \$1.10 per Chess depository instruments (CDIs) to commercialize its Endobarrier duodenal-jejunum sleeve for obesity and type 2 diabetes, raising a further \$60 million at 53 cents in 2013 and \$34 million at 52 cents in 2014 (BD: Aug 30, 2011; Jul 3, 2013; May 2, 2014).

In 2014, the Endobarrier was approved in Australia, South America and Europe earning revenue of \$2.5 million but with losses of \$35.6 million (BD: Mar 3, 2014).

Also in 2014, the European Union halted Endobarrier shipments pending a review of vigilance and reporting systems (BD: Oct 6, 7, 2014)

In 2015 the US Food and Drug Administration halted the pivotal trial with 325 of 500-patients enrolled, due to bacterial liver infections (BD: Mar 6, 2015).

Data from that trial showed the Endobarrier failed to meet its safety and efficacy endpoints (BD: Mar 15, 2016).

In May 2016, the Australian Therapeutic Goods Administration questioned compliance issues with the device and in October cancelled its approval (BD: Oct 24, 2016).

In March 2017, GI Dynamics chief executive officer Scott Schorer said the company had cut costs, reviewed its systems and trial data and hoped to begin a new trial by the end of 2017 (BD: Mar 30, 2017).

GI Dynamics fell 0.7 cents or 36.8 percent to 1.2 cents with 1.4 million shares traded.

## SUDA PHARMACEUTICALS

Suda says it has agreements with an unnamed US company and the Hong Kong-based Jezans to expand business development in the US, Europe, Russia and China.

Suda said that US business development and alliance manager Andrew Curtis had engaged an unnamed Illinois-based, life sciences commercial services company “to focus on the mid-tier US biotech and specialty pharmaceutical companies”.

The company said that Jezans was a commercial services company working in China, Europe and Russia, and would focus on mid-sized private and State-owned companies and Jezans chief executive Zona Yim had a track record in business development transactions throughout the territory.

Suda said that both companies would “work on a success-based remuneration model”.

Suda was up 0.1 cents or 25 percent to 0.5 cents with 13.1 million shares traded.

## PHARMAUST

Pharmaust says the Somerset, New Jersey-based Catalent has begun production of monepantel tablets for its phase II trial of dogs with B-cell lymphoma.

Pharmaust said it expected that the good manufacturing practice (GMP) tablets would be fit for routine trial use in both dogs and humans.

The company said it expected to start recruiting for the dog cancer trial by September.

Pharmaust chief scientific officer Dr Richard Mollard said the company intended the dog trials to “pave the way for registration and future clinical trials in human patients”.

Pharmaust was up 0.2 cents or 5.3 percent to four cents.

## MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has received its first marijuana bulk order from the Toronto-based Cannaglobal Canada and revenue from the delivery of products to Mabsut Life.

MGC said it received EU438,000 (\$A700,000) from Cannaglobal for the first bulk order of raw materials for dermatological products, sent to Switzerland for manufacture.

The company said it received EU108,000 (\$A173,000) from the Ljubljana, Slovenia-based Mabsut for orders completed in the three months to March 31, 2019 for Mabsut’s cannabidiol-based vaporizer cartridge formula marketed as Phenopen.

MGC was up 0.2 cents or 3.85 percent to 5.4 cents with 7.2 million shares traded.

## ADMEDUS

Admedus has requested a fourth extension to its voluntary suspension to finalize its re-capitalization plan.

In April, Admedus requested a trading halt “pending an announcement regarding the ... immunotherapies sale transaction” and later requested a voluntary suspension for the sale of Admedus Vaccines, formerly Coridon (BD: Apr 15, 17, 2019).

On April 23, the company responded to an ASX aware query, announced the termination of the Vaccine business sale and requested an extension to the suspension “to finalize the ... recapitalization plan” (BD: Apr 23, 2019).

In May, the company placed two further extension requests with the second expecting to last until June 4, 2019 (BD: May 7, 21, 2019).

Today, the company requested a further extension to the suspension which it expected to last until July 1, 2019 or the release of an earlier announcement.

Admedus last traded at six cents.

## NEUROTECH INTERNATIONAL

In two separate announcements to the ASX, Adrian Trevisan says he has sold his 19.37 percent holding of Neurotech selling all 19,005,699 shares.

The Malta-based Mr Trevisan said he sold 3,135,011 shares for \$55,125.23 or 1.76 cents a share on May 29, 2019, and sold his remaining 15,870,688 between May 30 and June 3 for a total of \$198,421.53 or an average of 1.25 cents a share.

In March, a Times of Malta report confirmed by Neurotech said that Mr Trevisan did not hold the Doctorate of Philosophy in Neuroscience from University College London he claimed in his prospectus and the company terminated him from his role as a scientific advisor, despite being a company founder (BD: Dec 20, 2018; Mar 27, 2019).

Neurotech was up 0.1 cents or 7.7 percent to 1.4 cents with 5.1 million shares traded.