



Biotech Daily

Tuesday June 2, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ACTINOGEN UP 28%; IMMUTEP DOWN 10%**
- * **FEDERAL \$66m FOR COVID-19 PROJECTS**
- * **APPLICATIONS OPEN FOR \$2.5m CSL CENTENARY FELLOWSHIPS**
- * **AVITA SUBMITS PIVOTAL RECELL FOR VITILIGO IDE TO US FDA**
- * **BIONOMICS APEIRON, RIGHTS TO RAISE \$22m; 2 DIRECTORS; 50% FEE HIKE**
- * **RESAPP: GERMAN HOSPITAL TO EVALUATE RESAPPDX-EU; COPD STUDY**
- * **SIENNA: TRIOLAB SWEDEN HTERT BLADDER CANCER TEST DISTRIBUTOR**
- * **RESPIRI UNMARKETABLE PARCEL FACILITY**
- * **LAZARD BELOW 5% IN MAYNE**
- * **ANTHONY GRIST, OAKTONE REDUCE, DILUTED TO 5.3% OF INVEX**
- * **INVEX CHAIR DR JASON LOVERIDGE BELOW 5%**
- * **REGAL FUNDS REDUCES TO 11.4% OF VISIONEERING**
- * **ELIXINOL CHAIR PAUL BENHAIM, RAW WITH LIFE DILUTED TO 28%**
- * **D&G, DAVID NEWMAN, GABRIEL ETTENSON REDUCE TO 6% OF ELIXINOL**
- * **TELEX APPOINTS DR COLIN HAYWARD CHIEF MEDICAL OFFICER**
- * **CLARITY APPOINTS DR MICHAEL IRONSIDE AS DIRECTOR OF OPERATIONS**
- * **DIMERIX REQUESTS 'COVID-19 TRIAL OPPORTUNITY' TRADING HALT**
- * **PHARMAUST TAKES 'SARS-COV-2 RESULTS' HALT TO SUSPENSION**
- * **IMPRESSION MARIJUANA, HYDROXYCHLOROQUINE ARDS MOUSE TRIAL**

MARKET REPORT

The Australian stock market was up 0.27 percent on Tuesday June 2, 2020, with the ASX200 up 15.9 points to 5,835.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and one was untraded.

Actinogen was the best, up 0.5 cents or 27.8 percent to 2.3 cents, with 15.4 million shares traded. Uscom climbed 17.8 percent; Imugene and LBT were up more than three percent; Genetic Signatures, Resonance and Starpharma rose more than two percent; with Ellex, Impedimed, Next Science, Orthocell, Paradigm and Proteomics up one percent or more.

Immutep led the falls, down two cents or 10 percent to 18 cents, with 5.4 million shares traded. Osprey lost 7.1 percent; Avita, Cynata and Optiscan fell more than four percent; Compumedics and Pro Medicus were down more than three percent; Neuren and Universal Biosensors shed more than two percent; Antisense, Kazia, Mesoblast, Pharmaxis, Prescient, Telix and Volpara were down more than one percent; with Clinuvel, Cochlear, Medical Developments, Nanosonics, Polynovo and Resmed down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it is providing \$66 million for projects to find a vaccine, antiviral therapies, clinical trials and to improve the response to Covid-19.

A media release from Federal Health Minister Greg Hunt said there was currently no vaccine or proven and effective treatment for Covid-19.

The Government said it would provide \$13.6 million to support Covid-19 vaccine development projects, including \$2 million for the University of Queensland's 'molecular clamp' technology, which allowed new vaccines to be developed within months.

The media release said grants for vaccine projects would open between June 15, 2020 and March 15, 2021, with expressions of interest to be assessed from July 15, 2020, November 15, 2020 and March 15, 2021.

The Government said it would provide \$7.3 million for nine research projects to support development of antiviral therapies to manage the disease, of which the most successful projects would have the opportunity to seek additional funding of up to \$10 million.

The media release said the Government would continue to invest in research to support a national health system response, including \$4 million for digital health research infrastructure to help health systems respond, with grants opening today.

The media release said it would provide \$2 million for research into the human immune response, with grants opening on June 12, 2020 and \$600,000 for research into community information needs and behavioral drivers, with grants opening today.

CSL

CSL says applications have opened for two Centenary Fellowships, each worth \$1.25 million over five years for discovery and translational research.

CSL said the fellowships were offered to "outstanding mid-career scientists seeking to undertake world-class medical research at an Australian academic institution".

The company said the fellowships paid tribute to its origins and aimed "to foster a thriving medical research community by supporting the development of Australian science".

CSL chief scientific officer Prof Andrew Cuthbertson said the company was committed to increasing "the quality and quantity of Australian research and our biotech ecosystem generally".

"I am confident that the recipients of the CSL Centenary Fellowships will go on to become some of Australia's most eminent scientist and will lead the next generation of Australian scientific endeavor," Prof Cuthbertson said.

For more information and to apply go to www.cslfellowships.com.au.

CSL was up six cents or 0.02 percent to \$284.73 with 1.1 million shares traded.

AVITA MEDICAL

Avita says it has submitted an investigational device exemption application with the US Food and Drug Administration for a pivotal trial of its Recell system for vitiligo.

Last year, Avita said the FDA had approved its investigational device exemption application for a 10-patient, 24-week, randomized, controlled, pilot Recell vitiligo safety and efficacy feasibility study (BD: Jan 19, 2020).

Today, Avita chief technology officer Andrew Quick said the pivotal trial data would form the basis of the FDA submission to expand use of the Recell for vitiligo.

"In parallel, and as previously announced, we are also conducting a complementary and more scientifically-oriented feasibility study," Mr Quick said.

Avita fell two cents or 4.1 percent to 47 cents with 31.2 million shares traded.

BIONOMICS

Bionomics says it hopes to raise \$22 million from Malta's Apeiron and a rights offer at four cents a share, accept an Apeiron director, and raise directors fees 50 percent.

Bionomics said Apeiron Investment Group was the family office of Christian Angermayer and would subscribe for 135,833,000 shares at four cents a share to raise \$5,433,320, with the funding in two tranches, with the second tranche subject to shareholder approval. Bionomics said it would then launch a pro-rata entitlement offer at four cents a share to raise up to \$15,000,000 following completion of the second tranche.

The company said Apeiron would underwrite further capital raisings within 15 months and if the \$15,000,000 was raised, Apeiron would be granted 150,000,000 warrants exercisable at six cents a warrant within three years, and it expected a further \$9 million if all warrants were issued and exercised.

The company said the funds would be used to progress phase II clinical trials of BNC210 to treat post-traumatic stress disorder (PTSD) and other anxiety and stress-related disorders.

Bionomics said that subject to shareholder and Foreign Investment Review Board approvals Apeiron would own 19.9 percent of the company and would be able to nominate two directors to the board.

The company said that an extraordinary general meeting would vote to approve the transaction as well as increase the director remuneration pool by 50 percent from \$500,000 to \$750,000 "to reflect the addition of two directors to the board".

Bionomics was up 1.1 cents or 22 percent to 6.1 cents with five million shares traded.

RESAPP HEALTH

Resapp says a German hospital will undertake a health economic evaluation of its Resappdx-EU and it has progressed its chronic obstructive pulmonary disease study. Resapp said the Lichtenberg-based Sana Klinikum would perform the health-economic evaluation pilot study, including an initial workflow assessment and quality assurance cohort of 50 subjects.

The company said it would then recruit up to 300 subjects for a baseline for resource use and costs associated with current care pathways for respiratory diagnosis.

Resapp said recruitment would be delayed due to the Covid-19 pandemic and until demand placed on the study site had subsided.

In December, Resapp said the Western Australian Aboriginal Health Ethics Committee had approved a pilot study of its chronic obstructive pulmonary disease screening smart phone application (BD: Dec 19, 2019).

Today, the company said the clinical trial research agreement had been signed and the pilot, double blind study had been registered, but recruitment had not started due to Covid-19 restrictions.

Resapp fell one cent or 5.6 percent to 17 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says it has appointed Addlife subsidiary Triolab AB as the exclusive distributor of its hTERT adjunct test for bladder cancer in Sweden.

Sienna said Swedish commercial laboratory Unilabs was currently evaluating the hTERT test for routine use and it would begin sales, marketing and technical support training with Triolab staff.

Sienna fell half a cent or 6.6 percent to 7.1 cents.

RESPIRI

Respiri says it has a share sale facility for holders of unmarketable parcels of shares, worth less than \$500, at 7.3 cents a share on the record date of May 29, 2020.

Respiri said that based on the 7.3 cents price, it had 2,434 shareholders, or 53 percent of its 4,584 shareholders, with unmarketable parcels of 6,850 shares or fewer.

The company said it would aggregate and sell the unmarketable parcels to allow shareholders to sell shares without brokerage or handling costs and to allow the company to reduce administrative costs of maintaining a large number of unmarketable parcels.

Respiri said the closing date for the facility would be July 14, 2020.

Respiri was up 0.2 cents or 2.9 percent to 7.2 cents with 1.05 million shares traded.

MAYNE PHARMA GROUP

Lazard Asset Management Pacific Co says it has ceased to be a substantial shareholder in Mayne Pharma.

Last week, the Sydney-based Lazard said it had become substantial in Mayne Pharma with 84,379,755 shares or 5.03 percent of the company (BD: May 26, 2020).

Today, Lazard said that on May 25, 2020 it bought 154,607 shares for \$69,364 or 44.9 cents a share and on May 28, sold 1,834,143 shares for \$807,676 or 44.0 cents a share. Biotech Daily calculates that Lazard holds 82,700,219 shares or 4.93 percent of Mayne Pharma.

Mayne was up one cent or 2.35 percent to 43.5 cents with 9.7 million shares traded.

INVEX THERAPEUTICS

Anthony Grist and Oaktone Nominees say they have reduced and been diluted in Invex from 4,000,000 shares (7.27%) to 3,543,750 shares (5.25%).

The Perth-based Mr Grist and Oaktone said that between July 8, 2019 and February 13, 2020 they sold 550,000 shares for \$602,499 or \$1.10 a share.

Mr Grist and Oaktone said that they acquired 93,750 shares for \$121,875 or \$1.30 a share in the \$26.2 million placement and were diluted (BD: May 22, 2020).

Invex fell one cent or 0.7 percent to \$1.47.

INVEX THERAPEUTICS

Dr Jason Loveridge has ceased to be a substantial shareholder in Invex.

The London-based Dr Loveridge said that his 3,336,000 share-holding was diluted on May 28, 2020 through the \$26.2 million placement at \$1.30 a share and through the liquidation of Warambi Sarl and transfer of a 50 percent interest of 1,770,000 shares to another shareholder for \$277,927 or 15.7 cents a share.

VISIONEERING TECHNOLOGIES

Regal Funds Management says it has reduced its substantial shareholding in Visioneering from 57,761,403 shares (12.40%) to 52,956,789 shares (11.37%).

The Sydney-based Regal Funds said that between May 1 and 28, 2020 it sold 4,804,614 shares for between 1.5 cents and 2.0 cents a share.

Visioneering was unchanged at 1.6 cents.

ELIXINOL GLOBAL

Elixinol chairman Paul Benhaim and Raw with Life says its 54,623,008 share-holding has been diluted from 39.61 percent to 28.33 percent.

The Mullumbimby, New South Wales-based Mr Benhaim said that he was diluted in the \$5.6 million one-for-2.51 rights offer at 20 cents a share (BD: May 5, 2020).

Elixinol fell one cent or 4.1 percent to 23.5 cents with three million shares traded.

ELIXINOL GLOBAL

D&G Health, David Newman and Gabriel David Ettenson say they have been reduced in Elixinol from 12,791,977 shares (9.22%) to 11,826,243 shares (6.133%).

The New York and Colorado-based D&G, Mr Newman and Mr Ettenson said they were diluted in the \$5.6 million rights offer at 20 cents a share (BD: May 26, 2020).

The group did not disclose the date or value of the sale of 965,734 shares.

TELEX PHARMACEUTICALS

Telex says it has appointed Dr Colin Hayward as chief medical officer and founder Dr Andreas Kluge will transition to a non-executive director role.

Telex said Dr Hayward was previously the chief medical officer of the Durham, North Carolina-based Premier Research and held senior medical, executive and board roles with F Hoffman-La Roche, Myriad Genetics, Prism Ideas and Symprove.

The company said Dr Hayward held a Bachelor of Medicine and Bachelor of Surgery from the University of London and was a fellow of the Faculty of Pharmaceutical Medicine.

Telex fell 2.5 cents or 1.8 percent to \$1.36 with 1.3 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Dr Michael Ironside as director of operations.

Clarity said Dr Ironside had more than 25 years' experience in the pharmaceutical industry in Europe, the US and Asia, and previously worked at Hovione, AMRI, Glaxosmithkline, Anacor and Biosignal.

The company said Dr Ironside held a Doctor of Philosophy from the University of Dundee.

Clarity is a public unlisted company.

DIMERIX

Dimerix has requested a trading halt "pending an announcement in respect of a new clinical trial opportunity in Covid-19 patients".

Trading will resume on June 4, 2020 or on an earlier announcement.

Dimerix last traded at 27 cents.

PHARMAUST

Pharmaust has requested a voluntary suspension following the trading halt requested last week "pending ... preliminary results from the Sars-Cov-2 pre-clinical trial".

Pharmaust has been trialing monepantel for sheep worm on dogs with cancer and in May said one of seven dogs had a 60 percent tumor reduction (BD: Apr 17, May 12, 2020).

Today, the company said it expected to release the announcement by June 3, 2020.

Pharmaust last traded at 9.7 cents.

IMPRESSION HEALTHCARE

Impression says it has begun a study of IHL-675A, comprising hydroxychloroquine and cannabidiol, for sepsis-associated acute respiratory distress syndrome in mice.

Impression said the trial included an initial 17-arm dose-escalation study to assess dose response in mice with induced sepsis and a second stage to assess specific combinations of cannabidiol and hydroxychloroquine and optimal inflammation dampening responses.

Impression said it would assay cytokine levels from blood collected across both stages of the study to investigate IHL-675A's mechanism of inflammation in septic shock.

The company said that sepsis-associated acute respiratory distress syndrome was the leading cause of mortality associated with Covid-19 and other lung, urinary tract, stomach and skin infections.

Impression said it expected stage one results in four to six weeks.

Impression was unchanged at 5.1 cents with 3.6 million shares traded.