



# Biotech Daily

Wednesday April 15, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: IMMUTEP UP 22%; PRESCIENT DOWN 10%**
- \* **VOLPARA, AMBRY PARTNER FOR ON-LINE GENETIC TESTING ORDERS**
- \* **IMPRESSION: MARIJUANA, HYDROXYCHLOROQUINE FOR COVID-19 ARDS**
- \* **INVION: 'PHOTOSOFT ANTI-TUMOR RESPONSE IN MICE'**
- \* **ALLEGRA HAS ORDERS FOR 105k FACE SHIELDS**
- \* **NUHEARA: MALAYSIA RESUMES POST-COVID-19 IQBUDS PRODUCTION**
- \* **IMPEDIMED LAUNCHES HEART FAILURE, KIDNEY DISEASE SOZO SOFTWARE**
- \* **BIONOMICS RECRUITS 90-PATIENT BNC105 COLORECTAL CANCER TRIAL**
- \* **MGC: SWISS MICELLE DEAL 'NOTHING TO DO WITH COVID-19'**
- \* **TBG TELLS ASX: 'MISCOMMUNICATION' ON NOW-BANNED COVID-19 TEST**
- \* **ANTEOTECH PLEADS SCHULTZ, RDTI TO ASX 42% QUERY**
- \* **MICRO-X REQUESTS CAPITAL RAISING TRADING HALT**
- \* **LITTLE GREEN EXPORTS '1<sup>st</sup> AUSTRALIAN MARIJUANA OIL'**
- \* **SIMAVITA: DUSSMAN 21%, THIRTY-FIFTH 6%, CHEVRON DILUTED TO 13%**
- \* **STEMCELL APPOINTS DR KEVIN YEE CHANG CHINESE MEDICINE ADVISOR**
- \* **BENITEC APPOINTS EDWARD SMITH DIRECTOR**

## MARKET REPORT

The Australian stock market fell 0.39 percent on Wednesday April 15, 2020, with the ASX200 down 21.4 points to 5,466.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell and seven traded unchanged.

Immutep was the best, up three cents or 22.2 percent to 16.5 cents, with 5.3 million shares traded. LBT climbed 13.0 percent; Neuren was up 9.3 percent; Opthea and Optiscan were up more than six percent; Medical Developments, Resonance, Starpharma and Volpara improved four percent or more; Cyclopharm was up 3.6 percent; both Pro Medicus and Telix rose 2.1 percent; Ellex and Mesoblast were up more than one percent; with Nanosonics and Resmed up by less than one percent.

Prescient led the falls, down 0.5 cents or 11.9 percent to 3.7 cents, with 1.9 million shares traded. Dimerix lost 10 percent; Osprey and Uscom fell more than seven percent; Antisense, Paradigm and Pharmaxis lost six percent or more; Alterity was down 5.6 percent; Next Science and Polynovo fell more than four percent; Proteomics was down 3.6 percent; Avita, Cynata, Genetic Signatures, Impedimed, Kazia and Orthocell shed more than two percent; Cochlear fell 1.2 percent; with CSL and Clinuvel down by less than one percent.

## [VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says it has partnered with genetic testing company Ambry Genetics to develop an online ordering process for breast cancer genetic testing

Volpara said it would market the Aliso Viejo, California-based Ambry's comprehensive, assessment, risk and education (Care) program in the US and automate the company's workflow using the Aspen breast reporting and tracking system, described as "breast practice management software".

Volpara chief executive officer Dr Ralph Highnam told Biotech Daily that the company would "automate the workflow to make it easy for sites to identify women who might benefit from genetics testing using its Aspen patient tracking software".

Dr Highnam said that Aspen was the software product of the Seattle, Washington-based Mammography Reporting Systems which his company acquired last year for \$21.15 million (BD: Jun 14, 2019).

"Ambry will receive the electronic referrals and work with the customer and women to see if they want genetics testing," Dr Highnam said.

The company said that its Volpara Density software for measuring breast density would be included as part of the risk calculation.

Volpara said that patients that qualified for supplemental imaging, based on genetic results and risk assessments, might benefit from early cancer detection.

The company said that the agreement would have the potential to significantly increase average revenue per user.

Dr Highnam said the commercial terms were confidential.

Volpara was up 6.5 cents or 4.4 percent to \$1.54 with 1.3 million shares traded.

## [IMPRESSION HEALTHCARE](#)

Impression says it will trial IHL-675A marijuana with hydroxychloroquine for sepsis-associated adult respiratory distress syndrome (Ards), in mice.

Impression said that sepsis-associated Ards was the leading cause of Covid-19 deaths.

The company said that IHL-675A, was invented by its chief medical officer Dr Sud Agarwal and chief scientific officer Dr Mark Bleackley.

Impression said that the trial would be conducted by pharmaceutical research organization Eurofins Scientific Taiwan.

The company said the clinical objective of Ards treatments was to reduce the acute pulmonary inflammatory response, to reverse pulmonary oedema and to limit damage to the lung.

Impression said IHL-675A's two compounds worked in different manners, the cannabidiol as an anti-inflammatory agent and the hydroxychloroquine as an immune-modulatory molecule, to quell the inflammation response to infection including cytokine production, T-cell activation and pro-inflammatory signalling.

The company said it expected the studies to begin on receipt of marijuana from Impression to Eurofins and following a marijuana import permit from Taiwanese authorities.

Impression said that it was not "certain that the relevant permit will be received by Eurofins to import [cannabidiol] to Taiwan or that the animal studies will be successful".

"Even if the animal studies are successful, it is not certain that IHL-675A will be designated FDA Emergency Use Authorisation [and] a failure or delay at any stage ... would adversely affect [the] ability to conduct clinical trials for IHL-675A and obtain registration for IHL-675A in the relevant markets," the company said.

Impression was up 0.6 cents or 10 percent to 6.6 cents with 12.8 million shares traded.

## [INVION](#)

Invion says data from a trial of Photosoft for ovarian cancer in 28 mice shows “the initiation of an anti-tumor immune response”.

In November, Invion said that its Photosoft technology reduced tumor size to less than half its original size in a pre-clinical trial of mice with ovarian cancer, undertaken by Melbourne’s Hudson Institute of Medical Research (BD: Nov 27, 2019).

Today, the company said the Hudson Institute assessed the T-cells in Photosoft-treated mice compared to a control group of untreated mice and found that on day-2, treated mice had significantly greater numbers of tumor-infiltrating T-cells and on day 22, T-cell numbers had returned to baseline, but “Photosoft-treated tumors contained significantly fewer immune-suppressive regulatory [regulatory T-cells] than the control group”.

Hudson Institute ovarian cancer biomarker laboratory head Dr Andrew Stephens said that for ovarian cancer patients, the ratio of effector T-cells (Teff) to regulatory T-cells (Treg) was “an important prognostic indicator”.

“A relative reduction of Treg cells compared to Teff cells in the tumor tissue generally correlates with longer survival and better treatment outcomes,” Dr Stephens said.

“Based on these early findings, it appears that tumor shrinkage using Photosoft technology is accompanied by a potentially beneficial change in the immune microenvironment in ovarian tumor tissue,” Dr Stephens said.

Invion chief executive officer Craig Newton said that Photosoft might be able to attack the cancer both directly and by activating the body’s immunity.

“[This discovery] is significant because most common cancer treatments, such as chemotherapy, suppress the body’s natural ability to fight pathogens,” Mr Newton said.

Invion was up 0.2 cents or 25 percent to one cent with 14.1 million shares traded.

## [ALLEGRA ORTHOPAEDICS](#)

Allegra says it has begun distributing and received orders for 105,000 Australian-made face shields, following disruption to the supply of personal protective equipment.

Allegra said discussions were ongoing with other major hospital groups to supply the face shields to protect healthcare workers from contracting and transferring Covid-19.

Allegra chief executive officer Jenny Swain told Biotech Daily that the face shields were co-designed with Sydney’s Sabre Medical, which manufactured the shields.

The company said that the face shields were approved by the Australian Therapeutic Goods Administration and had enabled it “to diversify its product range and provide Australian-made protective equipment to meet hospital needs now and into the future”.

“We feel very proud to be able to supply Australian designed and manufactured face shields for our front-line carers,” Ms Swain said.

“The current demand for [personal protective equipment] illustrates the need for companies to be ready to diversify during this global uncertainty surrounding COVID-19,” Ms Swain said.

Allegra was up 4.5 cents or 30 percent to 19.5 cents.

## [NUHEARA](#)

Nuheara says production of its Iqbuds Max hearing and sound filtering earbuds has resumed in Malaysia after some manufacturing Covid-19 restrictions were lifted.

Nuheara said that prior to the restrictions, it had secured its supply chain for 6,000 Iqbuds and begun production of units, which would be recommenced as a priority and scaled up.

Nuheara was up 0.3 cents or 21.4 percent to 1.7 cents with 4.8 million shares traded.

## IMPEDIMED

Impedimed says it has released its HF-Dex heart failure assessment and end-stage renal disease assessment software for its Sozo bio-impedance spectroscopy platform.

Impedimed said the HF-Dex software assessed fluid overload in heart failure patients, plotted against reference ranges and presented alongside extracellular fluid volume to provide physicians with information to risk-stratify and monitor patients.

The company said the software contained an end-stage renal disease assessment for patients undergoing dialysis to improve fluid management.

Impedimed chief executive officer Richard Carreon said that the software would bring “the benefits of Sozo to thousands of patients living with heart failure and renal disease”.

Impedimed fell 0.1 cents or 2.9 percent to 3.4 cents with 9.6 million shares traded.

## BIONOMICS

Bionomics says it has completed recruitment of a 90-patient phase II trial of BNC105 in combination with Bristol-Myers Squibb's nivolumab for metastatic colorectal cancer.

Bionomics said the two-arm, 24-month, randomized trial, sponsored by the Australasian Gastro-Intestinal Trials Group and supported by Bristol-Myers Squibb, would be conducted at 16 Australian clinical oncology sites.

The company said the first arm of the trial would administer nivolumab in combination with BNC105 and the second arm would administer nivolumab with a signal transducer and activator of transcription 3 (Stat3) inhibitor.

Bionomics said the primary objective would be to determine objective response rates in both drug combinations, and the secondary objectives included progression-free survival, the adverse event profile of the drug combinations and overall survival.

The company said it expected final results in early 2023.

Bionomics fell 0.1 cents or 1.8 percent to 5.4 cents.

## MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says the March 19 trading halt, suspension and series of extensions for a Swiss joint venture for Covid-19 has nothing to do with Covid-19.

MGC said that there was “presently no reasonable basis established for the product to treat or cure Covid-19 symptoms or that the product kills the Covid-19 virus”.

“This would require clinical testing to be conducted to establish such clinical basis,” the company said. “Therefore, MGC retracts the reference to Covid-19 in its recent trading halt and suspension notices, and investors should not rely on those references.”

Last week, the ASX suspended MGC pending a response to queries “regarding a strategic joint venture with a Swiss company in relation to Covid-19” (BD: Apr 8, 2020).

On March 19, MGC requested a trading halt pending the announcement and requested its first voluntary suspension on March 23, 2020, followed by seven extensions to the suspension (BD: Mar 19, 23, 24, 25, 26, 27, 31; Apr 2, 3, 2020).

Today, MGC said it had an agreement with Swiss company Micelle Technology AG for a product targeting viral infections with inflammatory complications, based on Micelle's Mycell delivery system technology, which delivered natural ingredients in higher concentrations to the cells and was used in the formulation of a “natural anti-infective based formulation” based on artemisinin.

MGC said it would supply Micelle with a food supplement, lead clinical studies and set-up production of the product for future commercial supply.

MGC climbed 1.1 cents or 64.7 percent to 2.8 cents with 20.6 million shares traded.

## TBG DIAGNOSTICS

TBG says it “genuinely and reasonably believed” that Conformité Européenne (CE) mark approval for a Covid-19 test was confidential as its share price climbed 1053.8 percent. TBG responded to a lengthy and detailed ASX query regarding the internal company discussions from Saturday March 14 to the posting of the news on the ASX platform on the morning of Tuesday March 17, 2020.

On Tuesday March 17, at 11.01am TBG requested a pause in trading followed by a trading halt “pending an announcement in relation to certification of a TBG Biotechnology Xiamen Inc novel coronavirus diagnostic kit”, by which time the company’s share price had climbed as much as 27.4 cents or 1053.8 percent to 30 cents before retreating to 27 cents before the trading halt (BD: Mar 17, 2020).

On March 18, the company said that 46.65 percent subsidiary TBG Biotechnology Xiamen Inc had CE Mark approval for its Covid-19 nucleic acid diagnostics kit (BD: Mar 18, 2020). The next day, TBG was suspended by the ASX “pending further inquiries” following an ASX “aware” query, in which the company said it became aware of CE mark certification on Saturday March 14, but “had only received informal notification ... and therefore did not consider that they had all information and materials necessarily required in order to confirm this matter and release an announcement to the market” (BD: Mar 19, 2020).

Today, TBG said that director Dr Stanley Chang was informally notified of the CE mark approval by TBG Xiamen director Bill Ou on March 14, 2020 and relayed the message to Australian directors Emily Lee and Jitto Arulampalam via private text messages, containing a hyperlink to a Wechat page in China, which made the information available to TBG Xiamen’s Wechat followers.

The company said its directors were not involved in the day-to-day management of TBG Xiamen and the information was considered to be material, but its directors believed that the information was “for internal communications only and was not publicly accessible”. The company said its directors had made enquiries and realized that TBG Xiamen had released an update to its employees and subscribers via Wechat on March 14 and that Mr Ou became aware of the certification through this Wechat page.

TBG said it was “taking steps to implement stronger communication protocols to ensure that relevant information from TBG Xiamen is communicated to them swiftly and prior to any public announcement”.

On April 6, TBG said that China had banned the export of its Covid-19 diagnostics kits without the required China medical device product registration and TBG chairman Jitto Arulampalam told Biotech Daily that TBG Xiamen would apply for Chinese approval and was also considering manufacturing the kits outside China (BD: Apr 6, 2020).

TBG remained suspended at 27 cents.

## ANTEOTECH (FORMERLY ANTEO DIAGNOSTICS)

Anteotech has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price rose 0.8 cents or 42.1 percent from 1.9 cents to 2.7 cents, yesterday April 14, and noted a “significant increase” in trading volumes.

Anteotech said that it expected to receive a \$966,562 Federal Government Research and Development Tax Incentive this week, for the year to June 30, 2019, which was mentioned in its most recent quarterly report and prospectus for its recent rights issue.

Anteotech fell 0.3 cents or 11.5 percent to 2.3 cents with 5.4 million shares traded.



### [MICRO-X](#)

Micro-X has requested a trading halt pending the release of an announcement “in respect of a material capital raising”.

Trading will resume on April 17, 2020 or on an earlier announcement.

Micro-X last traded at 17.5 cents.

### [LITTLE GREEN PHARMA](#)

Little Green Pharma says it has exported “the first” Australian marijuana oil to the UK.

Little Green Pharma said the products would be distributed by UK specialist importer Astral Health as part of a purchase agreement.

Little Green was up 2.5 cents or 8.5 percent to 32 cents.

### [SIMAVITA](#)

Simavita says Dussman Group has increased its substantial holding, Chevron Corp has been diluted and Thirty-Fifth Celebration has become substantial in the company.

Simavita said Dussman Group increased its shareholding from 102,019,031 shares (19.91%) to 115,769,031 shares (20.53%).

The company said Chevron Corporation Pty Ltd’s 72,178,317 shares had been diluted from 14.08 percent to 12.80 percent and Thirty-Fifth Celebration Pty Ltd became substantial with 30,277,184 shares or 5.37 percent of the company.

Simavita was untraded at two cents.

### [BENITEC BIOPHARMA](#)

Benitec says it has appointed Edward Smith as a director.

Benitec said Mr Smith had more than 20 years’ experience in finance and operations in the biotechnology industry and was currently chief financial officer of the Radnor, Pennsylvania-based Marinus Pharmaceuticals.

The company said Mr Smith was previously the chief financial officer of Polymedix and an executive director of Inkind Pharmaceutical Company.

Benitec was in a suspension at 2.6 cents.

### [STEMCELL UNITED](#)

Stemcell United says it has appointed Dr Kevin Yee Chang as an advisor on matters related to traditional herbal medicine and business development in Australia.

Stemcell said Dr Chang had been a traditional Chinese medicine practitioner for more than 20 years, was the president of the New South Wales Association of Chinese Medicine and was a lecturer on Chinese medicine at the University of Sydney, the University of Western Sydney and the Sydney Institute of Traditional Chinese Medicine.

Stemcell United fell 0.1 cents or 7.1 percent to 1.3 cents with 3.3 million shares traded.