



Biotech Daily

Monday June 27, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: IMUGENE UP 45.5%; STARPHARMA DOWN 8%**
- * **VICTORIA GOVERNMENT CABINET RE-SHUFFLE AND BIOTECH**
- * **IMUGENE CLIMBS 49% ON HER-VAXX GASTRIC CANCER TRIAL CLAIM**
- * **LUMOS WINS VIRADX CANADA INTERIM AUTHORIZATION**
- * **EMVISION EARNS \$600k 1st RESPONDER BRAIN SCANNER MILESTONE**
- * **TRAJAN COMPLETES CHROMATOGRAPHY ACQUISITION**
- * **STARPHARMA, GENENTECH EXPAND DEP RESEARCH AGREEMENT**
- * **DIMERIX: REMAP-CAP COVID ARDS TRIAL RECRUITMENT CLOSES**
- * **MEDLAB NANABIS 'TWICE THE BIOAVAILABILITY OF OTHER MARIJUANA'**
- * **NUHEARA TAKES 'CAPITAL RAISING' HALT TO SUSPENSION**
- * **INVESTORS MUTUAL REDUCES TO 6.3% IN MAYNE**
- * **MERCHANT FUNDS TAKES 9.6% OF BCAL**
- * **USCOM: NG JIH NANG FOR SE ASIA BUSINESS DEVELOPMENT**
- * **OPTISCAN APPOINTS CHINA'S SINI VIEWNVIVO DISTRIBUTOR**
- * **VECTUS APPOINTS SHANGHI JADESEN VB4-A32 CHINA ADVISER**

MARKET REPORT

The Australian stock market was up 1.94 percent on Monday June 27, 2022, with the ASX200 up 127.3 points to 6,706.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and two were untraded. All three Big Caps rose.

Imugene was the best, climbing as much as eight cents or 48.5 percent, before closing up 7.5 cents or 45.45 percent at 24 cents with 159.3 million shares traded. Resonance climbed 6.9 percent; Alcidion, Cochlear, Genetic Signatures, Nanosonics and Polynovo improved four percent or more; Emvision, Prescient, Pro Medicus and Telix were up more than three percent; Neuren rose 2.2 percent; Impedimed, Pharmaxis, Resmed and Uscom were up by more than one percent; with CSL up by 0.65 percent.

Starpharma led the falls, down six cents or 8.3 percent to 66 cents, with 488,488 shares traded. Kazia lost 6.1 percent; Atomo, Avita and Micro-X fell four percent or more; Compumedics, Immunetep, Medical Developments, Mesoblast and Paradigm were down more than three percent; Actinogen, Clinuvel, Cynata, Oncosil, Proteomics, Universal Biosensors and Volpara shed two percent or more; Next Science was down 1.3 percent; with Opthea down 0.4 percent.

VICTORIA GOVERNMENT

The Victoria Government says Treasurer Tim Pallas has had Trade, and the Ministries for Economic Development and Industrial Relations added to his responsibilities.

Following the resignation of four State Government Ministers, including the former Minister for Industry Support and Recovery, Trade and Business Precincts, Martin Pakula, Victoria Premier Daniel Andrews made several changes to his Cabinet.

The State Government said that the Minister for Transport Infrastructure Jacinta Allan had been appointed Deputy Premier, with Ben Carroll appointed the Minister for Industry Support and Recovery and Minister for Business Precincts and continued as Minister for Public Transport and Minister for Roads and Road Safety.

The Government said that Jaala Pulford continued as Minister for Employment, Innovation, Medical Research and the Digital Economy, Resources and Small Business and would “take carriage of the government’s landmark Sick Pay Guarantee program”.

The Government said that Mary-Anne Thomas had been appointed Minister for Health and Ambulance Services, with Frank McGuire continuing as Parliamentary Secretary for Medical Research.

IMUGENE

Imugene climbed as much as 48.5 percent on claims that its 36-patient, phase II trial of HER-Vaxx for gastric cancer was statistically significant ($p = 0.066$).

The company said that HER-Vaxx with the standard-of-care chemotherapy gave a 41.5 percent survival benefit compared to chemotherapy alone.

Imugene said that median overall survival for patients on HER-Vaxx with chemotherapy was 13.9 months, compared to 8.3 months for patients on chemotherapy alone.

Imugene said the trial confirmed “a favorable survival outcome with no added toxicity for HER-Vaxx combined with standard-of-care chemotherapy over chemotherapy alone and confirmed a dose of 100 μ g HER-Vaxx for future studies.

The company said that the one-sided false positive probability of 0.10, showed a 41.5 percent survival benefit for patients treated with HER-Vaxx plus SOC chemotherapy compared to chemotherapy alone, which “translated into an overall survival hazard ratio of 0.585 ... with a statistically significant p-value of 0.066”.

Imugene said there was “no difference in safety events between the two treatment arms, suggesting that HER-Vaxx does not add toxicity to chemotherapy”.

The company said that the longest HER-Vaxx treated patients remain alive 2.5 years, with one patient approaching three years, after starting therapy and these patients generated the strongest anti-human epidermal growth factor receptor-2 (HER-2) antibody levels from their dosing schedule on HER-Vaxx.

Imugene managing-director Leslie Chong said she was “delighted to report that we have achieved this significant milestone for patients with advanced gastric cancer”. “The final analysis favored the survival outcome for HER-Vaxx and I note the independent data monitoring committee previously suggested to shorten the study by lowering the number of patients,” Ms Chong said.

The company said that the Herizon-extension cohort review committee confirmed the higher 100 μ g dose of HER-Vaxx for use in the Nextherizon trial of pre-treated metastatic HER2 positive gastric cancer and the Neoherizon trial of peri-operative HER2 positive gastric cancer, which were due to begin “soon”.

Imugene said that it had delivery of “a large-scale batch of HER-Vaxx for use in all planned clinical trials ... in patients with HER-2 positive gastric cancer”.

Imugene closed up 7.5 cents or 45.45 percent at 24 cents with 159.3 million shares traded.

LUMOS DIAGNOSTICS

Lumos says Health Canada has awarded interim order authorization for its Viradx three-in-one rapid antigen test for Covid-19, influenza A and B.

Lumos said that it was ready to begin production and shipping of Viradx to Canada.

The company said that Viradx was under review by the US Food and Drug Administration for emergency use authorization, and if successful would expand its North American sales and marketing efforts.

Lumos chief executive officer Doug Ward said that “with a single sample, Viradx provides three simultaneous test results, giving clinicians in outpatient care settings the ability to differentiate these viruses and providing a higher level of confidence as they consider time-sensitive anti-viral treatment options”.

“At this stage, the potential demand for Viradx in Canada is uncertain due to the evolving public health response to Covid-19 and limited reimbursement coverage for [point of care influenza] testing,” Mr Ward said.

“However, this interim order authorization from Health Canada does provide clear validation of the quality of our clinical and regulatory data for Viradx and an opportunity to co-market it alongside Febridx,” Mr Ward said.

Lumos was up two cents or 16.0 percent to 14.5 cents with 1.0 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has received a \$600,000 milestone payment from the Australian Stroke Alliance for its first responder helmet-based portable brain scanning device.

Emvision said that it held workshops with Victoria Ambulance, New South Wales Ambulance and the Royal Flying Doctor Service, among others, to “ensure that the device being developed is fit for purpose, easy to operate and can integrate seamlessly into clinical workflows”.

The company said that its second-generation device had progressed positively, with an initial prototype targeted for later this year.

Emvision said that under the agreement with the Australian Stroke Alliance it would receive a total of \$8 million of non-dilutive cash funding, with \$6.2 million remaining, in staged payments over the five-year project, weighted to the earlier years, which would support the development and clinical validation of its planned first responder device for air and road ambulances (BD: Sep 16, 2021).

Emvision chief executive officer Dr Ron Weinberger said the company had “made important progress with the first responder version while working in parallel on our [first generation] in-hospital device”.

“The extensive work done by our team will ensure that the device is fit for purpose and meets all the end user needs, a critical part of the design process,” Dr Weinberger said.

Emvision was up 5.5 cents or 3.7 percent to \$1.54.

TRAJAN GROUP

Trajan says it has completed its acquisition of the Louisville, Kentucky-based Chromatography Research Supplies Inc.

Earlier this month, the company said it raised \$29.7 million in its underwritten placement at \$2.00 a share, hoped to raise \$5.0 million in a share plan, would borrow \$20 million and use \$13.4 million from existing cash to acquire Chromatography Research Supplies for \$US43.3 million (\$A62,573,293) (BD: Jun 17, 20, 2022).

Trajan was up three cents or 1.5 percent to \$2.04.

STARPHARMA

Starpharma says it has expanded its dendrimer-enhanced product (DEP) drug conjugates research agreement with the San Francisco, California-based Genentech. Starpharma said that with the Roche Group subsidiary Genentech, it would design and synthesize DEP conjugates and provide them to Genentech for testing and characterization.

The company said the agreement terms were the same as the agreement it signed with Genentech in December last year, but said fees were not expected to be material, that it was not required to fund the program, and that each company would maintain ownership of their own intellectual property (BD: Dec 7, 2021).

Starpharma fell six cents or 8.3 percent to 66 cents.

DIMERIX

Dimerix says the Remap-Cap Covid-19 trial has closed recruitment of moderate, non-critically ill Covid-19 patients, including those treated with its DMX-200.

In February, Dimerix said that with 779 of about 800 patients recruited, the Remap-Cap trial for Covid-19 acute respiratory distress syndrome (Ards) had been paused, but that safety concerns did not relate to its DMX-200, which it was trialed for kidney disease (BD: Jun 4, 2020; Feb 28, 2022).

Today, the company said the closure of the study in non-critically ill patients was “not based on any further safety concerns but [was] instead a pragmatic decision reflecting the Remap-Cap international steering committee’s belief that continued recruitment of moderately severe Covid-19 patients would be challenging, particularly given hospitalization rates of Covid-19 patients appropriate for this study [were] generally decreasing globally”.

Dimerix said that results of the study would be analyzed and prepared for publication.

Dimerix was unchanged at 12.5 cents.

MEDLAB CLINICAL

Medlab says the University of South Australia has confirmed Nanabis has “two times more bioavailability” than an Australian approved oral marijuana medicine.

Medlab said that the one-to-one tetrahydrocannabinol and cannabidiol Nanabis oral spray used its Nanocelle delivery platform, and that research was conducted by the University of South Australia’s School of Pharmacy and Medical Sciences examined the variability in drug concentrations within a patient population receiving clinically relevant doses of Nanabis and an Australian Register of Therapeutics Goods-approved oral marijuana medicine containing tetrahydrocannabinol and cannabidiol.

Medlab fell 1.1 cents or 20.0 percent to 4.4 cents with 2.3 million shares traded.

NUHEARA

Nuheara has requested a voluntary suspension “pending release of an announcement regarding a capital raising”.

Last week, Nuheara requested a trading halt pending an announcement “regarding a capital raising” (BD: Jun 23, 2022).

Today, the company said trading would resume on July 1, 2022 or on an earlier announcement.

Nuheara last traded at 12 cents.

MAYNE PHARMA GROUP

Sydney's Investors Mutual says it has reduced its substantial share-holding in Mayne Pharma from 125,723,514 shares (7.49%) to 111,269,143 shares (6.30%).

Investors Mutual said that between May 19, 2021 and June 23, 2022 it bought and sold shares, with the single largest sale on October 19, 2021 of 13,045,807 shares for \$4,435,574 or 34 cents a share.

Mayne was up half a cent or 1.9 percent to 26.5 cents with 3.4 million shares traded.

BCAL DIAGNOSTICS

Merchant Funds Management Pty Ltd says it has increased its substantial share-holding in Bcal from 17,420,171 shares (8.42%) to 20,000,000 shares (9.64%).

The Perth-based Merchant Funds said that between July 1, 2021 and June 27, 2022 it bought 11,000,000 shares for \$1,298,276 or an average 11.80 cents a share and sold 8,420,171 shares for \$1,152,347 or an average of 13.685 cents a share.

Bcal was unchanged at six cents with 1.4 million shares traded.

USCOM

Uscom says it has appointed Ng Jih Nang as its South East Asia distribution and business development manager, based in its Singapore regional headquarters.

Uscom said the Singapore Health Sciences Authority had listed its Uscom 1A ultra-sonic cardiac output monitor, its BP+ central blood pressure monitor and Spirosonic respiratory diagnostic devices for sale in Singapore.

The company said that Mr Ng had 20 years of experience in medical technology sales and business development, working for General Electric, Leica, Philips, Teleflex, and Eckert and Ziegler.

Uscom chair Prof Rob Phillips said that South East Asia was "an increasingly important medical market with a large population, rapidly growing economies and an expanding middle class with high expectations of quality medical care".

"Uscom has some [Association of Southeast Asian Nations] distribution, and as part of its growth strategy has recently established a regional [headquarters] in Singapore, with the appointment of Mr Ng consolidating this strategy," Prof Phillips said.

"Mr Ng's targets are simply to increase regional sales; he will drive results from our current distributors, identify and partner with new distributors of scale, and expand Uscom sales into regions which as yet are untouched," Prof Phillips said.

Uscom was up 0.1 cents or 1.7 percent to 6.1 cents.

OPTISCAN IMAGING

Optiscan says it has appointed the Beijing-based Sinsi Technology Co Ltd as its Viewnvivo confocal microscope distributor for China, Hong Kong and Macau.

The company did not disclose the commercial terms of the agreement.

Optiscan managing-director Prof Camile Farah said that "China represents an excellent growth opportunity for Optiscan's Viewnvivo product across a range of research and pre-clinical application areas".

Optiscan was up 0.2 cents or 2.1 percent to 9.8 cents.

VECTUS BIOSYSTEMS

Vectus says it has appointed Shanghai Jadesen Management Co Ltd as its adviser for potential licencing discussions for its VB4-A32 anti-fibrotic drug in China.

The company said that Shangahi Jadesen would represent it in discussions with pharmaceutical companies in China in regard to the VB4-A32 candidate for the treatment of hepatic fibrosis resulting from all forms of liver disease.

Vectus said that China was an “emerging market” for drug candidates addressing liver fibrosis, with up to 40 percent of the population at risk of hepatic fibrosis.

Vectus chair Dr Ronald Shnier said that Shanghai Jadesen was “well-positioned to provide ongoing support to the company in regard to licencing, conducting clinical trials, regulatory approvals, and marketing and commercializing VB4-A32 in China should one or more licences proceed”.

Vectus fell half a cent or 0.5 percent to \$1.00.