



Biotech Daily

Wednesday February 8, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: IMUGENE UP 8%; POLYNOVO DOWN 12%**
- * **CERTA FT011 '60% SCLERODERMA IMPROVEMENT'**
- * **GENETIC TECHNOLOGIES RAISES \$7.2m**
- * **INOVIQ: 'SUB-B2M BEATS ROCHE ELECSYS BREAST CANCER TEST'**
- * **INVION TAKES CHO PHOTOSOFT TO NORTH AMERICA, HONG KONG**
- * **RICHMOND HILL TAKES 6.1% OF UNIVERSAL BIOSENSORS**
- * **BIO-MELBOURNE 'STRATEGY, COMPANY CULTURE' FORUM**
- * **ONCOLOGY ONE APPOINTS DR TON BUNT DIRECTOR**
- * **AUSBIOTECH: 1 MONTH TO NSW WOMEN IN LIFE SCIENCES LUNCH**
- * **AUSBIOTECH, CSIRO VICTORIA 'BIO-CHEERS' NEXT WEEK**

MARKET REPORT

The Australian stock market was up 0.35 percent on Wednesday February 8, 2023, with the ASX200 up 26.0 points to 7,530.1 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and one was untraded.

Imugene was the best, up one cent or 7.7 percent to 14 cents, with 13.6 million shares traded.

Amplia, Cynata and Next Science climbed more than six percent; Antisense improved 4.8 percent; Avita, Mesoblast and Paradigm were up more than three percent; Actinogen, Emvision, Opthea and Pro Medicus rose more than two percent; Medical Developments, Pharmaxis, Resonance and Volpara were up more than one percent; with Resmed up by 0.35 percent.

Polynovo led the falls, down 32 cents or 12.1 percent to \$2.33, with 4.2 million shares traded.

Genetic Signatures lost 10.8 percent; Starpharma fell 4.3 percent; Immutep, Micro-X and Uscom were down more than three percent; Compumedics shed 2.7 percent; Alcidion, Nanosonics, Orthocell and Proteomics were down more than one percent; with Clinuvel, Cochlear, CSL, Cyclopharm, Neuren and Telix down by less than one percent.

CERTA THERAPEUTICS

Certa says a 30-patient, phase II trial of FT011 for scleroderma led to “a clinically meaningful improvement in 60 percent of patients treated”.

Certa said that FT011 could inhibit the biological target in the fibrosis mechanism, known as the G-protein-coupled receptor, which could become activated following injury or disease and had “multiple downstream pathways causing inflammation and fibrosis” meaning FT011 could potentially treat chronic fibrosis in multiple organs.

The company said that scleroderma was a debilitating auto-immune condition characterized by inflammation and fibrosis of the skin and other organs, including lungs, kidneys and heart, resulting in high morbidity and substantial detriment on quality of life. Certa said that the multi-centre, randomized, double-blinded and placebo-controlled trial dosed patients with 200mg or 400mg FT011, or placebo, daily and in addition to standard-of-care for 12 weeks.

The company said that, compared to placebo, FT011 led to significant improvements across multiple efficacy measures, including a “clinically significant” improvement of 60 percent of patients treated with 400mg FT011 ($p = 0.019$ vs. placebo), and 20 percent of patients in the 200mg group.

Certa said that three patients in the FT011 groups achieved the “greatest probability of clinical improvement”.

The company said FT011 clinical benefit was also shown in changes in skin thickness for patients treated, as well as a statistically significant improvement ($p = 0.019$) in the scleroderma health assessment questionnaire disability index scores in the 400mg FT011 group, while the placebo group showed “a worsening in outcomes”.

Certa said that global physician assessments of the patients’ health status showed a significant difference in favor of 400mg FT011 compared to placebo at four, eight and 12 weeks ($p = 0.022$), and there were no serious adverse events in the study.

The company said it would continue the trial with a sub-set of patients who had completed the main study and had elected to remain on 400mg FT011 for an additional nine months.

Certa founder and chief executive officer Prof Darren Kelly said “these exceptional trial results demonstrate the potential of this novel treatment for patients with scleroderma”.

“The changes seen in [diffuse cutaneous systemic sclerosis] score, lung function, and physician reported outcomes in addition to the patient reported outcomes within such a short treatment timeframe of 12 weeks, is unprecedented and paves the way for a confirmatory global phase III study,” Prof Kelly said.

“We know that this debilitating and life-threatening disease can severely impact the lives of patients and to date existing treatments only focus on the relief and management of symptoms, whereas FT011 precisely targets the root cause of fibrosis and has the potential to offer treatment across multiple organs within these patients,” Prof Kelly said. Certa is a private company.

GENETIC TECHNOLOGIES

Genetic Technologies says it has raised \$US5 million (\$A7.19 million) through the issue of 3,846,155 American depository shares (ADS) at \$US1.30 each.

Earlier this week, the company said there were 600 Australian shares for each US ADS, which implied a value of 0.31 cents per Australian share (BD: Feb 6, 2023).

Today, Genetic Technologies said the funds would go towards the commercialization of the Genetype multi-risk test, for product research and development, to increase sales and marketing, and for working capital.

Genetic Technologies was unchanged at 0.4 cents with 19.7 million shares traded.

[INVIQ](#)

Inoviq says a 94-serum sample study shows its Sub-B2M-CA15.3 cancer test can discriminate “between breast cancer and healthy controls across all cancer stages”. Inoviq has previously said that Sub-B2M is an engineered protein that detects the pan-cancer biomarker Neu5Gc (BD: Sep 16, 2022).

The company said that the study showed that its Sub-B2M test correctly identified 69 of 94 samples (73.4%) tested, with 69 percent sensitivity and 78 percent specificity for breast cancer across all stages, compared to 56 percent sensitivity and 71 percent specificity for the Roche Elecsys CA15.3 II test.

Inoviq said its test “discriminated early-stage breast cancer, stage I and II, from healthy controls, whereas the Roche test only discriminated stage IV cancer from controls”.

The company said its test had an area under the curve of 0.81, while the Roche test was 0.68, that it had a lower false positive rate compared to the Roche test (21% vs 29%, respectively) and a lower false negative rate (31.3% vs 43.8%, respectively).

Inoviq chief scientific officer Dr Gregory Rice said the data “show that Inoviq’s Sub-B2M-CA15.3 test discriminates breast cancer from controls across all stages and significantly outperforms the Roche test; reducing the number of samples misdiagnosed by approximately 10 percent”.

“Importantly, these tests were conducted by independent US-based laboratories; Sub-B2M-CA15.3 by contract research organisation Researchdx and Elecsys CA15.3 II by a clinical pathology service laboratory,” Dr Rice said.

“The results of this study are very promising given Inoviq’s test detects early-stage breast cancer, in contrast to Roche’s test, which did not discriminate between early-stage disease and healthy,” Dr Rice said.

Inoviq was up 4.5 cents or 7.5 percent to 64.5 cents.

[INVION](#)

Invion says it has expanded its co-development of Photosoft light therapy with the RMW Cho Group to atherosclerosis and infectious diseases in North America and Hong Kong. In 2017, the Hong Kong-based Cho Group took control of Invion providing \$5.5 million to develop its Photosoft technology for cancers (BD: Aug 31, 2017).

Last year, Invion said most of its \$3.3 million revenue came from the Cho Group for the research and development of Photosoft for cancer (BD: Aug 18, 2022).

Invion has previously said that the Photosoft technology used non-toxic photo-sensitizers and visible light combined with oxygen to produce cytotoxic-reactive oxygen that killed malignant cells, shut down tumors and stimulated the immune system.

Last year, the company said that Photosoft was active against bacteria and fungus, dengue and Zika viruses (BD: Sep 8, Oct 25, 26, 2022).

Today, Invion said that it would pay RMW Cho \$2.5 million “as a contribution to prior development costs invested by RMW in the Photosoft technology” for the infectious disease indications for the US, Canada and Hong Kong, and that it would receive exclusive distribution rights in those areas for those indications.

Invion said that it would continue with its existing research and development agreement with RMW Cho, with RMW Cho funding all cancer research and development work, as well as clinical trials in Australia and New Zealand.

The company said RMW Cho could cancel Invion’s distribution rights for Hong Kong, subject to paying “fair compensation” and it could elect to contribute a further \$1 million for the development of Photosoft for atherosclerosis for the US, Canada and Hong Kong.

Invion was unchanged at 0.8 cents with 12.8 million shares traded.

UNIVERSAL BIOSENSORS

Richmond Hill Capital Pty Ltd says it has increased its holding in Universal Biosensors from 10,685,532 shares (5.04%) to 12,903,212 shares (6.08%).

The Melbourne-based Richmond Hill said between June 24, 2022 and February 7, 2023, it bought 2,217,680 Chess depositary interests (CDIs) for \$650,231 or an average of 29.3 cents per CDI.

Universal Biosensors was unchanged at 33 cents.

BIO-MELBOURNE NETWORK

Bio-Melbourne says it will host a 'Continuous improvement, strategy and company culture' forum on Thursday, February 16, 2023.

The Bio-Melbourne Network said that the event would be an "opportunity to discuss why continuous improvement matters, how and when to adopt this approach, and who should be responsible for its implementation".

The Network said the event would include guest speakers from Cell Therapies, Seerpharma, Australian Red Cross Lifeblood and Bosch Australia.

The Bio-Melbourne Network said the event would be held at Swinburne Studio, The Australian Centre for the Moving Image, Federation Square, Corner of Flinders and Swanston Streets, Melbourne, from 4pm to 5:30pm, followed by a networking event.

To register go to: <https://bit.ly/3jEqGZZ>.

ONCOLOGY ONE

Oncology One says it has appointed Dr Ton Bunt as a non-executive director, effective from February 8, 2023.

Oncology One said that Dr Bunt was the co-founder and chief executive officer of Boston's Izumi Biosciences Inc and had previously worked for Albo, and at Oscient Pharmaceuticals as chief medical officer and head of research and development.

The company said that Dr Bunt held a medical degree and Doctor of Philosophy from Leiden University in the Netherlands and a Master of Business Administration from the Wharton School of the University of Pennsylvania in Philadelphia.

Oncology One is a private company.

AUSBIOTECH, MEDICINES AUSTRALIA

Ausbiotech and Medicines Australia say there is one month to go to the New South Wales Women in Life Sciences lunch, on Friday, March 10, 2023.

Ausbiotech said the event would bring together more than 500 delegates to celebrate International Women's Day and would feature a speech from Dr Kathryn Evans.

The industry organization said the event would also offer a 'big sister' program for industry leaders who were interested in supporting and encouraging women earlier in their careers.

Ausbiotech said the event would be held at Doltone House, Jones Bay Wharf, 48 Pirrama Road, Pyrmont, Sydney, on March 10, 2023 from 12pm to 3pm (AEDT), and that attendees could register their attendance at:

<https://www.ausbiotech.org/events/event/nsw-women-in-life-sciences-luncheon-2023>.

AUSBIOTECH

Ausbiotech says it will host a 'Bio-Cheers' social event to promote networking in the biotechnology sector on Thursday, February 16, 2023.

Ausbiotech said that members and non-members were invited to attend and "share ideas and build relationships" in Victoria's life sciences community, as well as to meet members from national advisory groups and its state branch committee.

The industry organization said that drinks and food would be provided by partner Commonwealth Scientific and Industrial Research Organisation, with the event held at CSIRO Clayton, 20 Research Way, Clayton from 5pm to 7:30pm.

To register go to: <https://www.ausbiotech.org/events/event/vic-biocheers-february-2023>.