Biotech Daily

Monday February 15, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRESCIENT UP 14%; ANTISENSE DOWN 9%**

*** BARD1: BREAST CANCER TEST '95% SENSITIVITY, 100% SPECIFICITY'**

*** NEUREN: NNZ-2591 'SAFE, NO ADVERSE EVENTS'**

*** CANN GROUP BUYS SATIPHARM FOR $4m SHARES; REVENUE WARNING**

*** ANTISENSE TO MEET FDA ON ATL1102 FOR DUCHENNE DYSTROPHY**

*** ORTHOCELL: US PATENT FOR CELGRO SOFT TISSUE REGENERATION**

*** VISIONEERING REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** NEUROTECH PLANS PHASE I MARIJUANA MENTE AUTISM TRIAL**

*** PHARMAUST: STARTS 2nd MONEPANTEL DOG LYMPHOMA TRIAL**

*** CRESO: ROUTE2 PAKISTAN, PHILIPPINES MARIJUANA DISTRIBUTOR**

*** MGC STUDIES NANO-MARIJUANA FOR GLIOBLASTOMA**

*** REGAL REDUCES TO 10% OF ALTERITY**

*** DR OLUDARE ODUMOSU REPLACES ZELIRA M-D DR RICHARD HOPKINS**

MARKET REPORT

The Australian stock market was up 0.91 percent on Monday February 15, 2021, with the ASX200 up 62.2 points to 6,868.9 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 12 fell and five traded unchanged.

Prescient was the best, up 1.5 cents or 13.6 percent to 12.5 cents, with 3.95 million shares traded. Optiscan climbed 11.5 percent; Alterity and Patrys were up more than seven percent; Imugene improved five percent; Actinogen, Oncosil and Pro Medicus were up more than four percent; Amplia was up 3.7 percent; Avita, Clinuvel, Immutep, Mesoblast, Nanosonics, Pharmaxis, Proteomics and Resonance rose more than two percent; CSL, Cyclopharm, Dimerix, Medical Developments, Nova Eye and Polynovo were up more than one percent; with Kazia and Resmed up by less than one percent.

Antisense led the falls, down two cents or 8.9 percent to 20.5 cents, with 4.65 million shares traded. Universal Biosensors lost 6.5 percent; Compumedics and Starpharma were down three percent or more; Cynata and Volpara shed more than two percent; Neuren, Next Science, Opthea and Orthocell were down more than one percent or more; with Cochlear, Paradigm and Telix down by less than one percent.

BARD1 LIFE SCIENCES

Bard1 says data from 118 blood samples shows that SubB2M can detect all stages of breast cancer with more than 95 percent sensitivity and 100 percent specificity.

Last week, Bard1 said that data from 69 samples showed that its SubB2M protein technology can detect “all stages of ovarian cancer with 100 percent specificity and 100 percent sensitivity” (BD: Feb 11, 2021).

Bard1 said it held the rights to the mutation of the B subunit of the subtilase cytotoxin (SubB2M) protein technology, developed by researchers at the University of Adelaide and the Gold Coast, Queensland-based Griffith University Institute for Glycomics.

Last year, the company said it would work with Griffith University to develop its ovarian, breast and lung cancer diagnostic technology (BD: Apr 2, 2020).

Bard1 said SubB2M could bind specifically to the Neu5Gc sugar molecule, a potential multi-cancer biomarker found on a range of human tumor cells and tumor-associated molecules.

Today, the company said the Institute’s Dr Lucy Shewell delivered the data in a virtual presentation, entitled ‘An engineered lectin, SubB2M, can detect N-glycolylneuraminic acid biomarkers in sera from breast cancer patients’ to the Lorne, Victoria Cancer Conference, last weekend.

Dr Shewell reported that serum from 96 patients with all stages of breast cancer had significantly-elevated mean levels of N-glycolylneuraminic acid (Neu5Gc) glycans compared to 22 cancer-free control individuals, when assayed by surface plasmon resonance.

Bard1 said the research demonstrated the potential of SubB2M for the monitoring of patients for disease recurrence.

Dr Shewell said that detection of Neu5Gc-glycans using SubB2M had “the potential to be useful as a diagnostic marker for the detection of early-stage breast cancer, as well as a tool for monitoring disease progression in late-stage cancer”.

Bard1 chief scientific officer Dr Peter French said that “these excellent results reported by the researchers at Griffith University support the commercial potential of SubB2M for both breast and ovarian cancer monitoring and detection”.

Griffith University Prof Mike Jennings said the SubB2M technology had “proved to have remarkable sensitivity and specificity for detection of these aberrant sugar biomarkers in blood for both breast and ovarian cancers”.

“There is potential to combine the detection of the Neu5Gc biomarkers by SubB2M with antibodies that recognize the cancer-specific biomarkers decorated with Neu5Gc,” Prof Jennings said. “Work to develop a breast cancer-specific test using this dual detection approach is already underway, supported by the Biomedical Translation Bridge grant from the Federal Government awarded to Bard1 to support work at Griffith University and the University of Adelaide.”.

Bard1 chief executive officer Dr Leearne Hinch said the SubB2M technology was “a revolutionary platform with potential for the development of tests for monitoring and detection of multiple cancers”.

“A non-invasive, accurate and reliable blood test for monitoring breast cancer has the potential to enable earlier detection, inform treatment decisions and improve health outcomes for women diagnosed with this deadly cancer,” Dr Hinch said.

Bard1 said it planned to develop and commercialize SubB2M-based blood tests for monitoring patients diagnosed with breast cancer for treatment response and recurrence and expected to report outcomes from its SubB2M enzyme-linked immunosorbent assay (Elisa) test validation studies by October 2021.

Bard1 climbed $1.78 or 103.5 percent to $3.50 with 14.9 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says its 16-volunteer phase I trial of NNZ-2591 shows that twice daily oral dosing for seven-day is “safe and well tolerated in healthy volunteers”.

Neuren said the double-blind, placebo-controlled trial of NNZ-2591 would be part of its investigational new drug application to the US Food and Drug Administration preparation for a phase II trial of NNZ-2591 for Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome in 2021.

Neuren chief executive officer Jon Pilcher said the trial was “the first human dosing of NNZ-2591 and we are very pleased with the outcome”.

“Twice daily oral dosing for seven days was safe and well-tolerated at doses we expect to be within the effective therapeutic range, which gives us confidence for dosing patients in our planned phase II trials,” Mr Pilcher said.

The company said no serious adverse events were recorded and the most common adverse event recorded was drowsiness and all subjects completed the dosing except one from the lower dose group following moderate drowsiness and lack of coordination.

Neuren fell 2.5 cents or 1.75 percent to $1.40.

CANN GROUP

Cann says it has bought Satipharm for $C4 million ($A4.06 million) in scrip, expects $1 million in revenue for the six months to June 30, 2021 and has issued a revenue warning.

Cann said it had downgraded its forecast revenues for the 12 months to June 30, 2021 from $15 million to between $8 million and $10 million.

The company said the acquisition of the Cham, Switzerland-based Satipharm would provide rights to proprietary and differentiated cannabinoid delivery technology and expected to generate revenue of $1 million in the six months to June 30, 2021 from the sales of marijuana-based Gelpell capsules.

Cann said Satipharm would provide “immediate entry into the cannabidiol market” as it had distribution rights in UK, Ireland and Eastern Europe

Cann chief executive officer Peter Crock said the Gelpell capsules were “clinically proven to improve the body’s absorption of [cannabidiol] and other cannabinoids”.

“The technology would allow us to develop more targeted and effective dosage forms of both low dose [cannabidiol] and differentiated [tetrahydrocannabinol] prescription formulations of medical cannabis,” Mr Crock said

The company said its forecast revenue change was due to delays obtaining regulatory approvals from Australia and Germany as authorities were “impacted by Covid-19 priorities and resource constraints”.

Cann Group was up half a cent or 0.65 percent to 77.5 cents with 3.8 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it will meet the US Food and Drug Administration to discuss guidance on ATL1102 for Duchenne muscular dystrophy on April 19, 2021.

Antisense said the FDA would provide clarification on pre-clinical requirements to support the development of ATL1102 for Duchenne muscular dystrophy.

The company said as part of the type-C meeting, it would request the FDA consider its data from the six-month monkey toxicity studies and six-month clinical safety data in non-ambulant patients to support a longer-term dosing of ATL1102 in patients.

Antisense fell two cents or 8.9 percent to 20.5 cents with 5.65 million shares traded.

ORTHOCELL

Orthocell says the US Patent and Trademark Office has allowed a patent relating to its Celgro platform for soft tissue regeneration and repair applications.
Orthocell said the patent, entitled 'Method for Producing a Collagen Membrane and Uses Thereof' would protect its intellectual property until June 2033.
Orthocell managing-director Paul Anderson said the patent "complements the recent market approval of the first Celgro product, Striate+ for dental bone and soft tissue repair procedures approved in the US, EU and Australia.
Orthocell fell one cent or 1.8 percent to 55 cents with 1.4 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering has requested a trading halt "for the purpose of considering, planning and executing a capital raising".
Trading will resume on February 17, 2021 or on an earlier announcement.
Visioneering last traded at two cents.

NEUROTECH INTERNATIONAL

Neurotech says it hopes to begin a phase I/II trial of its Mente Autism device combined with marijuana for autism at Melbourne's Monash Children's Hospital by April 2021.
Neurotech said the trial would assess the efficacy of the Mente Autism device in combination with its Dolce medicinal cannabis strain.
In 2016, the company said it had Conformité Européenne (CE) mark for its electro-encephalogram (EEG) based Mente Autism "neuro-feedback" device to help children with autism spectrum disorder (BD: Nov 11, 2016).
Today, the company said through in-vitro testing the Dolce plants demonstrated properties "in relation to suppressing and inhibiting inflammation in neuronal and microglial cells derived from the human brain".
Last year, Neurotech said the Australian Therapeutic Goods Administration revoked approval of the Mente Autism device, prohibiting its sale as a medical device, having approved it in 2017 (BD: Jun 5, 2017; Jan 28, 2020)
Neurotech was up half a cent or 8.6 percent to 6.3 cents with 6.1 million shares traded.

PHARMAUST

Pharmaust says it has started recruitment for its second trial of monepantel for dogs with treatment naïve B cell lymphoma.
Pharmaust said it had recruited "several" dogs and started treatment with its monepantel tablets and six non-eligible dogs were given compassionate treatment the Elanco drug, originally prescribed for sheep round worm.
Last year, Pharmaust said that monepantel for naïve B cell lymphoma in dogs was successful, with one of seven dogs having a 60 percent reduction in tumor size after treatment (BD: May 12, 2020).
Pharmaust was unchanged at 10.5 cents.

CRESO PHARMA

Creso says the Lahore, Punjab-based Route2 Pharm Pvt Ltd will distribute its marijuana products in Pakistan, the Philippines and other markets.
Creso said Route2 had agreed to minimum orders up-to CHF1.71 million ($A2.48 million) for Cannaqix10, Cannaqix50 and Cannadol in the first year of the three-year agreement, with other potential countries including Cambodia, Afghanistan, Azerbaijan, Bangladesh, Georgia, the Maldives, Myanmar, Tajikistan, Turkmenistan, Uzbekistan, and Vietnam.
Creso said Route2 had US Pharmacopeia good manufacturing practice-compliant facilities and the minimum orders would be applicable three months after each product was registered in each exclusive territory, with responsibility to launch and commence distribution within six months after product registration, and would be responsible for registrations, authorizations and certifications.
Creso was up half a cent or 2.2 percent to 23 cents with 54.0 million shares traded.

MGC PHARMACEUTICALS

MGC says its pre-clinical research into marijuana for glioblastoma multiforme has expanded to explore the use of nano technology for delivery systems.
MGC said it was working with the Slovenian National Institute of Biology and Neurosurgery Department at the University Medical Centre to determine the optimal cannabinoid preparation for effective treatment using cannabinoids alone and in combination with temozolomide.
The company said the in-vitro research aimed to develop formulations using a nano-particle delivery system to improve the bioavailability and the blood-brain-barrier issues.
MGC was up 1.1 cents or 16.9 percent to 7.6 cents with 232.15 million shares traded.

ALTERITY THERAPEUTICS

Regal Funds Management says it has reduced its substantial shareholding in Alterity from 238,853,236 shares (11.76%) to 208,853,236 shares (10.28%).
The Sydney-based Regal Funds said that it sold the 30,000,000 shares on February 9 and 10, 2021, for $1,371,000, or 4.57 cents a share.
Alterity was up 0.3 cents or 7.1 percent to 4.5 cents with 26.0 million shares traded.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says it has appointed the head of US operations Dr Oludare Odumosu as its managing-director, replacing Dr Richard Hopkins.
In 2019, the then Zelda said Dr Oludare Odumosu was appointed a director following the merger with Ilera Therapeutics to become Zelira (BD: Dec 2, 2019)
Today, the company said current managing director Dr Richard Hopkins would leave on May 15, 2021, following a transition period.
Zelira chair Osagie Imasogie said Dr Hopkins had “been instrumental in helping facilitate Zelira’s merger and transition to a global revenue generating company”.
“[Dr Hopkins had] overseen the development of a pipeline of clinically validated products that recently launched on the Australian market,” Mr Imasogie said.
Zelira fell 0.2 cents or 2.4 percent to 8.2 cents with 4.95 million shares traded.