Biotech Daily

Tuesday April 6, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMUGENE UP 8%; ACTINOGEN DOWN 5%**

*** CSL COVID-19 HYPERIMMUNE IMMUNOGLOBULIN MISSES ENDPOINTS**

*** BIONOMICS RIGHTS RAISE $20.4m; TOTAL $22.9m**

*** EXOPHARM 'POSITIVE' PHASE I PLEXARIS TRIAL RESULTS**

*** AROA: MYRIAD MORCELLS WOUND TREATMENT FDA 510(k) APPROVAL**

*** NOXOPHARM VEYONDA PATENT APPLICATION**

*** ALLEGRA: SR-HT-GAHNITE SPINAL CAGE SHEEP STUDY 'SUCCESSFUL'**

*** TOTAL BRAIN RECEIVES $1.4m US 'PAYCHECK' FUNDING**

*** CONTROL BIONICS TO RELEASE 7k ASX ESCROW SHARES**

*** CANN GLOBAL TRIALS MARIJUANA FOR MULTIPLE SCLEROSIS**

*** PHARMAUST REQUESTS 'MONEPANTEL SARS-COV-2 RESULTS' HALT**

*** GENETIC SIGNATURES APPOINTS DR NEIL GUNN DIRECTOR**

*** OPTHEA LOSES CO SEC, CFO MIKE TONROE**

*** CRESO APPOINTS JOHN GRIESE US BUSINESS DEVELOPMENT HEAD**

*** NEUROTECH APPOINTS KRISTA BATES DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.84 percent on Tuesday April 6, 2021, with the ASX200 up 57.2 points to 6,885.9 points. Twenty-five of the Biotech Daily Top 40 stocks were up, 12 fell and three traded unchanged.

Imugene was the best, up one cent or 8.3 percent to 13 cents, with 26.4 million shares traded. Osprey and Prescient climbed five percent or more; Amplia, Impedimed and Proteomics improved more than four percent; Next Science, Opthea and Polynovo were up more than three percent; Antisense, Clinuvel, Medical Developments, Oncosil, Optiscan, Resonance and Telix rose two percent or more; Avita, Cochlear, Dimerix, Immutep, Mesoblast, Nova Eye and Starpharma were up more than one percent; with CSL, Kazia, Pro Medicus and Volpara up by less than one percent.

Actinogen led the falls, down 0.2 cents or 5.3 percent to 3.6 cents, with 4.65 million shares traded. Universal Biosensors fell 4.8 percent; Orthocell, Patrys and Uscom were down more than three percent; Cynata and Neuren shed more than two percent; Nanosonics, Paradigm and Pharmaxis were down more than one percent; with Cyclopharm, Genetic Signatures and Resmed down by less than one percent.

CSL

CSL says a 600-patient, phase III trial of its Covig-19 anti-coronavirus intravenous hyperimmune immunoglobulin for Covid-19 did not meet its efficacy endpoints.
CSL said that the hyperimmune immunoglobulin (H-Ig) medicine, known as Covig-19, was hoped to reduce the risk of disease progression when added to standard of care treatment including remdesivir in hospitalized adult patients at risk for serious complications
The company said that the trial was sponsored and funded by the US National Institutes of Health, and was run by the Covig-19 Plasma Alliance.
CSL said that no serious safety signals were raised in the trial.
Last year, CSL said it would develop a plasma product to treat severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the virus that causes Covid-19 (BD: May 6, 2020).
The company said at that time it would develop the product using blood plasma donations by people who had recovered from Covid-19, as they had a high level of antibodies in their blood that fought Covid-19, and the antibodies would be pooled, purified and concentrated to make Covid-19 immunoglobulin, also known as a hyperimmune globulin.
Today, CSL Behring chief medical officer Dr Bill Mezzanotte said that "while the results … are disappointing, we are proud that as an industry we pro-actively and collaboratively pursued this work, and that the program may contribute to a growing understanding of this challenging virus and strategies for patient care".
"We have learned much from our scientific research," Dr Mezzenotte said. "Importantly, we learned that as an industry we have the fortitude and capability to quickly work together for the greater good of human health."
CSL said the phase III, double-blind, placebo-controlled, randomized trial enrolled nearly 600 adult patients at 63 sites in the US and 10 other countries on five continents, with CSL Behring working with Japan's Takeda.
In December, CSL said a phase I trial of the UQ-CSL V451 Covid-19 vaccine was "not going ahead as planned" due to false positive HIV results (BD: Dec 11, 2020).
The company said at that time that the trial had recruited 120 subjects aged 18 to 55 years of age and 96 subjects aged 56 years and above.
The University of Queensland's Prof Trent Munro said: "It was not a safety issue but a diagnostic interference issue," Prof Munro said.
"Eighty-five percent of those receiving two doses had immune responses greater than the convalescent [Covid-19] population," Prof Munro said.
CSL said there was "no possibility the vaccine causes infection" but the implications meant that "significant changes would need to be made to well-established HIV testing procedures … to accommodate rollout of this vaccine".
CSL was up 60 cents or 0.23 percent to $263.60 with 853,419 shares traded.

BIONOMICS

Bionomics says it has raised a total of $22.9 million in a one-for-six non-renounceable rights offer and a concurrent placement at 14.5 cents a share.
Last month, Bionomics said it hoped to raise $20,000,000 through a non-renounceable one-for-six rights issue at 14.5 cents a share as well as an up-to $3,065,063 in a placement (BD: Mar 8, 17, 2021).
In February, the company said it has commitments to raise $15,991,634 at 14.5 cents a share in an underwritten placement, for a phase IIb trial of its anti-anxiety drug BNC210 for post-traumatic stress disorder (BD: Feb 9, 2021).
Today, the company said it raised about $20.4 million in the over-subscribed rights issue.
Bionomics fell 1.5 cents or 6.4 percent to 22 cents.

EXOPHARM

Exopharm says it has “positive” results for its 11-participant, phase I, safety trial of Plexaris for wound healing in healthy volunteers.

Exopharm said the randomized, double-blind, placebo-controlled study was to demonstrate the safety of the product when given to healthy adults as a single sub-cutaneous dose at a skin-punch, biopsy-induced wound.

The company said its Plexaris off-the-shelf (allogeneic) platelet-derived extracellular vesicles (EV) product showed “no untoward or unexpected safety events” in all enrolled participants during the study and after the 30-day follow-up period.

Exopharm said all the wounds healed without skin defects, abnormal scarring or abnormal cosmetic appearance.

Exopharm founder Dr Ian Dixon said the results “confirm Exopharm as a leader in EV medicine manufacture and further validate our [ligand-based exosome affinity purification] manufacturing technology.”

Exopharm head of product evaluation Dr Angus Tester said the results were “very encouraging and are consistent with pre-clinical testing and the expected safety profile of a purified platelet product”.

“This is an important milestone proving Exopharm’s manufacturing capability of a medical-grade product,” Dr Tester said.

Exopharm was up 7.5 cents or 12.9 percent to 65.5 cents.

AROA BIOSURGERY

Aroa says the US Food and Drug Administration has given 510(k) clearance to its sheep stomach-derived Myriad Morcells for irregular wound beds.

Aroa said it received the clearance for the morcellized, or powder form, of its product Myriad Matrix which “conforms to optimize contact with irregular wound beds” and would be provided in a tray for hydration, mixing and pouring.

Aroa research and clinical development head Dr Barnaby May said the “combination of Myriad Morcells and Myriad Matrix helps provide rapid and sustained delivery of biological components important during tissue regeneration as well as a porous scaffold for cell infiltration”.

Last year, the company said it has Conformité Européenne (CE) mark for its Myriad for tissue growth and US Food and Drug Administration approval of its Symphony for wound closure (BD: Jul 30, 2020).

Today, Aroa founder Brian Ward said the clearance for Morcells followed studies showing positive clinical outcomes from the use of Myriad Matrix.

Aroa was up five cents or 4.4 percent to $1.19.

NOXOPHARM

Noxopharm says it has submitted an international patent application to IP (Intellectual Property) Australia for the use of Veyonda to treat septic shock from infections.

Noxopharm said the patent, titled ‘Methods for the treatment of inflammation associated with infection’ was filed on March 30, 2021 and told Biotech Daily that, if granted, the patent would protect its intellectual property until March 30, 2041.

Noxopharm said a granted patent would protect Veyonda, or idronoxil, “in blocking the development of septic shock associated with infections such as Covid-19 and influenza viruses”.

Noxopharm was up 4.5 cents or 7.1 percent to 67.5 cents with 1.2 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says it has successfully completed a sheep pilot study of its strontium hardystonite-Gahnite (Sr-HT-Gahnite) Spinal Cage device.
Allegra said the eight-week study provided “a viable pathway to obtaining a 90-day [US Food and Drug Administration] 510(k) clearance in the near future”.
The company said the study at Adelaide-based South Australian Health and Medical Research Institute conducted dynamic torsion, compression and shear tests for five million cycles and passed without any signs of fracture or failure.
Allegra said that computed tomography (CT) imaging taken at intervals throughout the study showed stable implants with complete fusion in both lumbar and cervical zones, confirming the spinal cage performed as intended.
Allegra said it hoped to reproduce the outcomes in a six-month sheep trial in Australia to obtain approval from the US Food and Drug Administration.
The company said following validation and verification testing it would apply for approval to the Australian Therapeutic Goods Administration in November 2021.
Allegra was unchanged at 34 cents.

TOTAL BRAIN

Total Brain says it has received $US1.05 million ($A1.4 million) from the US Government through the Paycheck Protection Program.
Total Brain said the funding would be used to offset payroll costs for its US employees.
Total Brain was unchanged at 27 cents.

CONTROL BIONICS

Control Bionics says it will release 6,579 shares from ASX escrow on April 16, 2021.
According to Control Bionics’ most recent Appendix 2A new share issue announcement, following the release from escrow, the company will have 50,125,259 shares available for trade on the ASX, with 33,295,381 shares remaining in ASX escrow.
Control Bionics was unchanged at 60 cents.

CANN GLOBAL

Cann Global says that Western Sydney University will trial the efficacy of marijuana for multiple sclerosis.
Cann Global said that the Western Sydney University trial followed the “successful research” by Dr Dedi Meiri at the Haifa, Israel-based Technion which showed that one strain of marijuana “stopped the progression” of multiple sclerosis in mice “and in some cases reversed the damage caused”.
Cann Global was up 0.1 cents or 14.3 percent to 0.8 cents with 45.1 million shares traded.

PHARMAUST

Pharmaust has requested a trading halt pending an announcement regarding testing monepantel against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).
Trading will resume on April 8, 2021 or on an earlier an announcement.
Pharmaust last traded at 9.8 cents.

GENETIC SIGNATURES

Genetic Signatures says it has appointed Dr Neil Gunn as a director.
Genetic Signatures said Dr Gunn had more than 30 years of medical device and diagnostics experience, managing operations in Europe and the US.
The company said Dr Gunn was previously head of Roche Sequencing Solutions and head of Roche's Molecular Diagnostic business unit.
Genetic Signatures fell half a cent or 0.3 percent to $1.57.

OPTHEA

Opthea says company secretary and chief financial officer Michael Tonroe has resigned, effective from June 24, 2021.
Opthea said it had begun a search for "a permanent replacement with requisite expertise".
Opthea managing director Dr Megan Baldwin said that Mr Tonroe joined the then Circadian in 2014 and had "become an integral and valued member of the team, navigating our transition to an ophthalmology focused company, through successful clinical trials, financings and more recently, our US listing on the Nasdaq".
The company said Mr Tonroe would assist in the transition of duties to an interim or permanent replacement in June 2021.
Opthea was up six cents or 3.85 percent to $1.62.

CRESO PHARMA

Creso says it has appointed John Griese as US business development director.
Creso said Mr Griese had about 30 years of experience in sales, consumer package goods operations and supply chain management.
The company said Mr Griese was formerly the chief operating officer at Supreme Cannabis Co and Bloom Farms and previously was employed by Nestle and Pepsico.
Creso said Mr Griese would pursue revenue generating opportunities in North America ahead of "potential legislation of recreational cannabis".
Creso fell one cent or 4.8 percent to 20 cents with 46.1 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed Krista Bates as a non-executive director, effective from April 5, 2021.
Neurotech said Ms Bates had more than 20 years' experience in "the legal market", in turnarounds, structuring, risk mitigation and strategic rollout of commercial initiatives.
The company said Ms Bates was currently a non-executive director of Auscann and Australia-Africa Minerals and Energy Group, a corporate partner at Lavan law firm and has previously held executive and non-executive directorship roles at Credit Intelligence and corporate partner roles at Anjarwalla & Khanna.
Neurotech said that pending shareholder approval Ms Bates would be granted 500,000 options exercisable at nine cents each by May 7, 2023.
Neurotech fell 0.1 cents or 1.3 percent to 7.6 cents with 2.6 million shares traded.