Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: IMPEDIMED UP 17%; NEUREN DOWN 4%**

*** CSL 2021 R&D BRIEFING: 'SPENDING UP, RECOMBINANT FOCUS'**

*** IMPEDIMED TRIAL: 'L-DEX SIGNIFICANTLY REDUCES LYMPHOEDEMA'**

*** ARTRYA $40m IPO FOR SALIX ARTERIAL PLAQUE DETECTION**

*** LIVING CELL $3.5m FOR NTCELL PARKINSON'S TRIAL; RIGHTS FOR $4m MORE**

*** WOKE, MONASH FORMULATE PSILOCYBIN FOR DEPRESSION TRIAL**

*** QUEENSLAND UNI'S JETRA $1.3m FOR FATTY LIVER DISEASE**

*** CLARITY CLOSES SAR-BOMBESIN C-BOBCAT TRIAL EARLY**

*** EMYRIA: EUROFINS TO SCREEN MDMA ANALOGS FOR CNS ACTIVITY**

*** RACE WINS 6th US ZANTRENE PATENT**

*** OSTEOPORE, SINGULAR WORK ON CRANIAL IMPLANT DESIGN TOOL**

*** OPTHEA AGM 20% OPPOSE DIRECTOR OPTIONS; DR JEREMY LEVIN**

*** NANOSONICS 353k CEO RIGHTS AGM**

*** CHIMERIC 7.5m DIRECTOR OPTIONS AGM**

*** ALTERITY EXPANDS BIOMUSE ATH343 MULTIPLE SYSTEM ATROPHY STUDY**

*** ZELIRA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ONCOSIL LOSES 8-YEAR DIRECTOR DR ROGER ASTON BEFORE AGM**

*** ADHERIUM APPOINTS ROBERT SPURR INTERIM CFO**

MARKET REPORT

The Australian stock market slipped 0.08 percent on Tuesday October 19, 2021, with the ASX200 down 6.2 points to 7,374.9 points. Twenty-six of the Biotech Daily Top 40 stocks were up, 11 fell and three traded unchanged. All three Big Caps were up.

Impedimed was best, up 2.5 cents or 16.7 percent to 17.5 cents, with 59.3 million shares traded. Imugene improved 8.4 percent; Oncosil climbed 6.8 percent; Immutep was up 5.4 percent; Actinogen, Osprey, Patrys, Pharmaxis, Prescient and Resonance rose more than four percent; Cyclopharm, Polynovo and Uscom were up more than three percent; Amplia, Kazia, Medical Developments, Mesoblast, Optiscan, Resmed and Volpara rose more than two percent; Clinuvel, Cochlear, Compumedics, Cynata, Orthocell and Pro Medicus were up one percent or more; with CSL, Nanosonics and Opthea up by less than one percent.

Neuren led the falls, down eight cents or 4.1 percent to $1.87, with 217,919 shares traded. Antisense, Dimerix and Proteomics lost more than three percent; Telix shed 2.4 percent; Avita, Next Science, Nova Eye, Paradigm and Universal Biosensors were down more than one percent; with Genetic Signatures down by 0.7 percent.

CSL

By NOAH NICHOLAS

CSL chief medical officer Dr William Mezzanotte says investment continues to increase and that the company has seen progress “across all six therapeutic areas”.

In its 2021 research and development briefing, CSL said it had advanced across all of its scientific platforms, including cell and gene therapy, recombinant technology, plasma fractionation and cell and egg, and mRNA-based vaccines.

The company said that in the year to June 30, 2021 research and development spending increased 8.6 percent to $US1,001.4 million ($A1,351.0 million), or 9.7 percent of total revenue (BD: Aug 18, 2021).

Dr Mezzanotte said CSL’s focus on its recombinant capability to develop immunoglobulin treatments for chronic disease was becoming more prominent due to the improved treatment of cancer and longer life expectancies.

Dr Mezzanotte said CSL was focussed on development of Hizentra for a “diffuse family of diseases”, including a one-year clinical trial “looking at the ability of Hizentra to reduce infectious complications in patients with [chronic lymphatic leukaemia]” to start this year.

CSL Behring head of research and chief scientific officer Dr Andrew Nash said that with the Walter and Eliza Hall Institute CSL would jointly fund a Centre for Biologic Therapies, as well as further collaborations with the Seattle Children’s Research Centre on gene therapies, both of which would “[provide] a potential pipeline for new opportunities”, and were designed to increase CSL’s exposure to innovation outside the company.

CSL Behring head of research and development strategic operations Deidre BeVard said the company would expand its Haegarda hereditary angioedema treatment to Japan with a new drug application in 2022, following promising results of its Haegarda phase III trial.

Ms BeVard said two trials for Hizentra, a phase II trial for systemic sclerosis, and a phase III trial for dermatomyositis were both enrolled and expected to be completed next year.

CSL said its Flucelvax quadrivalent cell-base vaccine paediatric efficacy study showed it was the “first new influenza vaccine with efficacy in children in 20 years”.

Seqirus head of research and development Dr Russell Basser said the paediatric study findings would provide significant strength to the regulatory approval process for the vaccine, and that while it had already achieved authorization for patients older than two in the US and Europe, the company had successfully sought authorization down to patients older than six months on the back of the data.

Dr Basser said that CSL was spending $800 million to build a new cell culture facility in the Melbourne suburb of Tullamarine which would open in 2026 and the project constituted a manufacturing and supply agreement with the Australian Government for antivenoms, Q-fever and seasonal flu vaccines.

Dr Basser said that the scale of CSL’s investment indicated “our optimism for [cell culture] technology and our faith in the Australian manufacturing landscape”.

Dr Basser said that CSL was continuing its work with self-amplifying mRNA vaccines, and had signed a contract worth $US35 million ($A47.0 million) with the US Biomedical Advanced Research and Development Authority to develop and evaluate a self-amplifying mRNA vaccine for H2Nx through to early proof-of-concept.

CSL did not state its financial investment in its collaboration with the University of Queensland on a severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) vaccine or on its Covig-19 intravenous hyperimmune immunoglobulin Covid-19 treatment, both of which had been terminated (BD: Apr 6, 2021).

In December, CSL said the 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).

CSL was up $1.88 or 0.6 percent to $296.18 with 580,253 shares traded.

IMPEDIMED

Impedimed says a 1,200-patient, three-year study shows that L-Dex bioimpedance spectroscopy significantly lowers chronic lymphoedema compared to standard-of-care.
Impedimed said patients using the L-Dex system had a 7.9 percent rate of chronic lymphoedema, compared to 19.2 percent for patients with early detection using a tape measure ($p = 0.016$).
The company said that L-Dex used bioimpedance spectroscopy to detect small lymphoedema-related changes to fluid levels in limbs.
Impedimed managing-director Rich Carreon said the results were “significant, not just for Impedimed, but for cancer patients and survivors at risk of lymphoedema”.
“This study is consistent with the previous studies showing regular monitoring with L-Dex and simple intervention substantially reduce the risk of developing cancer-related lymphoedema,” Mr Carreon said.
“What differentiates this study is, for the first time, we have a level 1, randomized, controlled trial of sufficient size and duration to result in a statistically significant difference between the outcomes using L-Dex and tape measure,” Mr Carreon said.
“This will expand the opportunity for providers to be reimbursed for L-Dex testing, which we believe will result in a significantly wider and quicker adoption of the Sozo technology,” Mr Carreon said.
Impedimed was up 2.5 cents or 16.7 percent to 17.5 cents with 59.3 million shares traded.

ARTRYA

The Perth, Western Australia-based Artrya says it hopes to raise $40 million at $1.35 a share to list on the ASX and develop its Salix arterial imaging software to detect plaque.
Artrya said that a successful offer would value the company at $105.45 million and it hoped to list on the ASX “in late November 2021” under the code AYA.
The company said that Salix used artificial intelligence to automate the analysis and diagnosis of heart computed tomography scans, to help clinicians identify and manage patients at risk of a cardiac arrest.
Artrya co-founder and managing-director John Barrington said there was “a large and growing need for better diagnostics around coronary artery disease”.
The company said that it had received $19 million in start-up funding over the past two years to develop and commercialize its software, with support from angel investors and the Federal Government’s Medical Research Future Fund Biomedtech Horizons program.
Artrya said the funds raised would be used for research and development and expansion into targeted markets in 2022, pending regulatory approvals.
The company said that from a single computed tomography (CT) scan at the point-of-care, Salix could detect and assesses the presence of vulnerable plaque in a patient’s arteries in about 15 minutes.
Artrya said the technology had been developed with the University of Western Australia, Perth’s Harry Perkins Institute of Medical Research and Ontario’s Ottawa Heart Institute.
Artrya said that the Salix system was included in the Australian Register of Therapeutic Goods as a Class 1 medical device in November 2020.
The company said its chair was Bernie Ridgeway, with John Konstantopoulos and executive director.
The offer is expected to open on October 25 and close on October 29, with trading to begin on November 26, 2021.
Artrya said that Bell Potter was the lead manager to the offer.
The prospectus is available at: https://artryaipo.thereachagency.com/offer/.

LIVING CELL TECHNOLOGIES

Living Cell says it has raised $3.5 million in a placement and hopes to raise a further $4 million in a rights issue for a third trial of NTCell for Parkinson's disease.
Living Cell said the placement through Melbourne's 180 Markets Pty Ltd included 142.4 million shares and 269.4 million mandatorily converting notes at 0.85 cents each.
The company said that pending shareholder approval, investors would receive one option for every three new shares, exercisable at 1.5 cents each within 30 months, and in lieu of interest, noteholders would receive one option for each two notes held.
Living Cell said that a two-for-three rights issue at 0.85 cents a share hoped to raise $4 million, with 180 Markets to place any shortfall "on a best endeavors basis".
The company said the record date would be on or about November 10, 2021.
Living Cell said 180 Markets would be paid six percent cash and 7,000,000 options on the same terms as placement options for each $1 million from the placement and shortfall.
The company said the funds would enable planning a third clinical trial of the NTCell encapsulated pig choroid cells for Parkinson's disease "to determine if NTCELL provides neuroprotection to halt or delay the natural progression of Parkinson's disease".
Living Cell said that earlier trials showed safety and some efficacy of NTCELL in patients with mid and late-stage Parkinson's disease, and regulators wanted a larger trial.
The company said it would approval for "the first xeno-transplantation trial … in Australia".
Living Cell fell 0.1 cents or 9.1 percent to one cent with 12.8 million shares traded.

WOKE PHARMACEUTICALS PTY LTD

Woke says it will work with Monash University's Medicines Manufacturing Innovation Centre to develop a low dose psilocybin WP001 for moderate depression.
Woke chief executive officer Nick Woolf told Biotech Daily that he co-founded the Sydney-based company with executive director Matt Hayne to investigate the use of low-dose psilocybin for the treatment of moderate depression and planned to start a phase IIb trial by October 2022 at Sydney's Macquarie University.
Mr Woolf said the company recently raised $1.25 million in seed capital for the project and the Medicines Manufacturing Innovation Centre at Melbourne's Monash University would "formulate a synthetic version of psilocybin into a capsule that modifies the release profile of the drug when ingested and improves the stability of the final product".
In the media release, Woke said that psilocybin was "a naturally occurring psychedelic pro-drug produced by more than 200 fungi".
"When used at a sub-hallucinogenic dose, or at a higher dose in combination with psychotherapy, it has been shown to be effective for the treatment of patients with depression and other mental health disorders," the company said.
Woke said that the randomized, placebo-controlled study at Macquarie University would be "the first of its kind with psilocybin".
The company said that the primary endpoint would be the Grid-Hamilton depression score, with secondary endpoints evaluating biomarkers, as well as neuro-physiological and physiological measures.
Mr Woolf said that the Monash Medicines Manufacturing Innovation Centre had "exceptional insights regarding formulation of novel dosage forms of active drugs such as psilocybin".
The Centre's director Prof Michelle McIntosh said her team was "excited by this opportunity to partner with Woke Pharmaceuticals and provide services that could lead to a novel treatment for patients suffering from depression".
Woke is a private company.

JETRA THERAPEUTICS PTY LTD, UNIQUEST

The University of Queensland says its start-up company, Jetra Therapeutics, has seed investment of $1.3 million from London's IP Group for its JTR-006 for fatty liver disease.
A media release from the University's commercialization arm Uniquest said that Jetra was developing the treatment, based on intellectual property developed by Brisbane's Mater Research Institute in partnership with the University "with the potential to reverse liver damage caused by non-alcoholic fatty liver disease and non-alcoholic steatohepatitis.
Uniquest said that the JTR-006 protein drug candidate for obesity-related liver disease was discovered by Mater and the University of Queensland immunopathology group leader Prof Sumaira Hasnain, with Prof Mike McGuckin and Prof John Prins.
Prof Hasnain said the drug candidate would be used to investigate early-stage liver inflammation, which was difficult to diagnose and typically asymptomatic, and hoped to begin human clinical trials in 2024.
Prof Hasnain said that Australian non-alcoholic fatty liver disease cases were expected to increase by 25 percent by 2030, "suggesting an enormous potential for a tsunami of future [non-alcoholic steatohepatitis] cases".
"We know [non-alcoholic steatohepatitis] is the pre-cursor for more serious end-stage liver disease, including cirrhosis and liver cancer," Prof Hasnain said. "In fact, [non-alcoholic steatohepatitis] is so prevalent in advanced economies around the world that it's predicted it will surpass hepatitis C as the leading cause of liver transplantation."
Prof Hasnain said that the researchers discovered that targeting the liver and pancreas with the engineered cell-signalling peptide interleukin-22 (IL-22) led to a decrease of both accumulated fat and inflammation, as well as improved metabolic measures such as glucose tolerance.
Uniquest chief executive officer Dr Dean Moss said that IP Group's investment "reflected the quality of research at [Mater Research Institute and the University of Queensland] and its ability to attract significant attention from investors".
"The funding will allow Jetra Therapeutics to continue its pre-clinical development plan, including testing the drug candidate in animal models," Dr Moss said.
Jetra is a private company.

CLARITY PHARMACEUTICALS

Clarity says it has recruited all seven patients in its pilot breast cancer trial of SAR-Bombesin, and two further prostate cancer patients at Sydney's St Vincent's Hospital.
Last year, Clarity said it hoped to enrol 10 patients in its 'C-Bobcat' trial assess the diagnostic value of its 64-copper SAR-Bombesin positron emission tomography/computed tomography (PET/CT) imaging for staging of oestrogen receptor (ER+) and progesterone receptor (PR+) positive and human epidermal growth factor receptor 2 negative (HER2-) breast cancer patients with metastatic disease in comparison with conventional imaging (BD: Jul 29, 2020).
Today, the company said its SAR-Bombesin had been used to image seven patients with ER/PR positive metastatic breast cancer and a number of patients through the Therapeutic Goods Administration special access scheme in breast cancer and two prostate cancer patients.
Clarity executive chair Dr Alan Taylor said the trial was closed early "to enable the human clinical data to be used for regulatory submissions, including ... investigational new drug application filings with the US Food and Drug Administration for SAR-Bombesin".
Dr Taylor said that a US SAR-Bombesin clinical trial was expected to begin in 2022.
Clarity was up three cents or 2.7 percent to $1.13.

EMYRIA

Emyria says Luxembourg's Eurofins will screen its library of 3,4-methylene-dioxy-meth-amphetamine (MDMA) analogs for central nervous system (CNS) activity.
Emyria said that the analysis plan developed with Eurofins would provide it and the University of Western Australia "insights to inform lead compound identification and further development … [and] strengthen the intellectual property portfolio for the library".
Emyria managing-director Dr Michael Winlo said the MDMA had completed purity and stability testing at the University of Western Australia.
Emyria was up half a cent or 2.2 percent to 23 cents.

RACE ONCOLOGY

Race says the US Patent and Trademarks Office has granted its sixth US patent for Zantrene, or bisantrene dihydrochloride, for cancer treatment.
Race said the patent, titled 'Combinatorial methods to improve the therapeutic benefit of bisantrene and analogs and derivatives thereof' would protect its intellectual property until July 25, 2034.
Race chief executive officer Phillip Lynch said the patent "provides Race with further protection around uses of Zantrene and related chemical structures that improve the efficacy of Zantrene treatments".
Race was unchanged at $3.16.

OSTEOPORE

Osteopore says it will collaborate with the Perth-based Singular Health on the validation of a patient-specific cranial implant design tool.
Osteopore said it would provide a dataset of 40 craniotomy scans and existing cranial implants with which Singular could validate its artificial intelligence-based cranial implant design engine, and a $10,000 contribution towards the project in cash.
Osteopore said the agreement centred on the design and improvement opportunities afforded by Singular Health's artificial intelligence technologies.
The company said that Singular Health had a $50,000 Commonwealth Scientific and Industrial Research Organisation Kickstart matched grant for the project.
Osteopore fell 1.5 cents or 5.3 percent to 27 cents.

OPTHEA

Opthea says about 20 percent of annual general meeting votes opposed rights for Dr Megan Baldwin and options for directors Dr Julia Haller and Judith Robertson.
Opthea said more than 20 percent of votes opposed the election of director Dr Jeremy Levin, with 31,696,498 votes (20.13%) against and 125,769,978 votes (79.87%) in favor.
The company's meeting results said the greatest opposition was to Ms Robertson's options, with 32,700,059 votes (20.42%) against and 127,431,720 votes (79.58%) in favor.
According to Opthea's most recent annual report, the company had 351,003,541 shares on issue, meaning that the votes against Ms Robertson's options amounted to 9.3 percent of the company, sufficient to call extraordinary general meetings.
The company said that all other resolutions, including the remuneration report, the election of directors Michael Sistenich, Lawrence Gozlan, Dr Haller and Ms Robertson, and the adoption of an amended long-term incentive plan, all passed easily.
Opthea was up one cent or 0.8 percent to $1.28.

NANOSONICS

Nanosonics says its annual general meeting will vote on the grant of 352,884 rights to chief executive officer Michael Kavanagh.
Nanosonics said shareholders would vote on the issue of 190,114 share appreciation rights, 30,010 service rights and 132,760 performance rights, pending separate vesting conditions.
The company said the meeting would vote on the company's remuneration report, the re-election of directors Dr David Fisher and Geoff Wilson, the adoption of a new constitution and the addition of proportional takeover provisions.
The virtual meeting will be held on November 19, 2021 at 11am (AEDT) and would be available at https://web.lumiagm.com/394301091.
Nanosonics was up five cents or 0.8 percent to $6.01 with 854,716 shares traded.

CHIMERIC THERAPEUTICS

Chimeric says its annual general meeting will vote to issue a total of 7.5 million options to directors Cynthia Elkins, Dr George Matcham and Jennifer Chow.
Chimeric said shareholders would vote to grant 2,750,000 options each to Ms Elkins and Dr Matcham, with Ms Elkins's options exercisable at 32 cents each, and Dr Matcham's at 36.5 cents each, as well as grant 2,000,000 options to Ms Chow exercisable at 34 cents each.
The company said that the options would be issued under separate vesting conditions.
Chimeric said that the meeting would vote on the remuneration report, the election of directors Leslie Chong, Dr Lesley Russell, Ms Elkins and Dr Matcham, the 10 percent placement capacity and the approval of the omnibus incentive plan.
The virtual meeting will be held on November 22, 2021 at 10am (AEDT) and would be available at https://web.lumiagm.com/377-737-607.
Chimeric was unchanged at 31 cents with 2.3 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has expanded its Biomuse natural history development program for ATH434 for multiple system atrophy.
In Septmeber, Alterity said the study objective was to define the localization and extent of iron accumulation in patients with early multiple system atrophy and it had enrolled nine patients with multiple system atrophy, 17 with Parkinson's disease and 18 healthy controls (BD: Sep 20, 2021).
Today, the company said it would expand the study to 20 patients with multiple system atrophy.
Alterity said the study "proved to be invaluable in generating data to inform and de-risk the phase II trial design and it will continue to provide longitudinal bio-marker and clinical data to characterize disease progression in a patient population that mirrors those to be enrolled in the phase II study".
The company said that it was planning a 60-patient, phase II, randomized, double-blind, placebo-controlled study of ATH434 in patients with early-stage multiple system atrophy in Australia, New Zealand, Europe, and the US.
Alterity said that the study would explore the effect of ATH434 treatment on imaging and protein biomarkers such as aggregating alpha-synuclein and excess iron, which we contributors to multiple system atrophy pathology.
Alterity was unchanged at 3.1 cents with 7.5 million shares traded.

ZELIRA THERPEUTICS

Zelira has requested a trading halt pending an announcement “in relation to a capital raising and placement in a subsidiary”.
Trading will resume on October 21, 2021, or on an earlier announcement.
Zelira last traded at 3.9 cents.

ONCOSIL MEDICAL

Oncosil says that founding chair and co-inventor of the Brachysil radiation therapy Dr Roger Aston has resigned as a director, effective from today’s annual general meeting.
In September, Oncosil said that Dr Aston would seek re-election as a director at the meeting (BD: Sep 20, 2021).
Oncosil chair Dr Chris Roberts thanks Dr Aston for his service to the company.
Oncosil was up 0.3 cents or 6.8 percent to 4.7 cents with 5.8 million shares traded.

ADHERIUM

Adherium says it has appointed Robert Spurr interim chief financial officer, effective from today.
Adherium said Mr Spurr previously worked for Pacific Hydro and Orica in Chile, Indonesia and Singapore and held a Bachelor of Business from Melbourne’s Deakin University.
Adherium was unchanged at 1.4 cents with 7.3 million shares traded.