



Biotech Daily

Thursday November 11, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: OPTISCAN UP 10%; IMMUTEP DOWN 7%**
- * **BRANDON, MRCF BACK \$40m CUREATOR**
- * **KAZIA ENROLS 1st PATIENT IN DIFFUSE MIDLINE GLIOMA TRIAL**
- * **UNIVERSAL BIOSENSORS, MAYO CLINIC WORK ON TN CANCER TEST**
- * **AROA: STUDY BACKS SHEEP STOMACH MATRIX FOR WOUND HEALING**
- * **ACRUX RECEIVES \$3m FEDERAL R&D TAX INCENTIVE**
- * **MEDLAB COMPLETES \$1.6m FOOD ADDITIVE SALE TO PHARMACARE**
- * **ADALTA HIRES SPARK PLUS FOR ASIA INVESTOR RELATIONS**
- * **AUDEARA, CONNECT HEARING, BLAMEY SAUNDERS PARTNERSHIP**
- * **ANALYTICA: US PATENT FOR PERICOACH PELVIC FLOOR SYSTEM**
- * **CLINUVEL AVOIDS REMUNERATION REPORT 2nd STRIKE**
- * **VANGUARD BELOW 5% IN CSL**

MARKET REPORT

The Australian stock market fell 0.57 percent on Thursday November 11, 2021, with the ASX200 down 42.0 points to 7,381.9 points. Nine of the Biotech Daily Top 40 stocks were up, 20 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Optiscan was the best, up two cents or 10 percent to 22 cents, with 150,000 shares traded. Actinogen climbed 6.1 percent; Amplia was up 5.6 percent; Cynata rose 3.6 percent; with Compumedics, Cyclopharm, Kazia, Volpara and Universal Biosensors up by less than one percent.

Immutep led the falls for the second day in a row, following a trial that showed IMP321 in combination gave “non-significant” breast cancer benefit, down 4.5 cents or 7.4 percent to 56 cents, with 8.7 million shares traded (BD: Nov 10, 2021).

Proteomics lost five percent; Nanosonics, Paradigm and Pharmaxis fell four percent or more; Imugene and Starpharma were down more than three percent; Cochlear, CSL, Genetic Signatures, Mesoblast, Opthea, Patrys, Polynovo and Prescient shed two percent or more; Clinuvel, Orthocell and Pro Medicus were down one percent or more; with Avita, Medical Developments, Next Science, Resmed and Telix down by less than one percent.

BRANDON CAPITAL, MEDICAL RESEARCH COMMERCIALISATION FUND

Brandon Capital says that researchers and entrepreneurs may apply for funding from the \$40 million Cureator: "Australia's first national biotech incubator".

Brandon said that Cureator was established with \$40 million from the Federal Government's Medical Research Future Fund and would be run by the Brandon-managed Medical Research Commercialisation Fund, with Dr Simon Wilkins as head of operations. The company said that previously Dr Wilkins was the University of Melbourne's co-founder and director of translating research.

Brandon said that Cureator aimed "to nurture up to 40 promising research discoveries, and early clinical stage assets, over the next three years to a point where they are ready for further investment".

The company said expressions of interest were being sought for funding "in early 2022". "Cureator is for any biomedical researcher who has had that crucial 'aha' moment," Dr Wilkins said. "The moment a researcher realises their discovery could change a disease state and make a real impact in the world."

"Australia already produces some of the world's leading biomedical research and we have a proven pedigree in clinical development, however, many promising discoveries are still not getting to the point where they can be developed into new drugs and therapies," Dr Wilkins said.

"We want to change this and give this field the runway and support here in Australia to go and capture global markets, just as our trailblazing tech companies have," Dr Wilkins said. The Brandon media release said Cureator would deliver two streams of activity and any Australian small-to-medium size enterprise, or life science researcher at an Australian university or research institute, was eligible to apply.

Brandon said the first stream of \$20 million would provide capital and hands-on expertise to guide the development of at least 25 promising pre-clinical biomedical technologies through to proof-of-concept where they are ready for further investment.

The company said successful applicants would have established, or would establish, a company structure, as part of the incubation process.

Brandon said the second \$20 million stream would support the development of clinical stage drug therapies, with successful recipients having the opportunity to apply for matching investment from the Medical Research Commercialisation Fund (MRCF).

"Together, both streams will result in up to a further \$60 million being invested into the biotech industry over the next three years," the media release said.

"Companies that successfully go through the incubator program may also be eligible for follow-on investment from the MRCF's \$700 million life sciences fund," the Brandon media release said.

"Despite Australia ranking in the top few countries globally for biomedical research, the long-time horizons, and capital-intensive nature of biotech investment, means commercializing promising biomedical discoveries is challenging," Dr Wilkins said.

MRCF chief executive officer Dr Chris Nave said that "while this initial three-year funding round for Cureator is an important step forward, the reality is that gaps, or even chasms, remain in terms of access to adequate capital for biotech translation".

"This is a great start, however, the reality is that to have a meaningful, long-term impact, Australian medical researchers and biotech entrepreneurs require permanent access to this type of funding, and more of it," Dr Nave said.

"While Cureator will provide grant funding, our strategy is to deploy it like venture capitalists, with clear milestones and deliverables," Dr Nave said

A webinar on Cureator will be held on Wednesday November 17, 2021 at 12pm (AEDT).

To register go to: https://zoom.us/webinar/register/WN_yCx0sliqTbm9Gc6Q-uy6ug.

KAZIA THERAPEUTICS

Kazia says the first of up-to 216 patients has been in a phase II, multiple drug trial for diffuse midline gliomas including diffuse intrinsic pontine glioma.

Kazia said the trial included its paxalisib among the experimental arms, along with the Durham, North Carolina-based Chimerix Inc's ONC201 and the Las Vegas, Nevada-based Securabio Inc's panobinostat.

The company said the trial was "expected to provide valuable data on the potential use of the drug in this highly aggressive form of childhood brain cancer".

Kazia said the randomized trial would enrol children and young adults with diffuse midline gliomas, allocate them into six experimental arms and be treated with ONC201 and a combination of ONC201 with paxalisib or ONC201 panobinostat.

The company said that the 'PNOC022' trial would enrol children and young adults with diffuse midline gliomas, a category of brain tumors that included diffuse intrinsic pontine glioma (DIPG).

Kazia said that the study would include separate cohorts comprising patients with newly diagnosed disease, patients who had completed initial radiotherapy and patients who had disease progression after treatment.

The company said the primary endpoint of the study was the proportion of patients who were progression-free at six months for newly diagnosed patients, and overall survival for recurrent patients.

Kazia said the study was sponsored by the Pacific Paediatric Neuro-Oncology Consortium (PNOC) and would be conducted at the University of California San Francisco, with Prof Sabine Mueller as lead investigator.

Prof Mueller said that "no individual drug therapy has ever shown convincing efficacy in this group of patients".

"We plan to apply novel trial design methodologies to understand the potential for combination therapy, using some of the most promising agents in the global pipeline, to change the outcome in this devastating disease," Prof Mueller said.

Kazia chief executive officer Dr James Garner said that "pre-clinical data supports the potential for paxalisib to combine well with certain other therapies, and we are keen to see if this approach is similarly promising in the clinic".

"There remains a desperate need for new treatment options in this disease, and we hope that paxalisib may be able to contribute to better outcomes for patients and their families," Dr Garner said.

Kazia was up three cents or 1.9 percent to \$1.58.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has a master collaboration agreement with the Rochester, Minnesota-based Mayo Clinic Biopharma Diagnostics.

Universal Biosensors said the collaboration would cover "multiple potential projects including work on [its] Tn antigen cancer biosensor".

In April, the company said it had co-developed a Tn antigen finger-prick test to detect most cancers, with Melbourne's Deakin University and Swinburne University and the New South Wales-based University of Wollongong, using Lubricin technology supplied by the Weston, Massachusetts Lubris Biopharma LLC, which would assist with the commercialization (BD: Apr 9, 2021).

Universal Biosensors was up 1.5 cents or 1.9 percent to 81 cents.

AROA BIOSURGERY

Aroa says that research shows its ovine forestomach matrix derived extracellular matrix (ECM) technology aids in wound healing.

Aroa said the study validated the structural and biological characteristics of the Aroa ECM and its multi-layered medical devices, Myriad Matrix for tissue growth and Symphony for wound closure.

The company said the products were also shown to promote and accelerate the migration and proliferation of keratinocyte, a process that is known to aid wound closure.

Aroa said that the hyaluronic acid within the Symphony device played a key role in wound healing, moisture retention, cellular processes, and blood vessel formation.

The company said the the study, titled 'Further Structural Characterization of Ovine Forestomach Matrix and Multi-Layered Extracellular Matrix Composites for Soft Tissue Repair' was published in the Journal of Biomaterials Applications and was available at: <https://journals.sagepub.com/doi/10.1177/08853282211045770>.

Aroa said the study was part of its research program to understand the healing properties and possible future applications for the core technology underpinning Endoform, Myriad, Symphony and Ovitex.

Aroa fell half a cent or 0.45 percent to \$1.115.

ACRUX

Acrux says it has received \$3,073,285 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Acrux said the rebate related to research and development expenditure for the year to June 30, 2021.

Acrux fell half a cent or four percent to 12 cents.

MEDLAB CLINICAL

Medlab says it has completed the \$1.6 million sale of its food additive business to Sydney's Pharmicare.

Last month, Medlab said it sold the food additive business to Pharmicare to reduce its costs and focus on its marijuana based Nanabis and Nanocelle drug delivery system (BD: Oct 20, 2021).

The company said Pharmicare would pay \$1.6 million on November 1, 2021, with a two-year earn out expected to be greater than \$250,000 or five percent of net sales per year during the first and second year.

Today, Medlab said the transaction had cash contributions of \$2.2 million for the transfer of specific intellectual property, pre-paid stock, stock on order and stock on hand.

Medlab was up 1.5 cents or 8.3 percent to 19.5 cents.

ADALTA

Adalta says it has hired Singapore's Spark Plus to assist with its capital markets and investor relations strategy in Asia.

Adalta said it would issue Spark 465,365 shares "in lieu of their entire cash fee" for the initial six-month engagement with Spark agreeing to a six-month voluntary escrow.

Adalta chief executive officer Tim Oldham said the company looked forward to Spark Plus assisting "to expand our coverage in Southeast Asia and Hong Kong".

Adalta was unchanged at 8.5 cents.

AUDEARA

Audeara says it has an Australia distribution partnership with Connect Hearing and Blamey Saunders for its A-01 Bluetooth headphone and the A-01 TV Bundle.

Audeara said both companies were subsidiaries of the Stäfa, Switzerland-based Sonova Holding AG, which specialized in hearing products.

The company said the partnership would take the number of Australian audiology clinics stocking Audeara to more than 800.

Audeara did not disclose any volumes or values of products to be distributed.

Audeara fell half a cent or four percent to 12 cents.

ANALYTICA

Analytica says it the US Patent and Trademark Office has granted a patent relating to its intra-vaginal Pericoach device for stress incontinence.

Analytica said the patent, titled 'Intra vaginal device to aid in training and determining muscle strength' would protect its intellectual property until January 9, 2032.

The company said Pericoach was patent protected in Australia, China and Japan.

Analytica was unchanged at 0.2 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says its annual general meeting narrowly avoided a second-strike remuneration report vote and a consequential potential board spill.

Clinuvel said the remuneration report was opposed by 4,506,261 votes (21.98%) with 15,998,785 votes in favor (78.02%).

Last year, Clinuvel said its annual general meeting voted 35.35 percent of votes against the remuneration report, earning a first strike (BD: Nov 12, 2020).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and, if passed, the directors must stand for re-election.

The resolutions to re-elect Dr Karen Agersborg and Sue Smith were opposed by 13.29 percent and 5.72 percent of the meeting, respectively.

According to the company's most recent filing, Clinuvel had 49,410,338 shares on issue, meaning that the opposition to the remuneration report amounted to 9.1 percent of the company, sufficient to requisition extraordinary general meetings.

Clinuvel fell 31 cents or one percent to \$31.97 with 183,786 shares traded.

CSL

Vanguard and its subsidiaries say they have ceased their substantial shareholding in CSL following a change in investment management for an institutional client.

The Valley Forge, Pennsylvania-based Vanguard Group said it held 2,133,003 shares in CSL with no sell down activity other than the change in investment manager.

CSL fell \$7.39 or 2.35 percent to \$306.83 with 665,475 shares traded.