



Biotech Daily

Wednesday March 20, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CLARITY UP 11.5%; UNIVERSAL BIOSENSORS DOWN 12%**
- * **RMIT OPTICAL GLUCOSE MONITOR FOR DIABETES**
- * **SCIENCE & TECHNOLOGY AUSTRALIA: RAISE R&D SPEND FOR \$100b**
- * **MONASH, SYDNEY UNI ALZHEIMER'S DIAGNOSTIC, IN MICE**
- * **CARTHERICS OPTION OVER OHIO STATE 'TISSUE FACTOR'**
- * **ONCOSIL PLACEMENT, RIGHTS TO RAISE \$7.1m**
- * **CYNATA: EU APPROVES PHASE II CYP-001 GVHD TRIAL**
- * **ADHERIUM ENROLS 1st HAILIE TELE-HEALTH STUDY PATIENT**
- * **AROVELLA: 'IMUGENE ENDS CAR-INKT, ONCARLYTICS COLLABORATION'**
- * **REGENEUS TO LET NON-US, JAPAN PROGENZA PATENTS LAPSE**
- * **INOVIQ FILES AUSTRALIAN EXO-ACE PATENT**
- * **ATO: INVEX CAPITAL RETURN 'NOT DIVIDEND FOR TAX PURPOSES'**
- * **NEUROSCIENTIFIC RECEIVES \$2.2m FEDERAL R&D TAX INCENTIVE**
- * **OPTISCAN RECEIVES \$672k FEDERAL R&D TAX INCENTIVE**
- * **GREGORY GEORGE, G TO THE FOURTH TAKE 10% OF MESOBLAST**
- * **HARVEST LANE TAKES 5% OF PROBIOTEC**

MARKET REPORT

The Australian stock market was down 0.1 percent on Wednesday March 20, 2024, with the ASX200 down 7.4 points to 7,695.8 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and two were untraded.

Clarity was the best, up 31 cents or 11.5 percent to \$3.00, with 1.5 million shares traded. Cynata climbed 5.9 percent; Dimerix was up 3.2 percent; Opthea, Orthocell and Telix rose more than two percent; Cyclopharm and SDI were up more than one percent; with Nanosonics, Neuren and Resmed up by less than one percent.

Yesterday's 53 percent best, Universal Biosensors, led today's falls, down three cents or 12.2 percent to 21.5 cents, with 3.1 million shares traded. Resonance lost 10 percent; Percheron (Antisense) was down 9.6 percent; Actinogen shed 6.25 percent; Paradigm was down 5.2 percent; Medical Developments fell 4.1 percent; 4D Medical, Emvision and Impedimed were down more than three percent; Amplia, Immutep, Nova Eye and Polynovo shed more than two percent; Pro Medicus, Proteomics and Next Science were down more than one percent; with Avita, Cochlear, Clinuvel, CSL and Volpara down by less than one percent.

ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY

RMIT says it has developed an optical sensor for continuous, non-invasive glucose monitoring for diabetes management that is comparable to hand-held finger-prick sensors. RMIT said that Australian Research Council-funded research showed that four infrared peaks in glucose could identify glucose levels in aqueous and biological environments. The Institute said researchers made a 5mm diameter glucose sensor with a 1,600-to-1,700 nanometre waveband that used Bluetooth, powered by a lithium coin battery. The Institute said the primary challenge of affordable, wearable optical glucose testing was the size of the device and filtering out the glucose signals from water absorption peaks in the near infrared spectrum, which made it “almost impossible to accurately differentiate between water and glucose in the blood”.

RMIT said the miniature sensor had shown it could detect glucose levels in the human body from 50-to-400 milligrams per decilitre (2.778mmol/L to 22.2mmol/L) in blood plasma, and had “a comparable limit of detection and sensitivity to larger, laboratory-based sensors”.

The Institute said the prototype device used a surface-mounted light emitting diode and circuits made of 110-micron copper-coated polyimide, making it lightweight and considerably more compact than traditional benchtop spectro-photometers.

RMIT said the flexible, patch-like design of the device could make it suitable as a wearable device on human skin, and “could see it one day integrated into smart watches and other pain-free wearable health trackers”.

The Institute said the performance of the device had been evaluated using aqueous glucose solutions as well as in blood plasma and computational analysis of light-skin interference had shown the surface-mounted device light emitting diode “would penetrate the skin”.

RMIT said results suggested “promising locations for future exploration of optical glucose sensing in clinical setups”.

The Institute said that the research team hoped to collaborate with academic and industry partners to conduct pre-clinical and clinical research for the device.

RMIT said non-invasive glucose sensing had been a target for about 30 years due to its implications for pain-free monitoring and that although optical glucose sensing techniques had been reported, “they require complex optical instrumentation usually found in laboratories, making them unsuitable for regular patient use”.

The Institute said it had filed a patent application related to the optical glucose sensor technology.

RMIT said the development of a wearable glucose sensor was part of the Australian Research Council’s Meta Health Sensors Flagship research program dedicated to developing meta-optical sensors for medical technology applications.

The Institute said the research, titled ‘Miniaturized Optical Glucose Sensor Using 1600–1700 nm Near-Infrared Light’ was published in *Advanced Sensor Research* with the full article available at: <https://onlinelibrary.wiley.com/doi/10.1002/adsr.202300160>.

Lead author Mingjie Yang said that prior to the discovery there was “no consensus on the unique spectroscopic signature of glucose, largely because the [oxygen-hydrogen] bonds targeted in near-infrared spectroscopy for glucose detection are also abundant in water”.

“This similarity makes it challenging to distinguish between glucose and water signals, especially in complex biological fluids and tissues,” Ms Yang said. “We optimized spectroscopy setup and analyzed transmittance to identify peaks unique to glucose.”

“Our discovery finally provides the information necessary to move forward with miniaturized optical glucose sensing and we have developed a device prototype to suggest the foundation for futuristic non-invasive glucose sensor,” Ms Yang said.

SCIENCE & TECHNOLOGY AUSTRALIA

Science & Technology Australia says investing three percent of gross domestic product (GDP) to research and development would return \$100 billion.

Science & Technology Australia said its president Prof Sharath Sriram presented the analysis at the National Press Club in Canberra today, showing that investing three percent of GDP into research and development would increase the Australian economy by \$100 billion and provide 42,000 jobs.

The industry organization said Australian spending on research and development as a percentage of GDP had been in decline for more than a decade, and was currently at less than 2.0 percent, half of US investment and a third of South Korean investment.

“If we don’t become an innovation-driven economy, then we will be a nation of consumers rather than creators,” Prof Sriram said.

“We will end up paying an ever-increasing rent to the rest of the world,” Prof Sriram said.

“Unless we become a smarter country, we’re doomed to become a poorer one,” Prof Sriram said.

Science & Technology Australia said Prof Sriram’s address was part of its Science Meets Parliament program and he had shown “how to create an innovation ecosystem that will secure the country’s economic future, and warn of the consequences of failing to do so”.

MONASH UNIVERSITY, UNIVERSITY OF SYDNEY

Monash University says with the University of Sydney it has developed sensors that can monitor neuro-degenerative disease progression, including Alzheimer’s.

Monash University said a team of researchers had found a method of detecting neuro-degenerative diseases by using sensors that could differentiate the amyloid protein clusters associated with Alzheimer’s.

The University said researchers tested the sensors’ performance on samples taken from the brains of models of Alzheimer’s disease in mice, and observed that the fluorescence patterns differed between 6-month and 12-month-stages of the disease.

Monash said the study, titled ‘A Coumarin-Based Array for the Discrimination of Amyloids’ was published in the journal American Chemical Society Sensors, with the full article available at: <https://pubs.acs.org/doi/10.1021/acssensors.3c01334>.

Lead researcher and Monash University fellow Dr Amandeep Kaur said Alzheimer’s was “an irreversible neurodegenerative disorder; however, there are many advantages to early detection including enhanced medical attention, management of symptoms and, hopefully, future treatments that will be able to target the disease in its earliest stages, before irreversible brain damage or cognitive decline has occurred”.

“Our team focused on developing a versatile fluorescent sensor array for amyloids to monitor Alzheimer’s and other disease progression and to distinguish these disease-associated amyloids from similar, naturally occurring amyloids that play functional roles,” said Dr Kaur. “It is our hope this method, using an array of sensors that can light up amyloids, could be used as a tool for researchers to help distinguish between many different types of amyloids and could inform new strategies for early and decisive diagnosis of amyloid-related diseases.”

The research study concluded: “The versatility of the array was also demonstrated through the discrimination of functional amyloids”.

“These results demonstrate the utility of our fluorescent sensing array for the detection of amyloids implicated in Alzheimer’s disease and the potential it holds as a tool for researchers investigating functional amyloids, such as hydrophobins,” the article concluded.

CARTHERICS PTY LTD

Cartherics says it has will evaluate Ohio State University's intellectual property using "tissue factor" as a target for its chimeric antigen receptor natural-killer (CAR-NK) cells. Cartherics said it would use its induced pluripotent stem cell-derived natural-killer cells to evaluate the Columbus-based Ohio State University's intellectual property and subject to the results, would then exercise the option to negotiate a commercial licence of the technology.

The company said tissue factor was a coagulation factor that was "aberrantly expressed in a range of tumor tissues and tumor blood vessels" and the Ohio State University's intellectual property included natural-killer cell line NK92 carrying a chimeric antigen receptor-targeting tissue factor that was effective in killing tumors in mice, including triple negative breast cancer and multiple myeloma.

Cartherics said it hoped to generate chimeric antigen receptor constructs based on the Ohio State University's technology and insert them into its induced pluripotent stem cell-derived natural-killer cells.

The company said the resultant tissue factor-chimeric antigen receptor natural-killer cells would then be assessed for in-vitro and in-vivo efficacy against relevant human cancer cell lines.

Cartherics chief executive officer Prof Alan Trounson said the company was "delighted to be working with Ohio State to explore tissue factor as a target for our CAR-NK platform". "Tissue factor represents a new tumor target for Cartherics, complementing and expanding the extensive work we've done with TAG-72, the target for our lead product, CTH-401," Prof Trounson said.

Cartherics Pty Ltd is a private company.

ONCOSIL MEDICAL

Oncosil says it has "commitments" for a \$1.48 million placement at 0.5 cents a share and hopes to raise up-to \$5.65 million in an underwritten, one-for-two entitlement offer.

Oncosil said the offer price was a 37 percent discount to the 15-day volume weighted average price on March 15, 2024.

The company said for every two shares subscribed in the placement and rights offer, investors would receive one long-dated attaching option and two short-dated options.

Oncosil said that the short-dated options would be exercisable at 0.9 cents each by June 30, 2025, while the long-dated options would be exercisable at three cents each, by April 30, 2027.

The company said funds would be used to seek regulatory approvals and commercialize its pancreatic cancer treatment device, including clinical trials of the device, manufacturing and supply chain costs and general working capital.

Oncosil said chair Douglas Cubbin had agreed to subscribe for \$75,000 of the placement, subject to shareholder approval.

The company said the entitlement offer had a record date of March 28, would open on April 4 and close on April 24, 2024.

Oncosil managing-director Nigel Lange said the company was "currently working on cost reduction strategies and will communicate this to the market in due course".

"In addition, funds will be applied to the validation and commissioning of the Macquarie Park facility to enhance the robustness of the supply chain," Mr Lange said.

Oncosil said Forrest Capital Pty Ltd and McFarlane Cameron Pty Ltd were joint lead managers to the raise, and would underwrite the entitlement offer to \$2 million.

Oncosil fell 0.05 cents or 6.7 percent to 0.7 cents with 9.1 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has EU regulatory and ethics approval for a 60-patient, randomized, phase II, clinical trial of CYP-001 for high-risk acute graft versus host disease (GvHD).

Earlier this month, Cynata said it dosed the first US patient in the phase II trial of CYP-001 with steroids for high-risk acute graft versus host disease (BD: Mar 5, 2024).

Today, the company said the trial would study the Cymerus stem cell drug CYP-001 with steroids compared to steroids and placebo in high-risk acute GvHD patients.

The company said half of the trial sites were located in the EU, including in Spain, France, Italy and Lithuania, and that the approval was the “final step in the regulatory and ethics approval process for the trial” following US, Australia and Turkey approvals.

Cynata chief executive officer Dr Kilian Kelly said “the successful outcome of this application further underlines the strength of the company’s regulatory dossier, and the global applicability of our technology”.

Cynata was up one cent or 5.9 percent to 18 cents.

ADHERIUM

Adherium says it has enrolled the first of 2,500 patients in a US electronic health study of its Hailie inhaler sensor for chronic obstructive pulmonary disease and asthma.

Adherium said the two-year study with the Salt Lake City, Utah-based Intermountain Health hospital system and New York’s Carecentra included a purchase order for 4,000 Hailie sensors and would involve five of Intermountain’s facilities.

The company said the study would use its Hailie sensors to provide real-time, remote data to Carecentra’s software which would continuously monitor patient risk levels including signals of when and how patients were using prescribed inhaler medication.

Adherium said Carecentra’s platform would assess health risk, recommend behavioral shifts in inhaler technique or adherence and alert Intermountain Health to intervene and tailor treatment to improve patient outcomes.

Adherium chief executive officer Dr Paul Mastoridis said the study was “a groundbreaking partnership that accelerates the trajectory of Adherium both clinically and financially in line with our recent pivot to full commercialization in the US through ... strategic partnerships”.

“The study will provide further clinical validation of Hailie’s next generation sensors and measure behavioral shifts and healthcare cost reductions, to validate how Hailie enables a new value-based e-healthcare model that benefits everyone,” Dr Mastoridis said.

Adherium was untraded at 4.1 cents.

AROVELLA THERAPEUTICS, IMUGENE

Arovella says its research collaboration to combine its ALA-101 with Imugene’s Oncarlytics therapy has been “terminated” by Imugene, effective immediately.

Last year, Arovella said with Imugene it would advance to in-vivo testing of Arovella’s chimeric antigen receptor-invariant killer T-cell therapy, called ALA-101, and Imugene’s Oncarlytics therapy CF33-CD19, in mice (BD: Feb 10, 2023).

Today, the company said in-vivo data would no longer be generated and the termination would not impact its development of ALA-101 for CD19-positive blood cancers.

Arovella said since the collaboration began it had secured a gastric and pancreatic cancer target, called claudin 18.2, and its IL-12-TM armoring technology, which it would develop for a range of solid tumors, and there was no financial impact from the termination.

Arovella fell three cents or 19.35 percent to 12.5 cents with 13.3 million shares traded.

Imugene was unchanged at 11 cents with 27.2 million shares traded.

REGENEUS

Regeneus says it will allow three patents to lapse, which protect its Progenza fat-derived stem cells in Australia, Singapore, Canada, the UK and European countries.

Last month, Regeneus said its extraordinary general meeting would vote to acquire the Atlanta, Georgia-based Cambium Medical Technologies for its Elate Ocular for dry eye disease and change its name to 'Cambium Bio' (BD: Feb 23, 2024).

Today, the company said Progenza required good manufacturing practice phase I results before a phase II study, and that given the patents would expire in mid-2032 it believed it was "unlikely that Progenza can be developed and approved in markets outside the US and Japan within the remaining patent term".

Regeneus said losing the patents would allow it to reduce overall intellectual property costs and allocate more resources to advance Progenza as a treatment for knee osteoarthritis in the US and Japan.

Regeneus was unchanged at half a cent.

INOVIQ

Inoviq says it has filed an Australian provisional patent application for its Exo-ace therapeutic exosome technology with IP Australia.

Inoviq said the patent, if approved, would protect its Exo-ace technology for large scale isolation of exosomes.

The company said the patent was titled 'Resin compositions and methods of use' and if approved would protect its intellectual property until 2045.

Inoviq fell half a cent or 0.85 percent to 58.5 cents.

INVEX THERAPEUTICS

Invex says the Australian Taxation Office will not consider its 14 cents a share capital return as a dividend for Australian tax purposes for its shareholders.

Last year, Invex said its extraordinary general meeting voted 99.98 percent in favor of the return of \$14.0 million in capital to shareholders (BD: Dec 6, 2023).

Invex was untraded at 8.9 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has received \$2,211,829 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Neuroscientific said the incentive related to expenditure for the year to June 30, 2023.

Neuroscientific was up half a cent or 10.6 percent to 5.2 cents.

OPTISCAN IMAGING

Optiscan says it has received \$672,320 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Optiscan said the rebate related to expenditure for the year to June 30, 2023.

Optiscan fell 0.2 cents or 2.4 percent to 8.1 cents.

MESOBLAST

Gregory George and G to the Fourth Investments say they have increased their holding in Mesoblast from 66,366,800 shares (8.15%) to 116,416,795 shares (10.23%).

The Tampa, Florida-based Mr George said with Grant George and James George he bought and sold shares between November 2, 2023 and January 22, 2024, with the largest purchases being 50,000,000 shares for \$15,000,000 in an entitlement offer and placement at 30 cents a share.

Last week, Mesoblast said that it had "firm commitments" for \$36.7 million in its retail rights offer to complete its capital raise at 30 cents a share, taking the total raised to \$97 million (BD: Mar 14, 2024).

Mesoblast was unchanged at 33.5 cents with 5.9 million shares traded.

PROBIOTEC

Harvest Lane Asset Management Pty Ltd says it has become substantial in Probiotec with the purchase of 4,163,291 shares, or 5.12 percent.

The Sydney-based Harvest Lane said that between December 22, 2023 and March 15, 2024 it bought the shares at prices ranging from \$2.76 to \$2.90.

Probiotec was unchanged at \$2.79.