

Biotech Daily

Thursday September 12, 2024

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 1.1 percent on Thursday September 12, 2024, with the ASX200 up 87.8 points to 8,075.7 points. Twenty of the Biotech Daily Top 40 companies were up, 11 fell, eight traded unchanged and one was untraded.

Impedimed was the best, up 0.8 cents or 18.2 percent to 5.2 cents, with 5.3 million shares traded. Dimerix climbed 11.5 percent; Percheron was up 6.2 percent; Cynata and Polynovo were up five percent or more; 4D Medical, Paradigm, Pro Medicus and Telix improved more than four percent; Mesoblast, Neuren, Nova Eye, Opthea and SDI rose more than two percent; Avita, Clarity, Clinuvel, Cochlear, Immutep, Medadvisor and Orthocell were up one percent or more; with CSL up by 0.6 percent.

Proteomics led the falls for the second day in a row, down eight cents or 11.3 percent to 63 cents, with 1.5 million shares traded. Universal Biosensors lost 10.7 percent; Actinogen was down 5.3 percent; Emvision and Prescient fell more than four percent; Compumedics, Imugene and Syntara were down three percent or more; Nanosonics shed 2.2 percent; Alcidion and Aroa were down more than one percent; with Resmed down by 0.05 percent.

VALE LEON SERRY (28.10.1941 – 11.9.2024)

Biotech Daily is deeply saddened by the death, yesterday, of the doyen of Australian biotechnology Leon Serry, AM.

Leon was the founder of Circadian Technologies (now Opthea) and its spin-out companies including Axon, Antisense (now Percheron), Metabolic (now Polynovo) and Optiscan. Leon was generous with his time and was constantly concerned with the further development of the Australian biotechnology sector, but he invested in other ASX-listed and non-listed companies and was very well-known across the industry.

He was awarded a Member of the Order of Australia (AM) on January 26, 2017 for "significant service to the biotechnology industry, to the development and commercialization of biomedical science, and as a mentor".

In 2008, Leon officially retired from Circadian but told Biotech Daily: "I left Circadian on Friday, set up this office on Sunday and was in here at 7.30am on Monday. My wife expected me to be home early, but on my first day I got home at 7pm." "Put it this way, I'm not retiring."

In that 2008 interview Leon avoided some questions about his childhood, but boasted that in 1960 he was the youngest qualified accountant in Australia.

He was born in Newcastle New South Wales where his father ran the Government parachute factory during the war and moved with his family to Melbourne, leaving Camberwell High School at 15 to join Nicholas Aspro as an assistant cost accountant. He studied accountancy part-time at Swinburne Tech (as it was then) qualifying at 19 and completed his Matriculation (Year 12) in one year of night school.

Despite winning a place in Law at the University of Melbourne and a Commonwealth Scholarship, he discontinued after six months "because I ran out of funds".

Instead, he joined the Leighton construction company and raised £A500,000 when he listed the company on the ASX in 1962.

"I read the Time magazine article on Interferon as a potential treatment for cancer," Leon said. "I'd already made some money and wanted to give something back to the community and that's when I started Circadian. I went to Monash University and found melatonin for jetlag and sleep disorders. "Universities don't have a bent for commercialization, but you have to get funding for science - and to cure diseases you need commercialization." He formed Circadian in 1984 and the company listed on the ASX the following year, Australia's first ASX-listed biotechnology company.

Leon Serry had a rapid-fire imagination and was a volcano of ideas. His desk was covered with his famous yellow Post-Its - notes to himself on things to be done.

Former Circadian and Opthea chief executive officer Dr Megan Baldwin said that "We and everyone at Opthea are deeply saddened by Leon's passing."

Graeme Kaufman writes: I was fortunate indeed to have spent seven years working with Leon Serry at Circadian. The funding model he pioneered has formed the blueprint for the Australian biotech industry. Leon was a true entrepreneur, having at an early age embarked on several business ventures, ranging from a recruitment agency through to a homewares store - each one a story in itself. But he saw the great medical research being conducted in Australia, recognising the difficulty in obtaining funding was a major obstacle for commercialisation. And so Circadian was born, and the landscape forever changed. But it was more than that. Leon fostered and mentored scores of future leaders in the sector – and I think it is for that he will be most remembered. We have all learnt a lot from Leon, and we will miss him.

Leon is survived by his wife Vivienne, children: David, Davina, Emily and Karen; and 15 grand-children.

GENETIC TECHNOLOGIES

Genetic Technologies says its rights offer at four cents a share has raised \$324,648, leaving a \$3,553,145 shortfall.

In July, Genetic Technologies said it hoped to raise \$3.85 million in a rights offer at four cents, with one option for every share issued (BD: Jul 26, 2024).

Today, the company said that in addition to pre-commitments of \$500,000 from directors and others along with applications totalled about \$1 million.

Genetic Technologies said that no allotments would occur until the minimum of \$2 million in applications were received and that it was actively working with brokers to place the shortfall with "significant interest already received".

Genetic Technologies fell 0.4 cents or 9.3 percent to 3.9 cents.

FIREBRICK PHARMA

Firebrick says it has opened a share plan to raise \$2,000,000 at 5.5 cents a share, with investors able to buy up-to \$30,000 worth of shares each.

Firebrick said the issue price was a 16.2 percent discount to the five-day volume weighted average price

The company said it would use the proceeds to expand marketing for its Nasodine nasal spray in Singapore and the US, including promotion to healthcare professionals and pursuing pharmacy distribution and marketing partnerships, as well as working capital. Firebrick said the share price was for shareholders on the record date September 11, would open on September 17 and close on October 7, 2024.

Firebrick fell 0.9 cents or 13.85 percent to 5.6 cents with 1.2 million shares traded.

MEMPHASYS

Memphasys says it has 'firm commitments' to raise \$1.0 million through a placement at 0.8 cents a share and hopes to raise \$1.0 million in a share plan.

Memphasys said both the capital raising issue price of 0.8 cents a share was a 20 percent discount to the five-day volume-weighted average price, and each share bought would come with one option exercisable at 1.1 cents within two years.

The company said the share plan had a record date of September 11, would open on September 20 and close on October 22, 2024.

Memphasys said proceeds would go towards a clinical trial of its Felix system in Japan, an equine fertility study, and an oxidative stress measurement system study.

The company said Canaccord Genuity was the lead manager for the placement.

Memphasys said that Peters Investments Pty Ltd had agreed to extend the maturity date for its \$3 million convertible note to June 30, 2025, conditional on shareholders approving the Peters Investments to increase its voting power from above 20 percent as a result of any conversion of convertible notes to shares, prior to November 30, 2024.

In 2022, the company said director Andrew Goodall had sold a \$1.35 million convertible note to major shareholder, the Cottlesloe, Western Australia-based Peters Investments, and that should the note be converted under the current capital structure, Peters Investments would own about 32 percent of the company. (BD: Jan 19, 2022). Memphasys fell 0.1 cents or 11.1 percent to 0.8 cents.

CLARITY PHARMACEUTICALS

Clarity says data from three patients in cohort four of its 44-patient phase I/IIa trial shows copper-67 Sar-bis-PSMA to be safe and potentially reduce prostate-specific antigen. In 2022, Clarity said it treated the first patient in its 'Secure' phase I/IIa trial of Cu-67 Sar-bis- prostate specific membrane antigen (PSMA) for metastatic non-resectable prostate cancer and in 2023 said it had treated the first cohort in the trial and would increase the dose to 8GBq (gigabecquerels) in cohort two (BD: Oct 7, 2022; May 24, 2023). In April, the company said the first patient treated with two doses of 8.0GBq of Cu-67 Sar-

Today, Clarity said it dosed three patients in cohort four, the last dose escalation phase of the trial, which administered two to four doses of Cu-67 Sar-bis-PSMA at 12GBg.

Bis-PSMA has had a "complete response" (BD: Apr 30, 2024).

The company said that two of the patients had completed the dose limiting toxicity period and one would complete it by the end of September.

The company said the safety profile of multiple doses was positive, with almost all adverse events being mild or moderate, "almost all" events either resolved or improved at the last assessment, and with no dose limiting toxicities observed to date.

Clarity said preliminary data showed a reduction in prostate-specific antigen following treatment in both patients who had completed the dose-limiting toxicities, with drops of "more than 60 percent" in the weeks following dosage, and that the largest drop was a fall of 92.3 percent in a patient who had failed several lines of prior therapy.

Clarity said the safety review committee recommended the trial proceed to enroll the last three patients of cohort four, and pending evaluation, it would begin phase II of the study. Clarity chair Dr Alan Taylor said the company would use the data to inform the next stages of the clinical development program, including the expanded cohort in the Secure study and subsequently the phase III trial prior to regulatory approval and commercial rollout. "The positive safety profile of copper-67 Sar-bis-PSMA, particularly compared to agents currently used to treat prostate cancer, lends itself to the treatment of patients much earlier in their disease," Dr Taylor said.

Clarity was up 12 cents or 1.6 percent to \$7.49 with 1.5 million shares traded.

NEUROSCIENCE RESEARCH AUSTRALIA

Neuroscience Research Australia says it has developed a new method of "functional conductivity" brain imaging, that reveals the electrical properties of tissue.

Neura, formerly the Prince of Wales Medical Research Foundation, said that, unlike traditional techniques like magnetic resonance imaging (MRI) and computed tomography (CT) which were structural, conductivity imaging directly detected brain electrical activity and allowed researchers to detect, map and quantify neural activity.

Neura said functional conductivity imaging offered a "precise and non-invasive way" to study how diseases of the brain impact patients, and worked by combining high-resolution imaging with real-time tissue function data.

The research, titled 'Functional Conductivity Imaging: Quantitative Mapping of Brain Activity', was published in Physical and Engineering Sciences in Medicine, with the full article at: https://link.springer.com/article/10.1007/s13246-024-01484-z.

Neura researcher Prof Caroline Rae said that while "conventional [functional MRI] is based on changes in blood flow to the brain that occurs some seconds after a stimulus, the new method may be directly detecting brain electrical activity, making it a powerful tool for early and precise diagnosis ... [and] abnormal conductivity in tissues can be an early indicator of neurological disorders such as dementia or Parkinson's disease, or even cardiovascular problems".

DIMERIX

Dimerix says it has opened enrollment at its first paediatric site for FSGS patients aged 12 to 17-years-old in its phase III trial of DMX-200 for kidney disease.

In 2022, Dimerix said it had recruited the first of 286 patients in the phase III trial of DMX200 for focal segmental glomerulo-sclerosis (FSGS) (BD: May 31, 2022).

Today, the company said 15 of its 170-planned trial sites were specifically for paediatric and adolescent patients, with the first site in Mexico, and it hoped to recruit about 22 patients who would be dosed with 120mg DMX-200 twice daily, the same dose as adults. Dimerix said FSGS was the one of the leading causes of kidney failure in children, with 20 percent of nephrotic syndrome presentations caused by it, and that if the paediatric cohort was successful, DMX-200 could be expanded for sale to adolescents in territories including the US and Europe.

The company said recruitment was "on-track" with interim analysis expected by mid-2025. Dimerix said it had appointed Dr Howard Trachtman to its medical advisory board. Dimerix was up 4.5 cents or 11.5 percent to 43.5 cents with 5.7 million shares traded.

BLINKLAB

Blinklab says the Groningen, Netherlands-based Inter-psy will run a prospective study of its autism diagnostic application in children between two-to-six years old.

Blinklab said Inter-psy was a "large, autism expertise centre in the Netherlands" that offered diagnostics, guidance and treatment for young children, adolescents, adults and the elderly with psychological and psychiatric complaints.

The company said Inter-psy's single-site, prospective, double-blind, within-subject comparison study would mirror the design of its proposed US Food and Drug Administration regulatory trial, with results to help refine the experimental parameters and optimize machine learning algorithms for its 510(k) FDA registrational study. Blinklab said the deal with Inter-psy would be for exclusive co-operation for three years starting from when the first data was collected from each patient, and that either party could terminate with six months' notice prior to yearly renewal.

Blinklab chair Brian Leedman said "Australia has comparable wait times for diagnosis of autism as experienced in Europe and the US ... our BlinkLab technology has the potential to significantly reduce wait times through early diagnosis resulting in treatment at a formative age where early intervention can lead to better outcomes for children and their caregivers".

Blinklab chief executive officer Dr Henk-Jan Boele said "our collaboration with Inter-psy is one of the final steps in the prospective validation of Blinklab's platform before we commence our FDA registration trial later this year".

"Our Blinklab team is in the final phase of fine-tuning our [artificial intelligence] models and algorithms to ensure they meet the highest standards of accuracy, safety, and efficiency," Dr Boele said.

Blinklab was up 2.5 cents or 11.6 percent to 24 cents.

STARPHARMA HOLDINGS

Starpharma says it has received \$5.5m from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.

Starpharma said the incentive related to research and development expenditure for the year to June 30, 2024.

Starpharma was unchanged at 9.3 cents.

COGSTATE

Cogstate says its annual general meeting will vote to approve 920,251 performance rights to chief executive officer Brad O'Connor pending revenue hurdles.

Cogstate said Mr O'Connor's performance rights, in addition to his \$US440,000 (\$A658,647) base salary, were part of his inventive plan and would vest in two equal tranches, with 20 percent of the first tranche vesting should the company reach an eight percent compound annual growth rate (CAGR), and the final 80 percent of the first tranche vesting if the company reached a 17 percent CAGR.

The company said 20 percent of the second tranche would vest should the company reach a 10 percent CAGR, with the final 80 percent to vest on reaching 25 percent CAGR. Cogstate said investors would vote to re-elect directors Dr Richard Mohs and Kim Wenn, as well as adopt the remuneration plan.

The meeting will be held at Level 13, 664 Collins Street, Melbourne and online, on October 23, 2024 at 9:30am AEDT.

Cogstate was up 2.5 cents or 2.6 percent to 97.5 cents.

LBT INNOVATIONS

LBT director Daniel Hill says that through Viking BCM Pty Ltd his 212,665,188 shareholding has been diluted from 13.69 percent to 12.34 percent.

The Adelaide-based Daniel Hill said that through the Brisbane-based Viking and between July 10 and September 11, 2024 he was diluted "through the successive issue of shares". LBT was unchanged at 1.3 cents with 2.1 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says chief executive officer Steven Yatomi-Clarke will resign to "pursue a new appointment" with Aurora Biosynthetics but will remain until the end of February 2025. In 2016, Prescient said that its founding non-executive director Steven Yatomi-Clarke had been appointed chief executive officer and managing-director (BD: Feb 15, 2016). Today, the company said the board would search for a new chief executive officer, with chair Steve Engle to act as executive chair if required until the new chief executive was appointed, with Mr Yatomi-Clarke to remain "available as a consultant" to provide ongoing assistance.

Prescient said Mr Yatomi-Clarke would be the inaugural chief executive officer of the private company Aurora Biosynthetics that researched RNA.

Prescient chair Steve Engle said "the board of directors and I deeply appreciate Steven's outstanding leadership and strategic vision in building the company and an international [research and development] team over the last eight years and gaining the support of some of the most renowned thought leaders in cancer therapies".

"He has led the development of our PTX-100 oncology candidate, which began as a research stage project, and has produced positive clinical results, such that the project is now on the cusp of initiating a phase II study," Mr Engle said.

"In addition, Steven has positioned Prescient very favorably in the nascent cell therapy field with two enabling platform technologies, by devising Cellpryme and leading its development, and identifying the potential of an innovative modular approach in cell therapy, creating Omnicar with licences from technology pioneers Penn and Oxford," Mr Engle said.

Prescient fell 0.2 cents or 4.65 percent to 4.1 cents with 5.1 million shares traded.

FIREBRICK PHARMA

Firebrick says non-executive director Dr Richard Treagus has resigned, effective September 30, 2024.

Firebrick said Dr Treagus had been a director since June, 2022 but had decided to focus on his other board roles and business commitments.

QBIOTICS

Qbiotics says it has appointed six members to a clinical advisory board, which would be shared by Prof Alexander Eggermont.

Qbiotics said the clinical advisory board would provide guidance and advice for its oncology program, and included Prof Aurelien Marabelle, Prof Kevin Harrington, Prof Ignacio Melero, Dr Edmund Bartlett, Prof Jason Luke and Dr Alan Barge.

The company said Prof Eggermont had worked in oncology for more than 37 years and was currently the chief scientific officer of the Princess Maxima Center for Paediatric Oncology and a professor at the Utrecht, Netherlands' University Medical Center. Qbiotics said Prof Marabelle was a professor of clinical immunology at the Paris-based Gustave Roussy Cancer Centre; Prof Harrington was London's Royal Marsden Hospital's head of radiotherapy and imaging; Prof Melero was a co-director of immunology and immunotherapy at Spain's university of Navarra; Dr Bartlett was a surgeon at New York's Sloan Kettering Cancer Center; Prof Luke worked at the University of Pittsburg; and Dr Barge co-founded Carrick Therapeutics.

Qbiotics is a public unlisted company