



Biotech Daily

Monday June 19, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: MESOBLAST UP 7%; MICRO-X DOWN 12%**
- * **CSIRO APPOINTS WEHI'S PROF DOUG HILTON CHIEF EXECUTIVE**
- * **AVITA: FDA APPROVES RECELL FOR VITILIGO RE-PIGMENTATION**
- * **TELEX DOSES 1st PATIENT IN TLX250-CDX SOLID TUMOR TRIAL**
- * **RHYTHM EXPANDS COLOSTAT PIPELINE**
- * **VAXXAS OPENS BRISBANE HQ, FACTORY**
- * **LIVING CELL PIG HERD, TRIAL REVUE, ADVISORY BOARD**
- * **INSIGNIA TAKES 7.5% OF IMMUTEP**
- * **MITHRA BELOW 5% IN MAYNE PHARMA**
- * **RUBRIC TAKES 5.1% OF MAYNE PHARMA**
- * **IMAGION APPOINTS DR ISAAC BRIGHT CEO, ON \$620k PA**

MARKET REPORT

The Australian stock market was up 0.6 percent on Monday June 19, 2023, with the ASX200 up 43.7 points to 7,294.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell and seven traded unchanged. All three Big Caps were up.

Mesoblast was the best, up 7.5 cents or 6.8 percent to \$1.175, with 6.8 million shares traded. Patrys and Polynovo climbed four percent or more; Proteomics was up 3.4 percent; Amplia, CSL, Kazia, Medical Developments, Prescient, Resonance, Starpharma and Universal Biosensors rose two percent or more; Cochlear, Dimerix, Resmed and Volpara were up more than one percent; with Telix up by 0.35 percent.

Micro-X led the falls, down 1.5 cents or 12.0 percent to 11 cents, with 734,823 shares traded. Atomo lost 11.1 percent; Pharmaxis shed eight percent; Alcidion, Antisense and Orthocell fell four percent or more; Avita and Genetic Signatures were down more than three percent; Emvision and Imugene shed two percent or more; 4D Medical, Cyclopharm, Immutep, Next Science and Nova Eye were down more than one percent; with Clinuvel, Nanosonics, Neuren and Pro Medicus down by less than one percent.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Minister for Industry and Science Ed Husic says Walter and Eliza Hall Institute director Prof Doug Hilton has been appointed the CSIRO's new chief executive.

A media release from Mr Husic said CSIRO executive director Kirsten Rose would be acting chief executive from July 1 when Dr Larry Marshall departed, until Prof Hilton began on September 29, 2023.

A CSIRO media release said its board had made the appointment and Prof Hilton was a molecular and cellular biologist and the University of Melbourne's chair of medical biology and head of the Department of Medical Biology.

The Organisation said that under Prof Hilton's direction over the past 14 years, WEHI had become "a multi-disciplinary organization that makes fundamental discoveries and works with partners to translate these into improved outcomes in cancer, infectious and immune diseases, developmental disorders and diseases of ageing".

The CSIRO said that Prof Hilton had continued "an active research program ... and his team hold more than 20 patents".

CSIRO chair Kathryn Fagg said that Prof Hilton was "a much-respected researcher, leader and communicator of the better outcomes science can deliver".

"Prof Hilton brings decades of experience to this role, which will no doubt prove invaluable to helping address some of Australia's greatest scientific challenges," Mr Husic said.

"Professor Hilton's research into blood cell production and communication has helped Australians live longer, healthier lives," Mr Husic said. "Beyond this, he has shown a real commitment to boost gender equality and diversity in sciences."

Mr Husic thanked Dr Marshall "for his significant contribution as chief executive [and said he had] demonstrated a deep commitment to Australian science, and led the organization through some difficult times, including the Covid-19 pandemic."

AVITA MEDICAL

Avita says it has US Food and Drug Administration pre-market approval for its Recell spray-on skin cells for the re-pigmentation of vitiligo.

Last year, Avita said 56 percent of an undisclosed number of Recell treatments in its pivotal trial for vitiligo resulted in re-pigmentation of more than 50 percent of the treated area (BD: Sep 13, 2022).

Today, the company said pre-market approval was based on results from its pivotal trial that evaluated the safety and effectiveness of the Recell system.

Avita said vitiligo was a disease that attacked the melanocytes, or pigment-producing cells, that resulted in a loss of pigmentation in patches of skin.

The company said Recell was a one-time treatment at the point-of-care that allowed clinicians to deliver a small amount of the patient's pigmented skin to stable depigmented areas affected by vitiligo.

Avita said that vitiligo affected 6.5 million patients in the US and Recell would help patients who suffered from poor body image along with low self-esteem due to the psycho-social impact of the lesions, or depigmented areas, associated with the disease.

Avita chief executive officer Jim Corbett said Recell was a "first-in-class treatment for re-pigmentation through the delivery of normal, healthy skin cells".

"This is a breakthrough for Avita Medical, significantly expanding the clinical applications of Recell and demonstrates our continued commitment to patient care," Mr Corbett said.

"We look forward to offering a meaningful one-time treatment option for patients with stable vitiligo across the US," Mr Corbett said.

Avita fell 19 cents or 3.8 percent to \$4.80 with 1.3 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has dosed the first of up-to 100 patients in a prospective, open-label, phase II, 'basket' study of its TLX250-CDx for diagnosing a range of solid tumors.

Telix said that carbonic, anhydrase (CAIX) was overexpressed on the surface of clear cell renal cell carcinomas and in other advanced-stage solid tumors with poor prognosis.

The company said the 'Starburst' study would evaluate the CAIX-targeting positron emission tomography and computer tomography imaging agent TLX250-CDx for solid tumors including breast, cervix, colorectal, gastric, oesophageal, head and neck, lung, ovarian, pancreatic and vulval cancers for diagnostic and therapeutic applications.

Telix said that the half-life of 89-zirconium meant that imaging the tumors with TLX250-CDx would enable predictive dosimetry for therapeutic radio-nuclides, effectively serving as a diagnostic and therapeutic scouting study for future studies.

Telix chief medical officer Dr Colin Hayward said dosing the first patient in the study was "a strategically important milestone" for the company.

"This study will add value and clinical insight to the platform and enable Telix to assess the potential of CAIX as a biomarker as we continue to scout the [diagnostic and therapeutic] potential of targeting CAIX beyond renal cancer," Dr Hayward said.

Telix was up four cents or 0.35 percent to \$11.45 with 1.1 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it will expand research and development of its Colostat diagnostics technology pipeline to include indications beyond colorectal cancer.

Rhythm said it had appointed Nexomics at Melbourne's Peter MacCallum Cancer Centre as its bio-analytical partner to advance the development program for Colostat as a screening tool for gastric cancer, following the engagement of Agilex Biolabs to research the device for breast cancer and the Baker Institute for lung cancer.

Rhythm said it had identified "a short list of candidate biomarkers with potential use in the early detection of breast, lung, gastric, cervical and pancreatic cancers" which would be evaluated for early-stage proof-of-concept research with the partners.

Rhythm technical director Dr Trevor Lockett said the partnership with Nexomics would strengthen the company's "ability to leverage strong bio-analytical expertise to assess options for advancing [its] technology platform".

Rhythm fell 2.5 cents or 5.15 percent to 46 cents.

VAXXAS PTY LTD

Vaxxas says in partnership with the Queensland Government it has opened a headquarters in Brisbane to manufacture its high-density microarray patches.

Vaxxas said the 5,500 square meter facility would allow it to scale-up its needle-free vaccine technology for late-stage trials and commercial production.

The company said the facility was funded by the Queensland and Federal Governments. Queensland Deputy Premier Dr Steven Miles said the State Government was "committed to supporting homegrown bio-medical start-ups to scale up successfully".

"This world-renowned technology has the potential to play a vital role in pandemic preparedness because it allows vaccines to be deployed quickly and easily to our communities," Dr Miles said.

Vaxxas chief executive officer David Hoey said the facility was a "significant milestone" for the company, which was founded in 2011 on research from the University of Queensland.

Vaxxas is a private company.

LIVING CELL TECHNOLOGIES

Living Cell says Nzeno has finalized the pig herd and surgical facility in Invercargill, a review of its NTCCell trial protocol is underway and it has appointed an advisory board. Living Cell said the facility allowed it to manage its own source of pathogen-free pigs for NTCCell encapsulated pig choroid bran cells for use in the third Parkinson's disease trial. The company said the trial protocol and development plan was under review by Prof Carolyn Sue to improve the therapeutic value of NTCCell and while the review was underway it had "enacted a temporary pause to the maintenance of the porcine herd to minimize unnecessary ongoing costs".

Living Cell said the herd would be expanded in 2024 following the review, which would include adjustments to the trial protocol and plans to engage clinical trial partners, with manufacture of NTCCell for the trial to recommence following the scientific review.

The company said its advisory board included the University of Sydney's Prof Glenda Halliday, the Royal Melbourne Institute of Technology's Prof Robert Kapsa, Scimita Ventures director Ali Abbas, Alithia Life Sciences Prof Tina Soulis and the Royal Adelaide Hospital's Prof Thomas Kimber.

Living Cell was unchanged at 1.3 cents with 2.9 million shares traded.

IMMUTEP

Insignia Financial Ltd says it has increased its substantial shareholding in Immutep from 45,657,561 shares (5.193%) to 85,419,914 shares (7.492%).

the Melbourne-based Insignia said on June 8, 2023 it bought 39,762,353 shares in four transactions for \$10,339,211, or 26 cents a share.

Earlier this month, Immutep said it had raised \$67.9 million in a placement and institutional rights offer at 26 cents a share (BD: Jun 2, 2023).

Immutep fell half a cent or 1.7 percent to 29.5 cents.

MAYNE PHARMA GROUP

Mayne Pharma says the Liege, Belgium-based Mithra Pharmaceuticals SA and Estetra SRL have reduced their holding in the company from 9.93 percent to 4.96 percent.

In 2021, Mithra said it held 168,872,626 pre-consolidation (9.57%) (BD: May 17, 2021).

Last year, Mayne Pharma said its annual general meeting approved a 20-to-one share consolidation (BD: Nov 30, 2022).

Today, the company said Mithra sold 4,221,815 post-consolidation shares and it retained 4,221,816 shares (4.96%) with no current intention for further sales.

Mayne Pharma was unchanged at \$3.90.

MAYNE PHARMA GROUP

New York's Rubric Capital Management LP says it has become a substantial shareholder in Mayne Pharma with 4,356,426 shares or 5.1 percent.

Rubric said it held the shares through "contract for difference (no voting power)" acquiring the shares between February 28 and June 16, 2023, with the largest acquisition 8,943,358 shares for \$2,314,155 or 25.9 cents a share on June 16.

According to Commsec data, Mayne Pharma traded between \$3.75 and \$3.91 on June 16, 2023.

It appears that Rubric had some of its numbers in the wrong column as 2,314,155 shares for \$8,943,357 computes to \$3.865 a share.

IMAGION BIOSYSTEMS

Imagion says it has appointed San Diego-based Dr Isaac Bright as chief executive officer, effective from June 20, 2023.

Imagion said Dr Bright was most recently Rubryc Therapeutics Inc co-founder, chief executive officer and chair and previously was a Synthetic Biologics Inc executive and Healthtell Inc chief business officer.

The company said Dr Bright held a Bachelor of Biochemistry from California's Pepperdine University, a Master of Business Administration from the University of Pennsylvania's Wharton School and a Doctor of Medicine from Stanford University.

Imagion said Dr Bright would receive a base salary of \$US425,000 (\$A620,000), with a short-term incentive of up to 55 percent of the base salary and a long-term incentive of 45,000,000 options over three years.

Imagion was up 0.1 cents or 8.3 percent to 1.3 cents with six million shares traded.