Biotech Daily

Thursday June 3, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ORTHOCELL UP 10%; ONCOSIL DOWN 11%**

*** PRO MEDICUS, MAYO WORK ON AI VISAGE IMAGING**

*** QBIOTICS RAISES $22.5m; 1st PATIENT IN EB46, MERCK CANCER TRIAL**

*** CORRECTION: TRAJAN**

*** PAINCHEK TAKES 60% OF LOCAL MARKET**

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*** TELIX, ECKERT ZIEGLER US CO-PROMOTION DEAL**

*** DIMERIX: EMA CONFIRMS PHASE III DMX-200 FSGS TRIAL DESIGN**

*** RESAPP, MEDGATE RESAPPDX TRIAL EXTENDED 2 MONTHS**

*** ZELIRA LICENCES MARIJUANA ZTL-106 TO LEVIN FOR PAIN TRIAL**

*** UP TO 19% OPPOSE $2 SOMNOMED DIRECTOR OPTIONS EGM**

*** ANTERIS RECEIVES $1.5m FEDERAL R&D TAX INCENTIVE**

*** RESPIRI REBUTS ADHERIUM REJECTION CLAIMS**

*** CRONOS LAUNCHES MARIJUANA GEL CLEANSER, MOISTURISER**

*** PRESCIENT PLEADS SCHULTZ TO ASX 23% QUERY**

*** SALLY MCDOW REPLACES PAINCHEK CO SEC IAN HOBSON**

MARKET REPORT

The Australian stock market was up 0.59 percent on Thursday June 3, 2021, with the ASX200 up 42.3 points to 7,260.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and one was untraded.

Orthocell was the best, up 5.5 cents or 10.4 percent to 58.5 cents with 1.2 million shares traded. Resonance and Uscom climbed more than five percent; Genetic Signatures and Impedimed improved more than four percent; Kazia, Patrys and Pro Medicus were up more than three percent; Antisense and Polynovo rose more than two percent; Cyclopharm, Next Science, Novo Eye and Pharmaxis were up more than one percent; with Cochlear, CSL, Cynata, Immutep and Nanosonics up by less than one percent.

Oncosil led the falls, down 0.8 cents or 11.0 percent to 6.5 cents, with 11.6 million shares traded. Amplia lost 10.7 percent; LBT lost 6.7 percent; Optiscan and Starpharma fell more than four percent; Mesoblast was down 3.1 percent; Dimerix and Telix shed more than two percent; Avita, Opthea, Paradigm, Proteomics and Universal Biosensors were down one percent or more; with Clinuvel, Medical Developments, Neuren, Resmed and Volpara down by less than one percent.

PRO MEDICUS

Pro Medicus says has a multi-year research deal with Mayo Clinic for development and commercialization of artificial intelligence for its imaging technology systems.

Pro Medicus said the agreement, through its US subsidiary Visage Imaging, with Rochester, Minnesota-based Mayo Clinic would be a framework for the two companies to leverage Visage's artificial intelligence (AI) Accelerator platform.

Visage chief technology officer Dr Malte Westerhoff said the AI Accelerator program was "designed to closely align Visage's engineering and product development capability with clinical research partners such as Mayo Clinic".

"It provides a unique set of tools for data de-identification, collection, curation, analysis and 'path-to-production' in research projects bringing the efficiency and speed of Visage technology to research, resulting in a unified link between the two domains," Dr Westerhoff said. "We see AI playing a significant role in healthcare particularly in our field of imaging [information technology]."

"We have optimized our Visage 7 platform for AI enabling both our own, as well as third-party algorithms to be seamlessly integrated into the clinician's desktop."

"We see this research collaboration agreement with Mayo Clinic as another significant piece of our AI strategy," Dr Westerhoff said.

Pro Medicus was up $1.46 or 3.2 percent to $47.61 with 219,572 shares traded.

QBIOTICS

Qbiotics says it has dosed its first patient in the phase Ib/IIa study of oncology molecule tigilanol tiglate with Keytruda and completed a $22.5 million placement.

In March, the company said it had raised $50 million at 90 cents a share from Sydney's TDM Growth Partners as a cornerstone investor (BD: Mar 17, 2021).

Today, Qbiotics said it raised a further $22,550,577 in a placement to sophisticated investors at the same price.

Last year, the company said it would run an up-to 25 patient trial of EB46, or tigilanol tiglate with Keytruda from the Kenilworth, New Jersey-based Merck and Co for unresectable melanoma (BD: Aug 13, 2020).

Today, Qbiotics said the first patient had been dosed in the trial to test the safety, optimal dose, and tumor response of the combination in patients with late-stage unresectable melanoma and previous exposure to immune checkpoint inhibitors.

Qbiotics said the trial would test up to three intra-tumoral doses of plant-derived tigilanol tiglate at three escalating dose levels, administered three weeks apart in combination with intravenous pembrolizumab or Keytruda administered every three weeks for up to 24 months.

Qbiotics is a public unlisted company.

CORRECTION: TRAJAN SCIENTIFIC AND MEDICAL

Last night's edition incorrectly cited Trajan's ASX code as "TJN".

Trajan is expected to list on the ASX on Monday June 7, 2021, under the code "TRJ".

Biotech Daily has not been able to ascertain how we made the error but we have launched an investigation and will consider the report in due course. Whether it is to be released to the public will depend on the sensitivity of its contents.

In the meantime, we have sacked the Wednesday sub-editor.

We apologize unreservedly for the error.

Trajan is currently a public unlisted company.

PAINCHEK

Painchek says signing 49,000 beds in April and May has taken the total using its pain test to 127,000 beds, or 60 percent of the Australian residential aged care market.

Painchek said it had agreements to licence its smart telephone-based device which used artificial intelligence to assess and score pain levels and update medical records in the internet cloud, covering more than 435 residential aged care providers that operated 1601 residential aged care facilities.

The company said the new clients included the London-based British United Providence Association (BUPA), Estia Health, Opal Healthcare, Catholic Healthcare and Bolton Clark.

Painchek said that a Federal Government 12-month grant ended on May 31, 2021.

Last year, the company said that it had a $5 million grant agreement with the Federal Government for the use of Painchek for residents living with dementia or cognitive impairment (BD: Mar 19, 2020).

Painchek chief executive officer Philip Daffas said “the goal of the Government grant was to accelerate access to Painchek for those residents living with dementia in Australian residential aged care”.

“We are delighted that close to 60 percent of all Australian aged care providers and facilities are now on board, many of which are already seeing the clinical benefits of Painchek for their residents and staff,” Mr Daffas said.

“Our goal is to continue to ensure pain is effectively assessed and managed for all people everywhere, with aged care being an initial critical first market where we’ve become a favorite clinical software tool,” Mr Daffas said.

“We now have a proven product and sustainable business model for entering the overseas aged care markets and the larger global home care and hospital markets, with the Painchek adult universal [application] and the infant [application] both of which recently received international regulatory clearance,” Mr Daffas.

In March, Painchek said it had both Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark approval and last November the company said it had Canadian approval (BD: Nov 19, 2020; Mar 17, 2021).

Painchek was up 0.4 cents or 6.15 percent to 6.9 cents with 1.8 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has a licence agreement to use Tekcyte’s wound dressing for a trial in diabetic foot ulcers and has an option to purchase the technology.

In March, Cynata said it would plan a trial of its Cymerus mesenchymal stem cells for diabetic foot ulcers with the Adelaide-based Tekcyte Pty Ltd (BD: Mar 1, 2021).

Today, the company said Tekcyte would work with the company to manufacture and supply the active dressing for the planned trial.

Cynata said the licence was for the lifetime of the relevant Tekcyte patents and involved an undisclosed signed fee and capped, milestone payments.

Cynata chief operating officer Dr Kilian Kelly said diabetic foot ulcers were a “significant unmet medical need, with the disease often resulting in hospitalizations, amputations and fatalities, with an estimated market value of nearly $US10 billion [$A12.9 billion]”.

“Unfortunately, there is also evidence that the burden of this disease is growing, and existing treatment options have limited success,” Dr Kelly said.

“The encouraging data from the pre-clinical studies provides a strong basis for us to proceed with our Cymerus [mesenchymal stem cells] product utilizing Tekcyte’s patch technology as a potential treatment,” Dr Kelly said.

Cynata was up half a cent or 0.9 percent to 58 cents.

TELIX PHARMACEUTICALS

Telix says it has a US co-promotion agreement with the Berlin-based Eckert and Ziegler Strahlen und Medizintechnik AG for the combination of Galliapharm and Illucix.

Last month, Telix said Eckert and Ziegler would be the exclusive commercial distributor of Illucix following German marketing authorization, which was expected to be "in late 2021" (BD: May 18, 2021).

Today, the company said the two would co-promote the combination of Eckert and Ziegler's gallium-68 generator or Gallipharm and the Telix Illuccix kit for the preparation of 68Gallium-PSMA-11, its prostate cancer imaging product.

Telix fell 11 cents or 2.5 percent to $4.34 with 409,072 shares traded.

DIMERIX

Dimerix says the European Medicines Agency has confirmed the design of its phase III study of DMX-200 in focal segmental glomerulosclerosis (FSGS) kidney disease.

Last year, Dimerix said its 10-patient, phase IIa trial of DMX-200 for focal segmental glomerulosclerosis met its endpoints, reducing proteinuria (BD: Jul 29, 2020).

Today, the company said the European Medicines Agency provided clarity for the trial including appropriate endpoints for conditional marketing approval such as protein in the urine (proteinuria) and its relationship to kidney function.

Dimerix said it has appointed Iqvia as the lead contract research organisation to run the late-stage FSGS clinical studies.

Dimerix managing-director Dr Nina Webster told Biotech Daily that the trial expected to enrol 120 to 180 patients, assuming the US Food and Drug Administration agreed to the trial design.

In a media release, Dr Webster said the formal response from the European Medicines Agency had given "a valuable opportunity to ensure that the proposed FSGS development program meets with European regulatory expectations for marketing approval, including conditional/accelerated marketing approval".

"The clinical data to date suggest that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard of care in patients with FSGS," Dr Webster said.

Dimerix fell half a cent or 2.2 percent to 22.5 cents.

RESAPP HEALTH

Resapp says Medgate AG has extended its pilot trial of Resappdx smartphone acute respiratory diagnostic test within its tele-medicine services, by two months.

In March, Resapp said that the Basel, Switzerland-based Medgate had started a three-month pilot trial and that both parties would assess the impact of Resappdx on Medgate's tele-health service (BD: Mar 4, 2021).

Today, the company said following an interim review the companies had decided to extend the trial to collect further data and optimize Medgate's integration of the Resappdx cough sensor for respiratory illnesses within its telemedicine services.

Resapp managing-director Dr Tony Keating said that "Medgate and our clinical experts have found the data collected during the initial pilot period was consistent with the data from our extensive clinical studies, further demonstrating the accuracy of our cough-based diagnostic technology".

Resapp fell 0.3 cents or 5.6 percent to 5.1 cents with 2.3 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has a licenced its marijuana-derived ZTL-106 to related-party Levin Health for a clinical trial in chronic pain for retired athletes.
Zelira said it also had a project management deal with Melbourne's Levin Health, which would pay Zelira an undisclosed fee to manage the trial at Melbourne's La Trobe University's Sport and Exercise Medicine Research Centre.
The company said it would hold marketing rights to North and South America with Levin holding the rights to all other markets.
Zelira said that profits from the commercialization of products would be shared between companies.
The company said that retired athletes were "more likely to suffer chronic pain and associated conditions such as depression and anxiety as a result of injuries and physical exertion over long periods of time".
"While clinical data is currently limited, medicinal cannabis may provide a safe and effective targeted treatment option," Zelira said.
The company said that directors Jason Peterson and Harry Karelis held shares and options in Levin Health with about 3.9 percent of the shares on issue between them.
Zelira was up 0.4 cents or 8.9 percent to 4.9 cents with 3.9 million shares traded.

SOMNOMED

Somnomed says that all resolutions at its extraordinary general meeting were passed but the issue of 'in-the-money' options to directors faced up to 18.6 percent opposition.
Somnomed said that the issue of 185,000 options to director Hamish Corlett, exercisable at $2.00 within six years, pending a 20-day volume-weighted average price of $3.50, was opposed by 5,107,441 votes (18.6%) and supported by 22,331,096 votes (81.4%).
The company said that the issue of 370,000 options to chair Guy Russo and 185,000 options each to directors Amrita Blickstead, Michael Gordon Hilton Brett and Karen Borg were opposed by the same number of votes 5,107,441 (10.7%), but with 42,528,238 votes (89.3%) in favor.
Somnomed said that the issue of up to 910,000 options to chief executive officer Neil Verdal-Austin was passed by a wider margin, as was the 100 percent increase in the directors' pay pool from $250,000 to $500,000 a year, and the employee and directors option plans.
According to the company's most recent Appendix 2A application for quotation of securities, it had 82,759,315 shares on issue, meaning that opposition to the directors' options amounted to 6.2 percent of the company, sufficient to requisition extraordinary general meetings.
Somnomed was up 10 cents or 4.3 percent to $2.45.

ANTERIS TECHNOLOGIES

Anteris says it has received $1,492,517 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Anteris said it would repay a short-term loan of $1.22 million from Mitchell Asset Management taken against the forecast Research and Development Tax Incentive.
The company said the rebate related to research and development expenditure for the year to December 31, 2021.
Anteris fell eight cents or one percent to $7.90.

ADHERIUM, RESPIRI

Respiri says that two qualified claims made by Adherium in responding to its takeover bid are inaccurate.
In April, Respiri offered to exchange one Respiri share for seven Adherium shares valuing Adherium at 2.25 cents a share or $19.14 million (BD: Apr 30, 2021).
In March, Adherium said it had raised $18 million in placement at 1.5 cents led by Trudell Medical and Bioscience Managers (BD: Mar 18, 2021).
In May, Adherium said that "Respiri has only one sensor, for which … there are no publicly available independent clinical trial results, and nor is it supported by any independently-conducted clinical trial publications in peer reviewed journals".
Today, Respiri cited peer-reviewed articles supporting its first device, the Pulmotrack sensor, and its 510(k) submission to the US Food and Drug Administration and subsequent approval (BD: Mar 23, 2021).
In May, Adherium also said that the clinical significance of measuring wheeze in the treatment of asthma and chronic obstructive pulmonary disease (COPD) and whether this would qualify for reimbursement, in particular in the US, had not been independently demonstrated or verified.
Today, Respiri said the Adherium statement was "inaccurate and very narrowly focused".
Respiri said that "Wheezo does not only measure wheeze, but it also measures and records breath sounds, which are each considered to be physiologic parameters, an assertion which is supported by independent expert evaluation".
Respiri said that an unnamed US "expert" and advisor to American Medical Association current procedural terminology (CPT) coding committees and US Medicare Access and Children's Health Insurance Program Reauthorization Act task forces "concluded that Wheezo analyzes breath sounds for the presence of a wheeze and that in the expert's opinion, breath sounds and wheezing are physiologic parameters".
To be continued …
Adherium fell 0.1 cents or 5.6 percent to 1.7 cents.
Respiri fell half a cent or 5.4 percent to 5.1 cents with 2.3 million shares traded.

CRONOS AUSTRALIA

Cronos says it has launched two hemp-based products, the gel cleanser Clean Hands No.1 and gel moisturizer Soft Hands No.1, under its Bathing Shed range.
Cronos said 300 ml bottles of its Clean Hands No. 1 and Soft Hands No. 1would be sold at $25.00 and $30.00, respectively, in Japan, Hong Kong and Australia.
The company said its gel cleanser contained cold-pressed Tasmanian hemp seed oil and Australian sea salt for exfoliation, while its gel moisturizer contained Tasmanian hemp seed oil and silver ion water for hydration and antibacterial and antiviral properties.
Cronos said both products contained a blend of eucalyptus, geranium, lavender and peppermint oils which provided it a "refreshing and uplifting scent".
Cronos was up one cent or 9.1 percent to 12 cents.

PRESCIENT THERAPEUTICS

Prescient has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose three cents or 23.1 percent from 13 cents to 16 cents today June 3, 2021 and noted a "significant increase" in the trading volume.
Prescient was unchanged at 13 cents with 58.3 million shares traded.

PAINCHEK

Painchek says it has appointed Sally McDow as company secretary following the resignation of Ian Hobson as joint chief financial officer and company secretary.

Painchek said that Ms McDow was an experienced company secretary.

Ms McDow told Biotech Daily that she holds a Bachelor of Laws for Brisbane's Queensland University of Technology and a Masters of Business Administration from the Vancouver, British Columbia Simon Fraser University.