

Biotech Daily

Thursday September 15, 2022

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: KAZIA UP 12%; ANTISENSE DOWN 7%
- * VICTORIA \$260k FOR REGIONAL MEDICAL TECHNOLOGIES
- * INVION INV043 'EFFECTIVE AGAINST ANAL CANCER, IN-VITRO'
- * HYDRIX INSTO, RETAIL RIGHTS TO RAISE \$6m; TRADING HALT
- * ALTHEA LAUNCHES 2 MEDICAL MARIJUANA PRODUCTS
- * ZELIRA MARIJUANA DIABETIC NERVE PAIN STUDY 67% ENROLLED
- * CONTROL BIONICS LOSES CEO ROB WONG FOR HEALTH REASONS
- * IDT LOSES CEO DR DAVID SPARLING; PAUL MCDONALD INTERIM \$310k
- * ONCOSIL APPOINTS BRIAN LEEDMAN DIRECTOR

MARKET REPORT

The Australian stock market was up 0.21 percent on Thursday September 15, 2022, with the ASX200 up 14.3 points to 6,842.9 points.

Thirteen of the Biotech Daily Top 40 were up, 20 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Kazia was the best, up 2.5 cents or 11.9 percent to 23.5 cents, with 145,699 shares traded. Amplia climbed 10 percent; Actinogen was up 8.3 percent; Micro-X improved 7.7 percent; Patrys was up 4.2 percent; Immutep and Pharmaxis were up more than three percent; Emvision, Neuren and Orthocell rose more than two percent; Atomo was up 1.7 percent; with Avita and Opthea up by less than one percent.

Antisense led the falls, down 0.7 cents or 7.2 percent to nine cents, with 291,806 shares traded. Genetic Signatures and Nanosonics lost more than five percent; Polynovo fell 4.2 percent; Imugene, Mesoblast, Next Science, Prescient, Proteomics, Starpharma and Uscom shed two percent or more; Cochlear, Cynata, Impedimed, Oncosil, Pro Medicus Telix and Volpara were down more than one percent; with Clinuvel, CSL, Medical Developments, Paradigm and Resmed down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it is providing \$260,000 to the University of Melbourne and Bendigo Health to fast-track the development of medical technologies.

A media release from Victoria's Minister for Industry Support and Recovery Ben Carroll said the partnership between the University and Bendigo Health was "the first time the program expands to regional Victoria, following successful partnerships led by the University of Melbourne with Western Health and the Royal Melbourne Hospital". The State Government said that previous partnerships led to the development of the 'McMonty by Medihood' a personal ventilator hood for hospital beds and the 'Stroke Rapid Diagnostic Test' allowing paramedics and clinicians to determine quickly the cause of a stroke and help them decide on treatment.

The Victoria Government said the Bendigo program would "bring together clinicians, researchers, engineers and manufacturers to support [medical technology] projects across the hospital [and] it will be fully run by Bendigo Health after 12 months".

The Member of the Victoria Legislative Assembly (MLA) for Bendigo East and Deputy Premier Jacinta Allan said the investment was "recognition of the skills and talent we have to develop innovative healthcare products right here in Bendigo".

The MLA for Bendigo West Maree Edwards said that it was "important that regional communities like Bendigo share the benefits of our investments in [medical technology] innovation that are creating jobs and improving the lives of people worldwide". Bendigo Health research and innovation director Dr Angela Crombie said that "regional clinicians understand the unmet health needs of our community and this collaboration offers the chance to translate their ideas into practical care solutions".

INVION

Invion says in-vitro tests showed that its photo-activated INV043 was effective against six squamous cell carcinoma (SCC) cell lines that cover the spectrum in anal cancers. Invion said that Melbourne's Peter MacCallum Cancer Centre assessed "the relative cytotoxicity of light activated INV043 [on] human anal [squamous cell carcinoma] cell lines" and found that INV043 was effective against the six SCC cell lines which cover the spectrum found in anal cancers.

The company said that the testing was a prelude to moving to clinical testing in human patients with anal cancer.

Invion said that the study results were consistent with "promising outcomes achieved at the Hudson Institute of Medical Research on other cancer types, including triple negative breast cancer".

In May, the company said its third proof-of-concept study with Melbourne's Hudson Institute of Medical Research showed that INV043 reduced tumor size 65 percent, in mice (BD: May 30, 2022).

Invion chief executive officer Thian Chew said that the study had "added a different and clinical important class of tumors to the spectrum of other tumors already shown to be highly sensitive to INV043 by the Hudson Institute".

"[Squamous cell carcinomas] occur throughout the body, but those associated with the ano-genital regions are particularly hard to manage if they fail first-line therapy," Mr Chew said.

Invion said anal cancers were "particularly difficult to treat and most are SCCs that line the surface of the anal canal" and the global anal cancer market was forecast to be \$US1.25 billion (\$A1.84 billion) by 2028.

Invion was up 0.1 cents or 8.3 percent to 1.3 cents with 51.8 million shares traded.

HYDRIX

Hydrix says it hopes to raise up to \$6 million in a one-for-two, pro-rata non-renounceable entitlement offer at six cents a share, and requested a trading halt.

Hydrix said that it had requested that the trading halt end after the completion of the institutional component of the offer, or on September 19, 2022.

The company said that the funds would support market development, regulatory applications, clinical trials and expansion of its cardiac devices, expand its business development and marketing and provide working capital.

Hydrix said that the retail offer's record date would be September 19, the offer would open on September 21 and close on October 6, 2022.

The company said that both retail and institutional participants could apply for excess of their entitlements under shortfall facilities.

Hydrix last traded at 9.2 cents.

ALTHEA GROUP

Althea says it has launched two "next-generation" medical marijuana products, CBD25 and THC25 "one of the highest-concentrated THC dried flower products available". Althea said that CBD25 was an oral soft gelatine capsule that contained 25mg of cannabidiol (CBD) and less than 0.25mg of delta-9-tetrahydrocannabinol (THC) per capsule, manufactured to European good manufacturing practice standards. The company said that CBD25 offered "a gradual onset and extended duration of effect, compared to the rapid onset and shorter duration of effect for products requiring inhalation" and that in-vitro studies showed that the capsules dissolved in less than 10 minutes.

Althea said that CBD25 was "a candidate to be supplied under the [Australian Therapeutic Goods Administration's] schedule 3, pharmacist only medicine entry for eligible CBD products" which would allow patients to purchase it over-the-counter after consultation with a pharmacist, without the need for a prescription.

The company said that THC25 was a "ultra-high THC cannabis dried flower product", and contained 25 percent THC and less than one percent of CBD, and was its "highest-concentrated THC dried flower product".

Althea managing-director Joshua Fegan said "we believe Althea's soft gel capsules will create incremental sales opportunities for the business, with market research clearly identifying this preparation as the most desirable choice of delivery format".

Althea was up half a cent or 5.7 percent to 9.3 cents with 1.8 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has enrolled 40 of 60 patients in its observational study of its marijuana products for diabetic nerve pain.

In May, Zelira said it had enrolled 20 patients in the investigative arm of the trial and in 2021, said it had US approval for the study to evaluate the safety and tolerability of its product compared to an unnamed "multi-billion-dollar big pharmaceutical company drug", with results expected by July 2022 (BD: Jul 12, 2021; May 30, 2022).

Today, the company said that an additional 20 subjects using the "big pharmaceutical company drug" had been enrolled in the second arm, as an active reference arm for the trial, with a third arm to evaluate the combined effects of the reference drug.

Zelira said it expected to complete enrolment and provide results by December 2022. Zelira was unchanged at \$1.47.

CONTROL BIONICS

Control Bionics says chief executive officer Rob Wong has resigned "due to an ongoing, degenerative medical condition" with founder Peter Ford taking on the role temporarily. The company said Mr Wong had been on sick leave for the last two months for treatment, and would be available in an advisory capacity, while a chief executive officer was sought. Biotech Daily joins Control Bionics in wishing Mr Wong "all the very best with his ongoing treatment and recovery".

Control Bionics fell one cent or 4.8 percent to 20 cents.

IDT AUSTRALIA

IDT says chief executive officer Dr David Sparling resigned yesterday and will be replaced by Paul McDonald on an interim basis, while it searches for a replacement. Last year, the Victoria Government said that Moderna had been chosen to manufacture mRNA vaccines in Australia (BD: Dec 14, 16, 2021).

IDT previously said that with Monash University it had manufactured a severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the product "met all specifications" and was expected to be supplied for a clinical trial (BD: Nov 30, 2021).

In December, the company said its submission to the Federal Government for an onshore mRNA manufacturing capability had not been selected to progress (BD: Dec 16, 2021). In March, IDT said it was unsuccessful in its Federal Government Collaboration Stream Grant bid to produce mRNA vaccines in Australia (BD: Mar 18, 2022).

Last month IDT said its submission for a Federal Government's Modern Manufacturing Initiative manufacturing translation grant was unsuccessful (BD: Aug 26, 2022). Today, IDT said that the acting chief executive officer role would lapse at the end of December 2022, unless extended and Mr McDonald would be paid a base salary of \$310,000 a year, with a short-term incentive of up to 50 percent of his base salary. The company said that Mr McDonald had more than 20 years of experience in the pharmaceutical industry, previously working for Pfizer, Novartis, Merck and Gilead. According to his Linkedin page, Mr McDonald held a Bachelor of Science from Geelong's Deakin University, a Master of Business Administration from Monash Business School and a Master of Science from the University of New England in, New South Wales. IDT was unchanged at 12 cents.

ONCOSIL MEDICAL

Oncosil says it has appointed Brian Leedman as a non-executive director. Oncosil said that Mr Leedman had more than 15 years of experience in the industry, having founded Resapp Diagnostics, which has been acquired by Pfizer Australia. The company said that Mr Leedman was previously the Psivida's head of investor relations, co-founded Oncosil Medical and previously was the chair of Neurotech International, Neuroscientific Biopharmaceuticals and a director of Alcidion. Oncosil said Mr Leedman held a Bachelor of Economics and a Master of Business Administration from Perth's University of Western Australia. Oncosil fell 0.1 cents or 1.9 percent to 5.1 cents.

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