



Biotech Daily

Wednesday September 29, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ACTINOGEN UP 8%; PROTEOMICS DOWN 8%**
- * **VICTORIA \$4m BACKS NEO-BIONICA FOR MEDICAL DEVICES**
- * **MICRO-X WINS 2 US AIRPORT SECURITY CONTRACTS; UP TO \$5.7m**
- * **WEHI: 'ANTIBODY COMBO BLOCKS SARS-COV-2 IN MICE, HAMSTERS'**
- * **PYC: 'VP-001 PENETRATES RABBIT RETINA'**
- * **IMMUTEP: \$3.4m FRENCH R&D TAX INCENTIVE**
- * **MAYNE APPOINTS UPSHER-SMITH US ISOTRETINOIN DISTRIBUTOR**
- * **BOTANIX TRIALS CANNABINOID BTX1204A FOR DOG ECZEMA**
- * **STEMCELL TAKES 'JOINT VENTURE' TRADING HALT TO SUSPENSION**
- * **REGAL FUNDS REDUCES TO 5.8% OF ADHERIUM**
- * **VERONIQUE MORGAN-SMITH REPLACES MACH7 CO SEC JENNI PILCHER**

MARKET REPORT

The Australian stock market fell 1.08 percent on Wednesday September 29, 2021, with the ASX200 down 78.9 points to 7,196.7 points. Ten of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and one was untraded. All three Big Caps fell.

Actinogen was the best, up one cent or 8.3 percent to 13 cents, with 2.2 million shares traded. LBT and Pharmaxis improved four percent or more; Orthocell was up 3.1 percent; Medical Developments and Neuren rose two percent or more; Cynata and Next Science were up more than one percent; with Opthea and Polynovo up by less than one percent.

Proteomics led the falls, down 7.5 cents or 7.8 percent to 89 cents, with 249,719 shares traded. Antisense and Universal Biosensors fell five percent or more; Avita, Dimerix, Resonance, Starpharma and Telix were down three percent or more; Amplia, CSL, Paradigm and Pro Medicus shed more than two percent; Clinuvel, Compumedics, Cyclopharm, Genetic Signatures, Mesoblast, Nanosonics, Resmed and Volpara were down more than one percent; with Cochlear, Immutep and Kazia down by less than one percent.

VICTORIA GOVERNMENT

Victoria says it has provided \$4 million to the Neo-Bionica facility at Melbourne's St Vincent's Hospital will fast-track medical devices, including treatments for type 2 diabetes. A media release from the Minister for Innovation and Medical Research Jaala Pulford said Ms Pulford opened the Neo-Bionica facility yesterday.

The Victoria Government said the facility was a joint venture with the Bionics Institute and the University of Melbourne to manufacture medical device prototypes for use in clinical trials.

The Government said that the laboratory would address "a nationwide shortage of medical device development and manufacturing facilities, boosting Victoria's reputation as a global centre for biomedical engineering".

The media release said that several devices under development at the Bionics Institute would be further developed at Neo-Bionica, including a potential treatment for type 2 diabetes.

The media release said that the type 2 diabetes device "activates the body's natural processes to treat type 2 diabetes and will eventually be implanted in people with uncontrolled type 2 diabetes using key-hole surgery".

The State Government said it was contributing \$4 million to support the fit-out of the facility, provide funding for research jobs and support industry start-ups to commercialize medical prototypes.

Ms Pulford said the facility would be "a link for Victoria between the concept phase and the clinical trial phase, which is crucial for the development and commercialization of medical devices".

Bionics Institute chief executive officer Robert Klupacs said Neo-Bionica "will completely change how we translate Australian innovation, enabling home-grown inventions to be manufactured rapidly in Australia for the benefit of patients throughout the world".

MICRO-X

Micro-X says it has contracts worth up to \$US4.1 million (\$A5.7 million) with the US Government for its baggage screening scanner and its self-screening portal.

Micro-X said the contracts, through the Department of Homeland Security's Science and Technology Directorate included about \$US1.3 million (\$A1.8 million) over 12 months for the design of an airport passenger self-screening portal, with the option for an eight months extension worth about \$US1.2 million to design the prototype.

The company said the concept of the portal was to "combine existing self-service technologies such as automated document scanning and validation, identity verification, and millimetre-wave body scanning with a ... miniature, self-service x-ray scanner for carry-on bags and personal property to create an integrated one-stop portal to control passenger access to airport sterile areas".

In a separate announcement, Micro-X said it had a \$US1,569,059 (\$A2,164,981) contract over 18 months for the design of a Miniature X-Ray Baggage Scanner to "become the key component in an airport passenger self-screening portal".

The company said it was contracted to design and manufacture a "robust prototype of a miniaturized, x-ray [computed tomography] baggage scanner for the self-screening portal" and would deliver the prototype scanner for independent testing and evaluation.

Micro-X said the miniaturized baggage scanner had the potential to "meet many different commercial security needs such as stadiums, public events, government and commercial buildings, as well as public transport systems".

Micro-X was up 2.5 cents or 7.8 percent to 34.5 cents with 2.5 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says monoclonal antibodies can block severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) from cells, in mice and hamsters.

WEHI said the discovery paved the way for clinical trials of monoclonal antibody treatments for the prevention of “severe Covid-19 infection”.

The Institute said antibodies from recovered Covid-19 patients and CSL’s proprietary antibody library were used to screen for antibodies that were effective against the Sars-Cov-2 virus, with the leading two monoclonal antibodies then combined into an ‘antibody cocktail’ and trialed on mice and hamsters.

WEHI said the research paper, titled, ‘Landscape of human antibody recognition of the SARS-CoV-2 Receptor Binding Domain,’ was published in Cell Reports and was available at: <https://doi.org/10.1016/j.celrep.2021.109822>.

The Institute said that potent neutralizing monoclonal antibodies were “one of the few agents currently available to treat Covid-19 ... [and were] potentially useful future anti-Sars-Cov-2 therapeutics”.

WEHI’s Prof Wai-Hong Tam co-led the research and said the researchers screened hundreds of potential antibodies, identifying the 12 most potent in blocking virus entry.

“By combining the leading antibodies into an antibody cocktail, we were able to test its effectiveness at blocking Sars-Cov-2 from entering cells and reducing viral loads in preclinical models,” Prof Tam said.

“This antibody cocktail effectively blocked virus entry in these tests and reduced the severity of disease in preclinical models, enabling the infection to be overcome,” Prof Tam said. “These monoclonal antibodies are leading candidates to be developed into a treatment for Covid-19.”

Prof Tam said monoclonal antibody treatments could be used to “form a protective ring around the most vulnerable people during an outbreak or in cases of infection in returned travelers”.

“Unlike vaccines, which take several weeks to generate antibodies, antibody-based therapies would provide immediate protection against the virus,” Prof Tam said. “In the future, we may be able to use these therapies in people who are immunocompromised or unable to mount a robust immune response to a vaccine.”

The Institute said the research was a collaboration with the Doherty, Burnet and Kirby Institutes, CSL, Affinity Bio and the CSIRO.

PYC THERAPEUTICS

PYC says its VP-001 RNA drug candidate is able to penetrate the retina of rabbits.

PYC said the trial was its first assessment of VP-001 “in an eye that resembles that of a human in both structure and size” and provided encouraging evidence for clinical trials expected to begin in about 12 months.

The company said that “the RNA therapeutic modality”, or VP-001, reached all layers of the retina following intra-vitreous administration, reached the nucleus of the target cell type and engaged the target pre-messenger RNA resulting in the desired change in the target messenger RNA.

PYC said the results, if accompanied by successful safety and tolerability studies, should validate its drug delivery technology in the eye.

“Effective drug delivery to the retina remains one of the most significant unresolved challenges in ophthalmology and overcoming this problem holds the promise of improved patient outcomes across a broad spectrum of blinding eye diseases,” the company said.

PYC fell half a cent or 3.45 percent to 14 cents.

IMMUTEP

Immutep says it has received a EUR2,126,617 (\$A3,431,574) research and development tax incentive payment from the French Government.

Immutep said the tax incentive under the Credit d'Impôt Recherche scheme reimbursed 30 percent of French companies' eligible research and development expenditure.

The company said it qualified to receive CIR tax incentive through its subsidiary Immutep SAS with research and development at its laboratory at Châtenay-Malabry in Paris.

Immutep said the funds would be used to support the ongoing and planned global clinical development of IMP321, or efitlagimod alpha, and the preclinical development of IMP761 for cancer and autoimmune diseases.

Immutep fell half a cent or 0.9 percent to 56 cents with 2.6 million shares traded.

MAYNE PHARMA GROUP

Mayne says it has appointed Upsher-Smith Laboratories as its US non-retail distributor for its isotretinoin capsules for severe recalcitrant nodular acne.

Mayne said the 10mg, 20mg, 30mg and 40mg isotretinoin capsules were a generic version of Absorbica.

The company said that US sales of isotretinoin for the year to July 2021 was \$US157 million (\$A216.8 million).

Mayne said it had a private label supply and distribution agreement with the Maple Grove, Minnesota-based Upsher-Smith to distribute isotretinoin to non-retail customers, manufactured under Upsher-Smith's abbreviated new drug application.

The company said it had access to the Upsher-Smith program supporting the supply of product to patients.

Mayne fell one cent or 3.4 percent to 28.5 cents with 4.5 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it plans to enrol 45 dogs in a proof-of-concept study of its topical synthetic cannabidiol BTX1204A for atopic dermatitis or eczema.

Botanix said it would evaluate high and low dose formulations of BTX1204A and a vehicle arm with 15 dogs each, with dogs treated twice daily over 28 days.

The company said the study's objective would be to evaluate the treatment's effectiveness, using the enhanced pruritus score (EPS) and the canine atopic dermatitis extent and severity index (CADESI-04).

In May, Botanix said a four-dog study of BTX1204A for atopic dermatitis, or eczema, showed "encouraging results" with "early positive efficacy signals" (BD: May 17, 2021).

The company said the pilot study showed that a higher dose formulation of synthetic cannabidiol in a new Permetrex formulation "showed significant reduction on average in both the EPS and the CADESI-04 scores over the 28-day treatment period".

In 2020, Botanix said its 200-patient, phase II trial of BTX1204 for atopic dermatitis did not meet its primary or secondary endpoints (BD: Mar 25, 2020).

Today, the company that a successful outcome would drive licencing programs for animal health and support a phase IIb clinical study in humans with atopic dermatitis.

Botanix executive chair Vince Ippolito said that "given the similarity in disease between humans and canines, this study is an efficient and effective pathway to establishing the potential for a higher dose Permetrex formulation to demonstrate a new option for treating this significant disease challenge".

Botanix was up 0.3 cents or 4.5 percent to seven cents with 1.4 million shares traded.

STEMCELL UNITED

Stemcell says it has requested a voluntary suspension to follow Monday's "proposed material joint venture" trading halt (BD: Sep 27, 2021).

The company said it expected the suspension to last until October 29, 2021, or until the release of an earlier announcement.

Stemcell last traded at 1.4 cents

ADHERIUM

Regal Funds Management says it has reduced its substantial shareholding in Adherium from 156,843,906 shares (7.37%) to 124,395,581 shares (5.83%).

The Sydney-based Regal Funds said between September 13 and September 24, 2021, it sold 32,448,325 shares for \$583,547 or an average of 1.8 cents a share.

Adherium was unchanged at 1.6 cents with 2.8 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says Veronique Morgan-Smith will replace company secretary Jennifer Pilcher effective from October 1, 2021.

Earlier this month, Mach7 said Ms Pilcher would resign as chief financial officer with Steve Parkes to replace her from September 27, 2021 (BD: Sep 9, 2021).

Today, the company said Ms Morgan Smith was an employee of Melbourne company secretarial services firm Leydin Freyer.

Mach7 was up one cent or one percent to \$1.03.