



Biotech Daily

Tuesday September 12, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ANTISENSE UP 6%; PATRYS DOWN 11%**
- * **UNIQUEST, QUEENSLAND UNI Q-2361 FOR POST-TRANSPLANT SKIN CANCER**
- * **ARGENICA: ST VINCENT'S APPROVES PHASE II ARG-007 STROKE TRIAL**
- * **WESTERN AUSTRALIA \$419k FOR ARGENICA NON-I-V ARG-007**
- * **CARDIEX CONVERTIBLE NOTE FACILITY RAISES \$3.62 million**
- * **OSTEOPORE, INNOVENTURES CHINA J-V**
- * **PAINCHEK REQUESTS 'CAPITAL RAISE' TRADING HALT**
- * **IMUGENE WINS PD1-VAXX JAPAN PATENT**
- * **EYE CO FLUDROCORTISONE MACULAR DISEASE JAPAN PATENT**
- * **TDM GROWTH TAKES 28% OF SOMNOMED**
- * **AUSTRALIAN ETHICAL TAKES 14% OF SOMNOMED**
- * **FIL (FIDELITY) TAKES 8.4% OF SOMNOMED**
- * **BTC HEALTH FINANCE HEAD JOSHUA KAHANOVITZ TAKES 13%**
- * **COPIA DILUTED BELOW 5% OF BTC HEALTH**
- * **CLINUVEL APPOINTS SCENESSE VITILIGO ADVISORY PANEL**
- * **BIO-MELBOURNE 'VOICE TO PARLIAMENT' INFORMATION SESSION**

MARKET REPORT

The Australian stock market was up 0.2 percent on Tuesday September 12, 2023 with the ASX200 up 14.6 points to 7,206.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 12 traded unchanged and three were untraded. All three Big Caps were up.

Antisense was the best, up 0.4 cents or 6.25 percent to 6.8 cents, with 1.8 million shares traded. Emvision, Imugene and Neuren improved more than five percent; Medical Developments and Micro-X climbed more than four percent; Atomo, Avita and Telix were up more than three percent; Cyclopharm and Opthea rose more than two percent; Nanosonics, Proteomics and Resmed were up more than one percent; with Cochlear and CSL up by less than one percent.

Patrys led the falls, down 0.1 cents or 11.1 percent to 0.8 cents, with 2.1 million shares traded. Pharmaxis fell 10.3 percent; Starpharma lost 7.1 percent; Next Science and Prescient fell more than four percent; Impedimed was down three percent; Nova Eye shed 2.5 percent; Mesoblast and Orthocell were down more than one percent; with Clinuvel, Paradigm and Pro Medicus down by less than one percent.

UNIQUEST, UNIVERSITY OF QUEENSLAND

Uniquet says the University of Queensland has developed topical Q-2361 to “help rescue cancer-killing cells affected by tacrolimus and stop the development of skin cancers”.

The University of Queensland’s Prof James Wells said the treatment was shown in immune-suppressed mice “to reactivate the immune system in the skin and reduce skin cancer growth caused by taking tacrolimus, an immune suppressant that stops organ rejection in transplant recipients”.

The organization said that researchers were appealing for funds to launch clinical trials.

Uniquet said the mouse study, titled ‘Local blockade of tacrolimus promotes T-cell mediated tumor regression in systemically immunosuppressed hosts’ was published in The Journal for Immunotherapy of Cancer and the full article was available at:

<https://jitc.bmj.com/content/11/9/e006783>.

The study said that the results showed that Q-2361 “permitted T-cells to become activated, which drove tumor rejection in the presence of tacrolimus”.

“The data presented here suggests that topically applied Q-2361 has great potential for the reactivation of T-cells in the skin but not systemically, and therefore represents a promising strategy to prevent or treat skin malignancies in immune-suppressed organ transplant recipients,” the study said.

Uniquet said the study was a partnership between the University of Queensland’s Frazer Institute and Uniquet’s Queensland Emory Drug Discovery Initiative, a small molecule drug discovery capability based at the University of Queensland’s St Lucia campus.

Uniquet said it had filed a patent for the Q-2361 molecule.

Prof Wells said that immune-suppressive drugs like tacrolimus transformed patients’ lives “because they reduce acute rejection rates and increase patient survival”.

“But their unwanted side-effect is that they increase the incidence of skin cancer for transplant recipients, in particular squamous cell carcinomas and Kaposi’s sarcoma,” Prof Wells said.

Uniquet chief executive officer Dr Dean Moss said: “We hope to bring this first-of-a-kind treatment to market for transplant recipients and we have engaged specialist clinicians who can run clinical trials”.

“But to do so, we need potential partners or investors to help progress it through pre-clinical development and, ultimately, bring it into the clinic,” Dr Moss said.

For more information, contact Uniquet.

ARGENICA THERAPEUTICS

Argenica says Melbourne’s St Vincent Hospital has approved an up-to 92-patient, phase II trial of ARG-007 for acute ischaemic stroke, with dosing expected by April 2024.

Argenica said the primary objective would be to evaluate the safety of a single, intravenous dose of ARG-007, with the secondary objective the effect on reducing infarct volume, or the volume of brain cell death, in patients.

The company said patients with confirmed acute ischaemic stroke would be eligible for the trial and would be randomly assigned to either ARG-007 or a saline placebo prior to a thrombectomy procedure, the standard treatment for acute ischaemic stroke.

Argenica said further endpoints included improved neurological outcomes, improved degree of disability and improved quality of life.

Argenica chief executive officer Dr Liz Dallimore said that “proving safety and preliminary efficacy in a human patient population is a pivotal moment for Argenica and the culmination of over a decade of research work to get to this point”.

Argenica was up 1.5 cents or 3.9 percent to 40 cents.

ARGENICA THERAPEUTICS

Argenica says the Western Australia Government has granted it \$419,000 to develop a non-intravenous ARG-007 for chronic conditions such as Alzheimer's disease.

Argenica said the grant was from the Western Australia Government's Innovation Seed Fund program for its project, titled 'Improving Therapeutics Delivery to Halt or Slow Alzheimer's Disease Progression', for a non-intravenous route for ARG-007.

The company said multiple drug delivery methods would help it develop additional drug products relevant to patient needs, with tablets or nasal sprays preferable for chronic conditions requiring ongoing treatment, while acute conditions, like strokes, which required rapid and one-off treatment, were more suited to intravenous delivery.

Argenica said it would use the intravenous formulation in acute conditions, such as acute ischaemic stroke, hypoxic ischaemic encephalopathy and severe traumatic brain injury where it was imperative that a single-dose be delivered quickly to the blood stream.

The company said that following the development of a non-intravenous formulation, the project would assess its efficacy in an animal model of Alzheimer's disease to ensure it provided optimal efficiency, and if successful it would refer to the drug as ARG-008.

CARDIEX

Cardiex says its convertible note facility has so far raised \$3.62 million of up-to \$4.1 million along with free-attaching options.

In June, Cardiex said it had raised \$2.3 million through a convertible note facility, with subscriptions supported by directors Niall Cairns, Craig Cooper and Jarrod White, with the facility made up of \$1.5 million in convertible note subscriptions and \$800,000 in converting note subscription, at 10 percent interest paid quarterly (BD: Jun 30, 2023).

Today, Cardiex said it had issued 3,620,000 notes and 4,990,000 options.

Cardiex fell half a cent or three percent to 16 cents.

OSTEOPORE

Osteopore says it has a joint venture agreement with the Shanghai-based Innoventures Inc to commercialize its orthopedic products in China.

Osteopore said it expected to launch the joint venture in Singapore, with Osteopore to provide Innoventures with an exclusive, royalty-free licence for specific intellectual property, in return for 30 percent equity in the joint venture.

The company said that Singapore's Vertex Ventures HC, "the venture capital offshoot" of the Singapore Government's Temasek Holdings was a "key investor" in Innoventures.

Osteopore said that Innoventures collaborated with medical device companies to guide products from development through to regulatory approval and commercialization.

The company said that Innoventures would "contribute efforts towards raising capital, recruiting, and retaining a support organization" for the joint venture.

Osteopore said it expected its high tibial osteotomy implant for surgical realigning of knee joints to be the first product for which the joint venture would seek regulatory approval.

The company said that Innoventures had identified a China-based medical device and pharmaceutical company as a prospective investor in the joint venture, and it hoped to have a definitive joint-venture agreement by November 30, 2023.

Osteopore said the business and affairs of the joint venture would be managed by a board of directors, with one Osteopore-appointed director, one Innoventures-appointed director and one independent director appointed mutually by both parties.

Osteopore was up 0.6 cents or 8.7 percent to 7.5 cents.

PAINCHEK

Painchek has requested a trading halt pending “an announcement regarding a capital raise by way of a placement”.

Trading will resume on September 14, 2023, or on an earlier announcement.

Painchek last traded at 2.8 cents.

IMUGENE

Imugene says the Japanese Patent Office has granted a patent relating to its PD1-Vaxx lung cancer treatment.

Imugene said the patent, titled ‘Human PD1 Peptide Vaccines and Uses Thereof’, protected its PD1-Vaxx composition of matter and method of treatment in cancer until March 28, 2038.

Imugene was up 0.3 cents or 5.1 percent to 6.2 cents with 40.1 million shares traded.

EYE CO PTY LTD

Eye Co says the Japanese Patent Office has granted a patent for its lead compound fludrocortisone acetate to modulate retina receptors for macular diseases.

Eye Co said the patent, titled ‘Composition and Method of Treatment for Geographic Atrophy or Dry AMD’ would protect its intellectual property until 2039.

The company said the patent recognized the ability of fludrocortisone acetate to modulate the activity of both the gluco-corticoid and mineralo-corticoid receptors in the retina, meaning that unlike other steroids it provided “a balance of suppressing inflammation and improving retinal function”.

Eye Co said the patent covers the use of fludrocortisone acetate as a prophylactic, or preventative, treatment.

Eye Co said it was in the process of raising funds to undertake two studies to demonstrate fludrocortisone acetate’s effectiveness in humans in the treatment of geographic atrophy and as rescue therapy in patients with diabetic macular oedema.

Eye Co is a private company.

SOMNOMED

TDM Growth Partners says it has increased its substantial shareholding in Somnomed from 22,311,159 shares (26.96%) to 28,151,777 shares (28.41%).

Last week, Somnomed said it had raised \$2.75 million in placements, \$7 million in an institutional rights offer and expected a further \$5.7 million in a retail rights offer, all at 60 cents a share (BD: Sep 4, 2023).

Today, the Sydney-based TDM said that on September 8, 2023, along with Madleowill Investments and Zoolander Investments, it bought 5,840,618 shares in a rights offer for \$3,504,371 or 60 cents a share.

Somnomed was untraded at 61 cents.

SOMNOMED

Australian Ethical Investment says it has increased its substantial shareholding in Somnomed from 10,544,525 shares (10.64%) to 13,835,756 shares (13.96%).

Today, the Sydney-based Australian Ethical said that on September 1, 2023 it bought 3,291,231 shares for \$1,974,739, or 60 cents a share (see above).

SOMNOMED

FIL (Fidelity Investment Ltd) says it has increased its substantial shareholding in Somnomed from 6,032,200 shares (7.29%) to 8,349,794 shares (8.43%).

The Hong Kong-based Fidelity said between December 31, 2020 and April 22, 2022, it bought shares in more than 35 transactions at prices ranging from \$1.8750 to \$2.4875, and on September 8, 2023 bought 1,986,237 shares at 60 cents a share (see above).

BTC HEALTH

BTC Health head of finance Joshua Kahanovitz says he has become substantial in the company with 42,276,854 shares, or 13.05 percent.

Earlier this month, BTC said it had appointed Mr Kahanovitz as its head of finance and had "binding commitments" for a \$887,816 placement at 2.1 cents a share with Kingfisher Medical, Tau Medical and GLK Medical (BD: Sep 1, 2023).

Today, the Sydney-based Mr Kahanovitz said that on September 7, 2023, along with GLK Medical Pty Ltd, Kingfisher Medical Pty Ltd and TAU Investments Australia Pty Ltd, he bought 42,276,917 shares for \$887,816 or 2.1 cents a share.

BTC was unchanged at 2.4 cents.

BTC HEALTH

The Melbourne-based Copia Investment Partners says its 14,435,715 share-holding in BTC Health has been diluted to below five percent due to a placement (see above).

CLINUVEL PHARMACEUTICALS

Clinuvel says it has appointed a vitiligo expert panel including Prof Viktoria Eleftheriadou, Prof Khaled Ezzedine, Dr Peal Grimes and Prof Thierry Passeron.

Clinuvel said the advisory panel would support and provide advice on the late-stage development and commercialization of its Scenesse, or afamelanotide 16mg, for vitiligo and would meet periodically with its scientific and clinical teams to monitor progress, undertake critical analyses, and confirm that the overall program reflects contemporary clinical and academic thinking on vitiligo, "a complex disorder where patients lose skin pigmentation".

The company said Prof Eleftheriadou was a consultant dermatologist at the UK's Walsall Healthcare and Royal Wolverhampton National Health Service Trusts and a professor at the University of Birmingham's Institute of Applied Health Research.

Clinuvel said Prof Ezzedine was a professor of dermatology at France's Assistance Publique, Hôpitaux de Paris and the Hôpital Henri-Mondor.

The company said Dr Grimes was the director of the Vitiligo and Pigmentation Institute of Southern California and the Grimes Center of Medical and Aesthetic Dermatology, as well as professor of dermatology at University California Los Angeles' School of Medicine.

Clinuvel said Prof Passeron was professor and chair at France's University Hospital of Nice's department of dermatology, as well as professor of dermatology at the University Côte d'Azur, and head of a laboratory at the Mediterranean Centre for Molecular Medicine.

Clinuvel fell two cents or 0.1 percent to \$16.80 with 218,736 shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will host an information session on the 'Voice to Parliament' referendum on October 5, 2023.

The Network said the event was in collaboration with the Gadens law firm, with Gadens lawyer Leo Rodrigo to present on the history of advocacy that led to the referendum; the process of the referendum, including what it requires of voters and what it requires to be successful; and the implications of a successful referendum for Federal Parliament, first nations peoples and Australia as a whole.

The Bio-Melbourne Network said the on-line information session would be hosted by Mr Rodrigo and Bio-Melbourne chief executive officer Jeff Malone.

The organization said that following the presentation, there would be a guided question-and-answer session and open discussion.

Bio-Melbourne said the event would be free for both members and non-members and would be held online through Zoom from 4pm to 5.15pm (AEST), with registration required at: <https://biomelbourne.org/event/voice-to-parliament-information-session/>.