



Biotech Daily

Monday October 17, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ACTINOGEN UP 9.5%; NOVA EYE DOWN 16%**
- * **FEDERAL GOVERNMENT: ANSTO, SINGAPORE UNI SYNCHROTRON DEAL**
- * **PACIFIC EDGE H1 CXBLADDER CANCER TESTS UP 34%**
- * **TELIX: CHINA OKAYS ILLUCCIX PROSTATE CANCER IMAGING TRIAL**
- * **TELIX, GE HEALTHCARE WORK ON TLX250-CDX, 18-F-FLAC**
- * **PATRYS PAT-DX3 'CROSSES BLOOD-BRAIN BARRIER, IN MICE'**
- * **CYNATA: AUSTRALIA, CANADA ALLOW CYMERUS PATENT**
- * **ARGENICA 1st ARG-007 SUBJECT DOSED, 'NO ADVERSE EVENTS'**
- * **PROTEOMICS RECEIVES \$1.7m FEDERAL R&D TAX INCENTIVE**
- * **NEUROTECH TO START MARIJUANA NTI164 CHILDREN'S PSYCHIATRIC TRIAL**
- * **OPTHEA DIRECTORS 8.5m OPTIONS, 1.15m RIGHTS AGM**
- * **CHIMERIC CEO JENNIFER CHOW 17m OPTIONS, 4m SHARES AGM**
- * **RADIOPHARM 22m DIRECTOR OPTIONS AGM; SUSPENSION**
- * **IMUGENE: 27m DIRECTORS OPTIONS, 150% FEE HIKE AGM**
- * **NANOSONICS: 537k CEO MICHAEL KAVANAGH RIGHTS AGM**
- * **EMVISION 1.9m DIRECTORS OPTIONS AGM**
- * **ANTISENSE TO LOSE DIRECTOR DR GARY PACE**

MARKET REPORT

The Australian stock market fell 1.4 percent on Monday October 17, 2022, with the ASX200 down 94.4 points to 6,664.4 points. Thirteen of the Biotech Daily Top 40 were up, 19 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Actinogen was the best, up one cent or 9.5 percent to 11.5 cents, with 7.2 million shares traded. Immutep improved seven percent; Patrys was up 5.3 percent; Compumedics, Impedimed and Neuren were up more than four percent; Micro-X, Polynovo and Telix were up more than three percent; Resonance rose 1.9 percent; with Emvision, Opthea and Volpara up by less than one percent.

Nova Eye led the falls, down 4.5 cents or 15.8 percent to 24 cents, with 29,511 shares traded. Antisense, Clinuvel and Oncosil fell four percent or more; Atomo, Medical Developments and Paradigm were down more than three percent; Cynata and Pharmaxis shed more than two percent; Amplia, Avita, Cochlear, CSL, Genetic Signatures, Next Science, Orthocell, Proteomics and Starpharma were down one percent or more; with Mesoblast, Nanosonics, Pro Medicus and Resmed Neuren down less than one percent.

FEDERAL GOVERNMENT, AUSTRALIAN SYNCHROTRON

The Federal Government says National University of Singapore researchers will be able to use the Australian Synchrotron in Melbourne, in a five-year bi-national agreement.

A media release from Minister for Industry and Science Ed Husic said the researchers would use the Australian Nuclear Science and Technology Organisation (Ansto) facilities at the Synchrotron, located next to Monash University in Clayton.

The media release said that Mr Husic welcomed the bilateral agreement “as an opportunity to advance Australia’s and Singapore’s science and research collaboration”.

“This agreement demonstrates that Australia’s strong track record in operating the Australian Synchrotron,” Mr Husic said.

“As custodian of some of Australia’s most significant science infrastructure, Ansto makes an important contribution to science outcomes across the fields of human health, energy, advanced manufacturing, food science, and the environment,” Mr Husic said.

The media release said it was the first partnership supported by Singapore’s International Synchrotron Access initiative under its National Synchrotron Program.

PACIFIC EDGE

Pacific Edge says the number of Cxbladder tests processed in the six months to September 30, 2022 has increased 34.3 percent to 14,916 tests compared to last year. Pacific Edge did not disclose the value of tests, but last year said that its revenue primarily from the sales of its Cxbladder urine test for bladder cancer for the six months to September 30, 2021 was \$NZ5,378,000 (then \$A5,136,904) (BD: Nov 25, 2021).

The company said at that time that \$NZ4,982,000 of revenue came from the US and \$NZ396,000 from the rest of the world.

Today, Pacific Edge said that US tests for the six months to September 30, 2022 were up 42.1 percent to 12,769 tests, with New Zealand tests slipping from 2,153 for the six months to September 30, 2021 to 2,147 tests for the six months to September 30, 2022.

With a total of 11,109 tests in the six months to September 30, 2021 earning revenue of \$NZ5,378,000, Biotech Daily calculates the tests cost about \$NZ484 each.

Pacific Edge was untraded at 40.5 cents.

TELIX PHARMACEUTICALS

Telix says the Chinese National Medical Products Administration has approved its 110-patient, phase III study of TLX591-CDx Illuccix kit for prostate cancer imaging.

In August, Telix said that its partner Grand Pharma had filed applications to the China regulator for trial approvals for its TLX591-CDx Illuccix kit for prostate cancer imaging and TLX250-CDx for kidney cancer imaging (BD: Aug 2, 2022).

At that time, the company said the TLX591-CDx application had been accepted for review for a phase III study to bridge to the US Food and Drug Administration approval of Illuccix.

Today, Telix said that the phase III study of Illucix, would enrol patients with suspected recurrent prostate cancer and was expected to begin by April 2023.

Telix Asia Pacific chief executive officer Dr David Cade said that “each year 115,000 Chinese men will be diagnosed with prostate cancer, which makes it the most rapidly rising cancer in terms of incidence and mortality in China”.

Dr Cade said that prostate-specific membrane antigen positron emission tomography imaging had “the potential to profoundly impact the management of this disease, enabling clinicians to detect prostate cancer right throughout the body”.

Telix was up 18 cents or 3.3 percent to \$5.59 with 1.1 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has a development and reseller deal with GE Healthcare for its TLX250-CDx and 18-fluorine-3-fluoro-2-hydroxypropionate (18-F-Flac).

Telix did not disclose the commercial terms of the five-year agreement with the Chicago, Illinois-based GE Healthcare but said that it would be responsible for manufacture and development of each product, while GE would market and sell its imaging agents to pharmaceutical companies.

The company said that with GE Healthcare, it would explore validation of 18-F-Flac in GE's automated positron emission tomography (PET) radio-chemistry synthesizer, and that TLX250-CDx and 18-F-FLac complemented GE's investigational non-invasive 18-fluorine-CD8 and 18-fluorine-Granzyme-B imaging tracers for use in clinical trials, with the potential to predict and monitor responses to immunotherapy.

Telix head of business development Johnathan Barlow said the partnership would "see our investigational imaging agents used more widely in third-party clinical trials... [and] will also help to expedite the development of 18-F-Flac, while expanding the utility of our TLX250-CDx imaging candidate".

GE Healthcare immune-oncology business leader Sanka Thiru said the partnership expanded the company's products which aimed to "enrich clinical trials ... with the possibility of determining the metabolic environment and immune status of tumors, and if successful, help to improve speed to market for potential therapies".

PATRY'S

Patry's says its PAT-DX3 shows potential for deoxymabs to deliver gene therapies across the blood-brain barrier to treat neurological conditions, in mice.

Patry's said the study radioactively labelled PAT-DX3 and a control antibody to monitor their relative uptake into various tissues over four days, to establish "the distribution of PAT-DX3 in a range of different tissues to assist in the selection of future targets and payloads for future potential antibody drug conjugate development programs".

The company said the study found that uptake into the brain per cubic centimetre of PAT-DX3 was three to four-fold higher than that of a control antibody, persisting for the duration of the study, with significant concentrations of antibody still in the brain after four days.

Patry's said that PAT-DX3 compared favorably to antibodies that had been specifically engineered for enhanced blood-brain barrier crossing that had reported brain uptake values two to three-fold higher than control antibodies.

The company said that the ability of PAT-DX3 to cross the blood-brain barrier was "consistent with current data which indicates that Patry's' deoxymabs enter cells using the ENT2 transporter protein" and that "elevated levels of PAT-DX3 were found in brain tissue but not in a range of other tissues including the lung, the liver and the thyroid adding further support to this proposed mechanism for crossing the blood-brain barrier".

Patry's managing-director Dr James Campbell said "this is an important result that opens up a range of potential applications for Patry's and its development partners".

"PAT-DX3 appears to out-perform antibodies specifically developed by other companies for the delivery of payloads to brain tissue... [and] unlike deoxymabs, none of these other antibodies are able to deliver their payloads into the cell and the cell nucleus," Dr Campbell said.

"These properties open up a range of applications for using deoxymabs to deliver small molecule therapeutics and gene editing technologies directed to various neurological targets and conditions," Dr Campbell said.

Patry's was up 0.1 cents or 5.3 percent to two cents with 18.0 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has a “notice of acceptance” from Intellectual Property Australia and the Canada Intellectual Property Office for its Cymerus mesenchymal stem cell technology. Cynata said it had a patent application in Canada, titled ‘Pluripotent Stem Cell Assay’. The company said that an Intellectual Property (IP) Australia notice of acceptance was “sent to an applicant when IP Australia intends to issue a patent”.

Cynata said it expected the Australian patented to be granted by “late January 2023, with an expiration date of March 14, 2037”, and the first Canadian patent to be “granted by mid-January 2023, with an expiration date of March 14, 2037” and the additional ‘Pluripotent’ application expiring by November 15, 2037.

Cynata chief executive officer Dr Ross Macdonald said the patents “support our proprietary method of manufacturing [mesenchymal stem cells] which enables efficient manufacture ... at scale with consistent quality and without requiring multiple donors”. Cynata fell one cent or 2.9 percent to 33 cents.

ARGENICA THERAPEUTICS

Argenica says it has dosed the first of 32 subjects in its phase I, dose-escalation, trial assessing the safety and tolerability of intra-venous ARG-007.

In September, Argenica said the first-in-human trial of its brain protective ARG-007 would take place at the Perth-based Linear Clinical Research (BD: Sep 7, 2022).

Today, the company said there were “no serious safety issues 24 hours after dosing” and dosing of the remaining participants in cohort one would be done in the next three days. Argenica said the first volunteer in each cohort was a “sentinel subject” which meant the subject received the drug at least 24 hours prior to the other volunteers in the dose cohort. Argenica was up one cent or 2.2 percent to 46 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received \$1,711,904 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.

Proteomics said the rebate related to expenditure for the year to June 30, 2022.

Proteomics fell 1.5 cents or 1.55 percent to 95.5 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has begun a 10-children, phase I/II, single-arm, open-label trial of oral marijuana-based NTI164 in children with neuro-psychiatric disorders.

Neurotech said the study would investigate NTI162 the safety and efficacy in children with auto-immune neuro-psychiatric disorders associated with streptococcal infections (Pandas) and paediatric acute-onset neuro-psychiatric syndrome (PANS).

The company said that Pandas and Pans were diagnoses given to children who had a dramatic onset of symptoms including intense anxiety, obsessive-compulsive disorder and/or severely restrictive eating, and that the cause was mostly unknown, with no approved US or European therapies and “limited trials of new therapeutic interventions”.

Neurotech said that the primary endpoint was the change from baseline for clinical global impression scales and the children’s Yale-Brown obsessive compulsive scale, with secondary outcomes to examine safety and tolerability of orally administered NTI164 at 5mg/kg, 10mg/kg, 15mg/kg and 20mg/kg a day.

Neurotech was up half a cent or five percent to 10.5 cents.

OPTHEA

The Opthea annual general meeting will vote to issue 8,500,000 options and 1,150,000 performance rights to directors.

Opthea said shareholders would vote to issue managing-director Dr Megan Baldwin 3,000,000 options, exercisable at the 5-day volume-weighted average price (VWAP) at the grant date, vesting equally over three years and expiring 10 years from the grant date.

The company said the meeting proposed to issue directors Lawrence Gozlan and Daniel Spiegelman 2,000,000 options each, Michael Sistenich 1,500,000 options, all exercisable at the 5-day VWAP at the grant date within 10 years, as well as 500,000 performance rights each to Dr Baldwin and Mr Gozlan and 150,000 rights to Mr Spiegelman.

Opthea said shareholders would vote to re-elect chair Dr Jeremy Levin and directors Mr Spiegelman and Dr Julia Haller and adopt the remuneration report.

The virtual meeting will be held on November 16, 2022 at 9am (AEDT) at:

<https://meetnow.global/M9GHMNU>.

Opthea was up half a cent or 0.5 percent to \$1.02.

CHIMERIC THERAPEUTICS

Chimeric says that its annual general meeting will vote to issue 17,222,368 options and 4,338,990 shares to chief executive officer Jennifer Chow.

Chimeric said that investors would vote to issue Ms Chow 17,222,368 options, exercisable at 9.2 cents each by July 1, 2027 and 4,338,990 shares vesting over three years.

The company said the options were worth \$1,205,566 and the shares \$399,187.

Chimeric said investors would vote on two resolutions relating to placements to L1 Capital of up to \$30 million, to renew the employee incentive plan, re-elect chair Paul Hopper as a director, approve the 10 percent placement facility and accept the remuneration report.

The meeting will be held at Level 3, 62 Lygon Street, Carlton on November 15, 2022 at 10am (AEDT) and virtually at: <https://web.lumiagm.com/351-025-252>.

Chimeric fell half a cent or 5.75 percent to 8.2 cents with 1.25 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says its annual general meeting will vote to issue 22,166,931 options to directors and has extended its trial result trading halt to a suspension.

Radiopharm said investors would vote to issue managing-director Riccardo Canevari 12,505,088 options, and chair Paul Hopper 4,210,329 options, exercisable at 17 cents each within five years, vesting in three equal tranches over three years

The company said it proposed to issue 1,900,002 options each to directors Hester Larkin and Dr Leila Alland, exercisable at 60 cents each within four years and 1,651,51 options to director Ian Turner exercisable at 17 cents each within five years.

Radiopharm said that shareholders would vote to elect directors Mr Hopper, Ms Larkin and Dr Alland, accept the remuneration report, renew the incentive plan and approve the 10 percent placement facility.

The meeting will be held at Level 3, 62 Lygon Street, Melbourne on November 16, 2022 at 10am (AEDT) and virtually with registration available at:

https://us02web.zoom.us/webinar/register/WN_jW7vtbhDS_CmAE97r5fbQw.

Separately, Radiopharm requested a voluntary suspension following its trading halt for an announcement about the Pivalate phase II data in brain 'mets' trial (BD: Oct 13, 2022).

Trading will resume tomorrow, October 18, 2022, or on an earlier announcement.

Radiopharm last traded at 16.5 cents.

IMUGENE

The Imugene annual general meeting will vote to issue 27,100,000 options to directors and increase the director remuneration pool by 150 percent to \$1,000,000.

Imugene said shareholders would vote to issue managing-director Leslie Chong 3,000,000 options, exercisable at 40 cents each, and 17,300,000 options exercisable at 30.6 cents each, vesting in equal parts over three years, expiring on July 1, 2026.

The company said it proposed to issue chair Paul Hopper 2,900,000 options, directors Dr Jens Eckstein, Dr Lesley Russell and Charles Walker 600,000 options each, and director Dr Jakob Dupont 400,000 options, all exercisable at 30.6 cents an option, vesting in equal parts over three years, expiring on July 1, 2026, and issue 1,700,000 options to Dr Dupont, exercisable at 18.4 cents each by September 30, 2026.

Imugene said shareholders would vote to increase the non-executive director fees from by \$600,000 or 150 percent, from \$400,000 to \$1,000,000 a year.

The company said the meeting would vote to elect directors Mr Hopper, Dr Russell, Dr Eckstein and Dr Dupont, approve a prior placement, renew the share option plan and adopt the remuneration report.

The meeting will be held at Level 3, 62 Lygon Street, Melbourne on November 17, 2022 at 10am (AEDT) and virtually, with registration available at:

https://us02web.zoom.us/webinar/register/WN_TwP1xIMzRKiRgJ4wtDd6_w.

Imugene was unchanged at 17 cents with 13.1 million shares traded.

NANOSONICS

The Nanosonics annual general meeting will vote to issue chief executive officer Michael Kavanagh 537,715 rights, and increase directors pay pool by 20 percent.

Nanosonics said shareholders would vote to approve 21,871 service rights to Mr Kavanagh exercisable for nil consideration as part of his 2022 short-term incentive, expiring on August 31, 2027, as well as 283,930 share appreciation rights exercisable at \$4.143 and 231,914 performance rights with a nil exercise price as part of his long-term incentive, vesting on performance hurdles and expiring September 30, 2029.

The company said that the meeting would vote on a 20 percent increase in the maximum aggregate director's remuneration from \$1,000,000 to \$1,200,000, to re-elect Marie McDonald as a director and accept the remuneration report.

The meeting will be held at the Four Seasons Hotel, 199 George Street, Sydney on November 18, 2022 at 11am (AEDT) and virtually at: <https://meetnow.global/MN4WZNM>.

Nanosonics fell one cent or 0.3 percent to \$3.60 with 295,829 shares traded.

EMVISION MEDICAL DEVICES

Emvision says its annual general meeting will vote to issue 1,900,000 options to directors, all exercisable at \$2.25, by December 31, 2025.

Emvision said investors would vote to issue managing-director Ron Weinberger and executive director Scott Kirkland 500,000 options each, with half vesting on December 31, 2023 and the remainder on December 31, 2024, to issue chair John Keep 300,000 options and directors Philip Dubois, Tony Keane and Geoff Pocock 200,000 options each.

Emvision said that shareholders would vote to re-elect Mr Kirkland and Mr Pocock as directors, accept the remuneration report and approve the 10 percent placement facility.

The meeting will be held at Emvision, Suite 4.01, 65 Epping Road, Macquarie Park, Sydney on November 16, 2022 at 10am (AEDT).

Emvision was up one cent or 0.75 percent to \$1.34.

ANTISENSE THERAPEUTICS

Antisense says Dr Gary Pace will retire as a non-executive director at its annual general meeting on November 17, 2022.

Antisense said Dr Pace had been a director for seven years, since 2015 and managing-director Mark Diamond thanked Dr Pace “for his stewardship and service during his tenure ... in which time the company successfully advanced its program in Duchenne muscular dystrophy from concept to advanced stage clinical development”.

“Gary’s extensive corporate experience, particularly in governance, has been an important asset to the board and the company,” Mr Diamond said.

Antisense fell 0.4 cents or 4.4 percent to 8.6 cents.