



Biotech Daily

Thursday October 12, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH FLAT: KAZIA UP 10%; DIMERIX DOWN 10%**
- * **CONTROL BIONICS NEUROSTRIP 'BROADENS APPLICATIONS'**
- * **NUHEARA INSTITUTIONAL RIGHTS RAISE \$2.5m; RETAIL FOR \$7.5m**
- * **TRUSCREEN H1 REVENUE UP 33% TO \$986k**
- * **VISIONEERING NATURALVUE 'REDUCES MYOPIA PROGRESSION'**
- * **AROVELLA \$300k SCRIP FOR SPARX SPX-101 FOR GASTRIC CANCER**
- * **IMRICOR: CROATIA'S DUBRAVA HOSPITAL ORDERS ICMR**
- * **AROVELLA 2.2m M-D OPTIONS, \$190k DIRECTOR OPTIONS AGM**
- * **CYNATA 1.9m DIRECTOR OPTIONS AGM**
- * **RESONANCE 100% DIRECTORS PAY POOL HIKE TO \$500k AGM**
- * **ANTEOTECH RECEIVES \$3.8m FEDERAL R&D TAX INCENTIVE**
- * **CSL LOSES DIRECTOR BRUCE BROOK**
- * **SOMNOMED LOSES DIRECTOR HILTON BRETT**

MARKET REPORT

The Australian stock market edged up 0.04 percent on Thursday October 12, 2023, with the ASX200 up 2.6 points to 7,091.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and three were untraded. All three Big Caps fell.

Yesterday's 37.5 percent worst, Kazia, was the best, up one cent or 10.0 percent to 11 cents, with 1.6 million shares traded. Next Science climbed 6.1 percent; Amplia and Nova Eye improved more than four percent; Starpharma and Volpara were up three percent or more; Clinuvel and Orthocell rose more than two percent; 4D Medical, Emvision and Mesoblast were up more than one percent; with Cyclopharm, Nanosonics, Polynovo and Pro Medicus up by less than one percent.

Yesterday's 28.1 percent best, Dimerix, led the falls, down two cents or 9.8 percent to 18.5 cents, with 25.4 million shares traded. Actinogen lost 9.5 percent; CSL, Impedimed and Imugene were down six percent or more; Pharmaxis, Resmed and Universal Biosensors shed more than five percent; Opthea and Proteomics fell more than four percent; Avita, Paradigm and Prescient were down three percent or more; Neuren and SDI shed more than two percent; Antisense, Immutep and Telix were down more than one percent; with Cochlear down by 0.7 percent.

[CONTROL BIONICS](#)

Control Bionics says it has launched its 5gm Neurostrip wearable device for assistive communication and other uses, using a range of electro-physiologic activity.

Control Bionics said the flexible electrode circuit board could conform to the curvature of the desired body part to monitor a range of physiological activities.

The company said that Neurostrip could monitor electro-myography (EMG or muscle movement), electro-oculography (eye movement) and spatial data like its predecessor Neuronode, as well as monitor for electro-encephalography (EEG or brain waves) and electro-cardiography (ECG or heart activity and rhythm).

Control Bionics chief executive officer Jeremy Steele told Biotech Daily that the Neurostrip had increased range of potential uses for the electro-myography-based systems beyond the disability sector to other conditions including Parkinson's disease, as well as fitness and health status monitoring.

The company said that Neurostrip's electrode interface allowing for "unrivalled" signal clarity and eliminated "the need for wires, electrode snaps or other interface techniques that invariably degrade the physiological signal".

"From an EMG standpoint, this means there are instances where the Neurostrip can register the user's intent to move a finger, for example, without any actual movement of that finger," Control Bionics said.

The company said that the existing Neuronode system was currently used in the disability market, and was a key differentiator in its Trilogy system.

In 2022, Control Bionics said that Japan's Double R&D would bring the Neuronode Trilogy to people with conditions including amyotrophic lateral sclerosis, cerebral palsy, intellectual disability, stroke and traumatic brain injuries (BD: Apr 11, 2022).

Today, Control Bionics said that Neurostrip allowed for similar features with a significant advancement in power management, discreteness and data transfer capabilities.

The company said that the direct-to-skin electrode interface meant Neurostrip's non-invasive electrode interface allowed designers and researchers to access the body's "signal highway" with high signal fidelity.

Control Bionics said that it expected Neurostrip to expand its "reach and impact across a wide range of fields, including healthcare, fitness and critical care".

Mr Steele said Neurostrip was "a testament to our commitment to pushing the boundaries of wearable technology".

"We are thrilled to introduce this revolutionary device, which not only enhances the lives of individuals with disabilities but also holds immense potential for other applications," Mr Steele said.

Control Bionics fell half a cent or 7.1 percent to 6.5 cents with 1.2 million shares traded.

[NUHEARA](#)

Nuheara says it has raised \$2.5 million of a hoped-for \$10 million in an institutional entitlement offer at 13 cents a share, with a \$7.5 million retail offer to follow.

On Tuesday, Nuheara it hoped to raise about \$10 million in an accelerated, one-for-2.64, non-renounceable, non-underwritten entitlement offer (BD: Oct 10, 2023).

Today, the company said its largest shareholders Realtek and Farjoy applied for their full entitlements, and it hoped to raise the remaining \$7.5 million through the retail offer which would open on October 17 and close on October 30, 2023.

Nuheara said the funds raised would support its expansion with several US retailers.

The company said Bell Potter Securities was lead manager of the retail offer.

Nuheara was up half a cent or 3.7 percent to 14 cents.

TRUSCREEN GROUP

Truscreen says revenue for the six months to September 30, 2023 was up 33.2 percent to \$986,051, with sales of its sensors up about 28 percent to 95,040 units.

Truscreen said sales of its single-use, disposable sensors in China increased to pre-Covid-19 levels, supported by recognition in “major national guidelines” including the Chinese Society of Colposcopy and Cervical Pathology journal and the China Blue Book. The company said Saudi Arabia had begun commercial operations in July and it expected a positive result from the Mexico national regulator Cofepris later this year, allowing it to distribute its Truscreen Ultra in the public hospital system and government programs.

Truscreen said four “major screening hospitals” in Vietnam were pending approval to use its screening device with “strong” local authority support, and Masvingo province in Zimbabwe had screened 14,000 women under the National Aids Council program, with a further Truscreen tender was underway, with a decision expected in October 2023.

The company said a positive decision could see the next order of 10,800 sensors “give a strong start” to sales for the three months to December 31, 2023.

Truscreen was up 0.1 cents or 4.2 percent to 2.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says one-year results from its Naturalvue contact lens trial show 69 percent eye refractive error progression and 59 percent axial length compared to controls.

In 2022, Visioneering said it had enrolled its first of 144 near-sighted, healthy children for the multi-centre, randomized, double-masked clinical trial of its Naturalvue Multifocal one-day contact lenses for myopia progression control (BD: Jan 24, 2022).

At that time, the company said patients would be randomly assigned Naturalvue Sphere single vision contact lenses, as the control lens, or Naturalvue Multifocal contact lenses, as the test lens, to study changes in refractive error progression and eye length over time. Today, Visioneering said the results showed the safety and efficacy of its Naturalvue multifocal lenses in slowing myopia progression and that, combined with its previous six-year data and two independent studies, showed the lenses “effectively manages eye growth and refractive error change among progressing myopic children”.

Visioneering said the three-year study had interim analyses stipulated after one-year and two-year patient follow-ups, with interim analyses from studies of similar design being predictive of the three-year results.

The company said the data showed its Naturalvue contact lenses were consistent with those of the only treatment approved in the US for myopia progression control.

Visioneering said it would continue to review and analyze the one-year data set and planned to share additional details in January 2024.

Visioneering chief medical officer Dr Ashley Tuan said “the preliminary one-year data validates our expectations of the safety and effectiveness of Naturalvue Multifocal contact lenses for paediatric patients”.

“Naturalvue Multifocal one day also provides clear vision for myopia correction and effectively slows myopia,” Dr Tuan said.

Visioneering chief executive officer Dr Juan Aragón said the data release “signals the beginning of a new chapter for Visioneering as we secure our place on the global map as a positive intervention option in myopia management”.

“The new interim results are outstanding and may support imminent partnering opportunities and commercial growth in key markets throughout Asia and Europe,” Dr Aragón said.

Visioneering was unchanged at 25 cents.

AROVELLA THERAPEUTICS

Arovella says it will issue Sparx Group \$300,000 in shares for its antibody SPX-101 to be used with Arovella's invariant natural killer T-cell treatment for gastric cancers.

Arovella said the Chicago-based Sparx Group had developed SPX-101 to target Claudin 18.2 which was expressed in gastric cancers and that it had completed the safety and toxicology studies required to begin a phase I trial.

The company said it would incorporate SPX-101 into its invariant natural killer T-cell platform to generate a chimeric antigen receptor platform to target gastric cancer, gastroesophageal junction cancer, pancreatic cancer and other solid tumors.

Arovella said the Claudin 18.2 invariant natural killer T (INKT)-cells would be an off-the-shelf treatment with "direct cancer-killing ability" and were expected to provide superior cancer killing properties relative to an antibody alone.

Arovella said INKT-cells had inherent properties that might make them amenable to targeting solid tumors such as the ability to infiltrate tissues and tumors, block or kill cells that promote tumor survival and release cytokines to stimulate immune responses.

The company said the agreement included an upfront fee of \$300,000 in equity, or 4,347,826 shares at the five-day volume weighted average price of 6.9 cents each, subject to 12-months in escrow.

Arovella said the agreement also included milestone payments in cash and equity for milestones such as confirming the compatibility of the antibody, investigative new drug acceptance, beginning phase II and III trials and regulatory approval.

The company said the remaining milestone equity payments totaled \$900,000 which, if all were achieved, would be 13,043,478 shares at the current volume weighted average price, which could be issued under its existing placement capacity.

The company said potential further contingent cash milestone payments totaled \$US14 million (\$A21.8 million), \$US12.5 million of which was payable if the treatment received US Food and Drug Administration approval.

Arovella said the majority of the cash milestone payments were dependent on regulatory approvals, and based on other therapeutic drug development programs would "typically be longer than seven years".

Arovella said the capital requirements necessary to show the potential of the antibody with its invariant killer T-cell product was expected to be less than \$500,000 during the next year and would be funded from its existing cash reserves.

The company said several products in clinical development targeted Claudin 18.2 (CLDN18.2), with Astellas Pharma-owned zolbetuximab the most advanced.

The company said SPX-101 had "superior target affinity, specificity and anti-tumor activity" in mice compared to zolbetuximab in internal pre-clinical studies, and had an open investigational new drug application with the US Food and Drug Administration.

Arovella said the agreement contained standard termination provisions, and Sparx retained ownership of the licenced technology and the validity of the licence agreement.

Arovella managing-director Dr Michael Baker said that "Sparx has completed excellent work demonstrating the superior activity of its CLDN18.2 [monoclonal antibody], and also its robust safety and specificity".

"CLDN18.2 is an exciting target, generating a lot of interest globally," Dr Baker said.

"Arovella will be the only company in the world developing a [chimeric antigen receptor invariant killer] T-cell therapy targeting CLDN18.2," Dr Baker said.

"The natural benefits that [invariant natural killer T-cell] may bring to solid tumors, combined with the CLDN18.2 [chimeric antigen receptor], is a compelling concept for cancer patients Arovella," Dr Baker said.

Arovella fell 0.3 cents or 3.85 percent to 7.5 cents with 27.9 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says the Zagreb, Croatia-based Clinical Hospital Dubrava will use its interventional cardiac magnetic resonance (ICMR) imaging systems.

Imricor said Dubrava would order a minimum of 50-procedures-worth of consumable product within the next months, with installation by the end of this month.

Imricor chief executive officer Steve Wedan said the clinical market was “showing signs of opening up once again, and we are thrilled to be commencing procedures at Dubrava”.

“While this site is not a dedicated cardiology-owned ICMR lab, they have good [magnetic resonance imaging] capacity and a great partnership between cardiology and radiology, so we do not expect the cases to be limited by the lab’s availability,” Mr Wedan said.

“As I noted previously, activating sites is a key focus for our European sales team, and Dubrava is the direct result of that focus,” Mr Wedan said.

Imricor fell 1.5 cents or 2.75 percent to 53 cents.

AROVELLA THERAPEUTICS

Arovella says its annual general meeting will vote to issue 2,178,531 “incentive” options to managing director Dr Michael Baker and issue \$190,000 of director options.

Arovella said Dr Baker’s options would be exercisable at 7.5 cents each by June 30, 2027 and were 150 percent of the five-day volume weighted average price to June 30, 2023.

The company said that the issue of options to Mr Baker was part of his long-term incentive plan, in addition to his \$340,000 annual salary.

Arovella said to preserve cash its directors had agreed to receive part of their salary as options in lieu of cash, including \$40,000 in options to Gary Phillips, Dr Debora Barton and Dr Elizabeth Stoner and \$70,000 in options to Dr Thomas Duthy.

Arovella said the directors would also receive cash payments of \$40,000 for Mr Phillips, \$US40,000 (\$A62,300) for Dr Barton and Dr Stoner and \$90,000 for Dr Duthy.

The company said the meeting would vote to adopt the remuneration report, elect Dr Duthy as a director, approve the long-term incentive plan and the additional 10 percent placement capacity.

Arovella said the meeting would be held online on November 10, 2023 at 11am (AEDT).

CYNATA THERAPEUTICS

Cynata says its annual general meeting will vote to issue 1,910,000 options to directors worth a total of \$145,250 on top of their annual pay, under its employee incentive plan.

Cynata said shareholders would vote to issue 500,000 options worth \$37,500 to chair Dr Geoff Brooke, above his \$118,973 fees, 220,000 options each to Dr Paul Wotton, Janine Rolfe and Dr Darryl Maher, as well as their \$59,487 directors’ fees, and 750,000 options to Dr Kilian Kelly, along with his \$400,000 base salary.

The company said the options would be exercisable at a 45 percent premium to the five-day volume weighted average price to November 12, 2023, within five years from grant and vested in monthly tranches.

Cynata said the meeting would vote to re-elect director Dr Darryl Maher, approve the issue of equities under the employee incentive plan, renew its proportional takeover approval provisions, adopt its remuneration report and approve an additional 10 percent placement facility.

The meeting will be held at the Amora Hotel Riverwalk Melbourne, 649 Bridge Road, Richmond, on November 13, 2023 at 11am (AEDT).

Cynata was untraded at 13 cents.

[RESONANCE HEALTH](#)

Resonance says its annual general meeting will vote to increase the total directors pay pool from \$250,000 to \$500,000 due to the appointment of two additional directors.

Resonance said the increased level of directors fees ensured it maintained its capacity to remunerate existing and any further directors, remunerate directors “appropriately for the expectations placed upon them” and had the ability to attract and retain directors.

The company said that since the approval of the \$250,000 limit in 2016 it had appointed Aaron Brinkworth as an additional director and Mitchell Wells had reverted to a non-executive director from his role as managing-director.

Resonance said that shareholders would vote to re-elect directors Dr Martin Blake, Mr Wells and Mr Brinkworth, adopt the remuneration report, approve its 10 percent placement facility and undertake a selective share buyback and cancel 20 million shares from Acuity Capital.

In August, Resonance said its “at-the-market” standby equity capital facility with Acuity Capital expired on July 31 and it issued Acuity 20,000,000 shares as collateral, which it had agreed to return and cancel for no consideration (BD: Aug 2, 2023).

Resonance said the meeting would be held at 141 Burswood Road, Burswood, Perth, Western Australia on November 16, 2023 at 10am (WST).

Resonance was untraded at 7.1 cents.

[ANTEOTECH](#)

Anteotech says it has received \$3.77 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Anteotech said the rebate related to expenditure for the year to June 30, 2023.

Biotech Daily asked Anteotech for the complete amount but a response was not received by the time of publication.

Anteotech was up 0.1 cents or 3.2 percent to 3.2 cents with 1.6 million shares traded.

[CSL](#)

In an Appendix 3Z notice to the ASX, CSL director Bruce Brook says he resigned on October 11, 2023, following the company’s annual general meeting.

At its annual general meeting, CSL chair Dr Brian McNamee said Mr Brook would retire as a director and thanked him for “his service over the last 12 years”.

CSL fell \$16.03 or 6.3 percent to \$238.24 with 2.5 million shares traded.

[SOMNOMED](#)

Somnomed says that three-year non-executive director Hilton Brett has resigned, effective from today.

Somnomed said Mr Brett had accepted a co-chief executive officer role with the fast-food company Guzman y Gomez, of which he had been a director of “for many years”.

Somnomed was unchanged at 59 cents.