



Biotech Daily

Tuesday October 25, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ACTINOGEN, RESONANCE UP 9%;
- PHARMAXIS DOWN 11%**
- * **AROA H1 REVENUE UP 64% TO \$27m**
- * **CANN GROUP SHARE PLAN TO RAISE UP-TO \$10m**
- * **LBT RIGHTS OFFER TO RAISE \$3.5m**
- * **CANADA APPROVES POLYNOVO NOVOSORB BTM**
- * **4D MEDICAL LAUNCHES COMPUTED TOMOGRAPHY LVAS**
- * **RESONANCE RELEASES 'RESONANCE CLINICAL'**
- * **BCAL TO ESTABLISH SYDNEY CLINICAL SERVICE LAB**
- * **OPTISCAN 6m SHARES TO M-D PROF CAMILE FARAH FOR DATASETS**
- * **INVION PHOTOSOFT ACTIVITY AGAINST DENGUE, IN-VITRO**
- * **SINGAPORE GRANTS FIREBRICK NASODINE PATENT**
- * **EMVISION RECEIVES \$2m OF \$5m FEDERAL MANUFACTURING GRANT**
- * **DIMERIX RECEIVES \$6m FEDERAL R&D TAX INCENTIVE**
- * **IMAGION RECEIVES \$2.5m FEDERAL R&D TAX INCENTIVE**
- * **CRESO BREAKS ASX RULE, TO SELL 14.5m ALVIN BLUMENTHAL SHARES**
- * **PRESCIENT INTERIM PTX-100 CANCER DATA 'NO SERIOUS EVENTS'**
- * **CLARITY 1.9m DIRECTOR OPTIONS AGM**
- * **IMRICOR: ASX REMOVES US PROHIBITION ON CDIS**
- * **NEUROTECH REQUESTS 'RESULTS, CAPITAL RAISING' TRADING HALT**
- * **PERENNIAL TAKES 14.9% OF MICROBA**
- * **FOUNDER DR GRAHAM KELLY REDUCES TO 12% OF NOXOPHARM**
- * **CORRECTION: CANN GROUP**
- * **OPTHEA APPOINTS TIMOTHY MORRIS US-BASED CFO**

MARKET REPORT

The Australian stock market was up 0.28 percent on Tuesday October 25, 2022, with the ASX200 up 19.2 points to 6,798.6 points. Fifteen of the Biotech Daily Top 40 were up, 14 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

Actinogen and Resonance were the best, both up 9.1 percent to 12 cents and six cents, respectively, with 2.9 million shares and 394,119 shares traded, respectively.

Dimerix was up 6.1 percent; Oncosil improved 4.2 percent; Clinuvel climbed 3.3 percent; Imugene, Nanosonics, Pro Medicus and Volpara rose more than two percent; Amplia, Antisense, Avita, CSL, Next Science and Telix were up one percent or more; with Cochlear, Emvision and Resmed up by less than one percent.

Pharmaxis led the falls, down 0.8 cents or 11.1 percent to 6.4 cents, with 2.5 million shares traded.

Nova Eye lost 10.2 percent; Genetic Signatures shed 9.1 percent; Immutep fell 5.1 percent; Alcidion, Micro-X, Neuren and Polynovo were down more than three percent; both Medical Developments and Uscom were down 1.8 percent; with Cyclopharm, Mesoblast, Opthea and Paradigm down by less than one percent.

AROA BIOSURGERY

Aroa says unaudited revenue for the six months to September 30, 2022, was up 63.7 percent to \$NZ29.8 million (\$A26.9 million).

Aroa said receipts from customers for the six months to September 30, 2022 were up 79.8 percent to \$NZ24,938,000, primarily from sales of its sheep stomach-based wound treatments, including Myriad for soft tissue repair and Symphony for wound closure.

The company said receipts from customers for the three months to September 30, 2022 were up 28.15 percent to \$NZ11,021,000, compared to the prior corresponding period.

Aroa said it had a cash burn rate of \$NZ4,324,000 for the quarter, and cash equivalents of \$NZ50,120,000 or 11 quarters of funding available.

Aroa was up 8.5 cents or 10.6 percent to 89 cents.

CANN GROUP

Cann Group says it has an \$8 to \$10 million share purchase plan at 22 cents a share, to expand its Mildura manufacturing capabilities.

Cann Group said that the share plan was at an 18.8 percent discount to the five-day volume-weighted average price of its shares to October 24, and eligible shareholders could apply for a minimum of \$500 and up to \$30,000 of new shares.

The company said the share plan's record date was October 24, the opening date was October 31 and the closing date was November 18, 2022.

Cann Group said the funds would be used to scale up production at its Mildura facility in preparation for demand for its over-the-counter cannabidiol products, develop tetrahydrocannabinol Satipharm products and working capital.

Cann Group fell four cents or 14.8 percent to 23 cents with 3.6 million shares traded.

LBT INNOVATIONS

LBT says it will offer a one-for-six, non-renounceable rights offer to raise \$3.5 million at 6.5 cents a share, an 8.9 percent discount to the closing price on October 24, 2022. LBT said that investors would receive one option for every three shares subscribed for, exercisable at 13 cents, within two years of issue.

The company said the record date was October 28, the offer would open on November 1 and close on November 22, 2022.

LBT said that the funds would be used for US and European sales and marketing activities, completion of analysis modules for its Apas automated plate assessment system instrument, and working capital.

LBT fell 1.2 cents or 16.4 percent to 6.1 cents with 1.6 million shares traded.

POLYNOVO

Polynovo says Health Canada has approved registration of its Novosorb biodegradable temporizing matrix (BTM) for skin regeneration, including full thickness burns.

Polynovo said the Novosorb BTM registration approval was for "all indications currently approved in the European and Australian markets, which includes full thickness burns".

The company said it would launch the product at the Canadian Burn Conference on October 21 to 23, 2022.

Polynovo chief executive officer Swami Raote said "having previously met the needs of surgeons requesting BTM for critical cases under the special access scheme, we are very pleased BTM will now be made available to all surgeons and patients in Canada".

"This registration puts us well on our way to accelerating our global impact," Mr Raote said.

Polynovo fell 6.5 cents or 3.2 percent to \$1.945 with 1.8 million shares traded.

4D MEDICAL

4D Medical says it has released its computed tomography lung ventilation analysis software (CT LVAS).

4D said the image processing software provided an "almost identical report" to its XV LVAS but used computed tomography (CT) imaging rather than x-ray equipment.

In June, the company said it had an expanded contract with Sydney's I-Med Radiology Network to deliver its lung imaging technology to selected clinics (BD: Jun 28, 2022).

Today, 4D said CT LVAS used existing CT hardware and could be integrated easily into I-Med's clinical workflows and existing CT network, creating "a framework for the rapid commercialization of the CT LVAS product in Australia".

4D chief executive officer Prof Andreas Fouras said the product extension showed "rapid progress in developing a more comprehensive product pipeline".

"CT LVAS also represents significant progress towards release of our CT:VQ technology, which will allow quantitative functional imaging of both ventilation (airflow) and perfusion (blood flow) within the lungs from a traditional CT scan," Prof Fouras said.

"This advance will obviate the need for either CT contrast or nuclear imaging radiotracers, representing a material step forward for medical imaging and offering 4D Medical access to significant pricing premiums over XV LVAS and CT LVAS," Prof Fouras said.

4D Medical was up 1.5 cents or 2.5 percent to 62.5 cents.

RESONANCE HEALTH

Resonance says it has launched 'Resonance Clinical', to "capitalize on the... rapidly expanding global clinical trial marketplace" and provide clinical research services. Resonance said it would relocate personnel from its Murdoch University and University of Western Australia facilities to a dedicated Resonance clinical laboratory at Bentley Tech Park in Perth which would provide clinical research organization services such as image-analysis and trial management.

The company said it would focus on drugs and therapies being developed to treat liver disorders such as iron-overload, non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (Nash).

Resonance Clinical program-director and chief scientist Dr Sherif Boulos said "this initiative will unleash the full potential of the company's scientific, commercial and compliance capabilities that have evolved and strengthened over the years".

"By expanding its services in this way, Resonance Health will open itself up to new lucrative markets that demand high-value, high-quality services that we are familiar with and qualified to provide, but in the past have only provided in a limited way," Dr Boulos said.

Resonance managing-director Mitchell Wells said his company was known for its services and technologies relating to the liver and had "assisted many [pharmaceutical] customers with their development of drugs to treat liver diseases, which is also our highest profit margin work".

"We currently provide services to 10 clinical trials and by leveraging the full range of capabilities across the group, including in liver wet-lab molecular medicine, we can provide many more services to clinical trials," Mr Wells said.

"Some customers are asking more of us than has historically been the case and we have a great opportunity to capitalize on this, from within our existing customer base, and from the mostly untapped, prolific global liver clinical trial marketplace," Mr Wells said.

"The Resonance Clinical initiative is specifically aimed at new commercialization opportunities from enhanced CRO service provision and new central wet lab services," Mr Wells said.

Resonance was up half a cent or 9.1 percent to six cents.

BCAL DIAGNOSTICS

Bcal says it has established a development and clinical service laboratory in Sydney, to validate its breast cancer test.

Bcal said it had a commitment to lease a facility in Sydney but did not disclose the commercial terms of the agreement.

The company said that the laboratory would be the testing site for clinical studies and would establish quality systems and protocols to be compliant with ISO15189 and National Pathology Accreditation Advisory Council laboratory standards.

Bcal executive chair Jayne Shaw said "the establishment of a development and clinical laboratory is a key step in making the Bcal blood test for breast cancer available to Australian women, providing an additional important tool for clinicians to screen and diagnose breast cancer".

"Over the next several months we will be hiring personnel and certifying the necessary equipment with the aim to have the laboratory fully functional by the end of February 2023," Ms Shaw said.

Bcal was unchanged at 6.6 cents.

OPTISCAN IMAGING

Optiscan says it will issue 6,000,000 shares to managing-director Prof Camile Farah for his clinical and histopathological datasets, subject to shareholder approval.

Optiscan said the dataset included 228 matched patient libraries of oral cancer, precancer subtypes and normal tissues, including confocal image files, corresponding non-confocal optical images histopathological images with consensus diagnoses, and matching annotated clinical data, with long term follow-up details.

The company said the datasets would benefit it by improving its US Food and Drug Administration submissions for fluorescein, increasing utility of its Invivage oral imaging system, creating artificial intelligence algorithms, facilitating new developments for confocal microscopy, and increasing data access.

Optiscan said it expected to issue the shares on or around December 1, 2022.

Optiscan was up one cent or 7.1 percent to 15 cents.

INVION

Invion says in-vitro studies show eight out of 10 Photosoft photodynamic compounds display anti-viral activity against the Dengue virus after exposure to light.

Invion said the compounds showed activity against Dengue after exposure to a specific light wavelength, 660 nanometres (nm) and that the compounds had superior therapeutic index values to Monesin, an antibiotic with known activity against Dengue virus.

The company said the tests were part of the testing on infectious diseases using its Photosoft technology and the "results from this study and others would help it decide which infectious disease targets have the most promise of advancing to human applications".

Invion was up 0.05 cents or five percent to 1.05 cents.

FIREBRICK PHARMA

Firebrick says Health Services Authority of Singapore has granted a patent for its Nasodine nasal spray to treat and prevent the common cold.

Firebrick said the patent, titled 'Treatment and prevention of the common cold using povidone-iodine' would protect its intellectual property until 2035.

The company said that patent applications were pending in Canada and Japan, it had withdrawn its China application and its 'core' patent had been granted in 27 countries.

Firebrick was up one cent or 3.8 percent to 27.5 cents.

EMVISION MEDICAL DEVICES

Emvision says it has received an initial \$2 million of a \$5 million grant from the Federal Government's Modern Manufacturing Initiative.

In August, Emvision said its \$5 million grant for its first-generation portable brain scanner product from the Department of Industry, Science, Energy and Resources would be split into \$3,750,000 for the year to June 30, 2022, and \$1,250,000 for the year to June 30, 2023, and support initial production of the first-generation portable brain scanner as well as quality systems, engineering personnel and other expenditure (BD: Aug 29, 2022).

Emvision was up 1.25 cents or 0.9 percent to \$1.355.

DIMERIX

Dimerix says it has received \$6,032,858 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Dimerix said the tax incentive related to expenditure for the year to June 30, 2022.

Dimerix was up one cent or 6.1 percent to 17.5 cents.

IMAGION BIOSYSTEMS

Imagion says it has received \$2,500,966 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Imagion said the tax incentive related to research and development expenditure for 2021.

Imagion was unchanged at three cents with 2.7 million shares traded.

CRESO PHARMA

Creso says it has breached ASX Listing Rule 10.11 by not stating that Alvin Blumenthal's Suburban Holdings Pty Ltd was a related party.

The company said that in an announcement on February 25, 2022 it said it intended to place \$5 million to certain participants (BD: Feb 25, 2022).

Today, Creso said that "while drafting a notice of meeting in relation to the placement, the company became aware that Suburban Holdings Pty Ltd an entity controlled by the parent of former director Adam Blumenthal had participated in the placement".

Creso said that under section 228 of the Corporations Act 2001 "a holding controlled by a parent of a director is deemed to be a related party of the company" and Suburban's participation in the placement required prior shareholder approval under ASX Listing Rule 10.11 and constitutes a breach of Listing Rule 10.11".

The company said that the breach "was the result of an administrative oversight during the direct settlement of the placement between the broker who managed the placement, and the company's share registry".

Creso said that Suburban held all 14,492,755 shares it received in the placement and "in accordance with a direction from ASX, Suburban has agreed to dispose of all shares it received in the placement within six weeks ... [and] any profit made on the disposal of the holding will be donated to an entity that is listed with the Australian Charities and Not-For-Profits Commission as a charity".

In February, Creso said that the placement was at 6.9 cents a share. The company is currently trading at about three cents a share.

Creso said that Suburban was entitled to attaching options in relation to the placement and the ASX has directed the company not to issue the options to Suburban.

The company said it had "reviewed its internal processes around settlements of placements and has implemented appropriate controls to ensure such a breach does not happen in the future".

In 2016, Alvin Blumenthal and Suburban Holdings said they had had become 11.26 percent substantial in Suburban Holdings, but apparently meant they were substantial in Creso Pharma (BD: Oct 26, 2016).

In 2017, Suburban Holdings said it had ceased its substantial holding but appeared to retain 4,046,079 shares (BD: Apr 3, 2017).

In 2019, Roots Sustainable Agriculture, whose chair is Adam Blumenthal, said that up to 37.3 percent of shareholders opposed the issue of shares to director Adam Blumenthal, Suburban Holdings Pty Ltd and Horatio Street Pty Ltd.

Creso fell 0.1 cents or three percent to 3.2 cents with 10.2 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it has dosed seven of the up-to 12-patients in the expansion cohort of its phase Ib trial of PTX-100 for T-cell lymphomas, with no serious adverse events.

In April, Prescient said it had opened recruitment for the open-label, non-randomized study at Melbourne's Epworth Hospital for eight to 12 patients with relapsed and refractory T-cell lymphoma, aiming to complete recruitment this year (BD: Apr 5, 2022).

Today, the company said that eight patients had been screened, seven had been dosed with 2,000 milligrams per square metre (mg/m²) PTX-100, four patients remained on therapy, and that three patients had left the study for reasons unrelated to the trial, with additional patients to be recruited.

Prescient said that PTX-100 exhibited "an excellent safety profile on the study" with no serious adverse events related to PTX-100, and that several patients had either partial or almost complete responses.

Prescient managing-director Steven Yatomi-Clarke said it was "very exciting to see PTX-100 show clinical activity in a patient population that is notoriously difficult to treat, and where these patients have failed several lines of prior therapies".

"Furthermore, PTX-100 continues to exhibit an excellent safety profile, which is uncharacteristic of available [T-cell lymphomas] therapies," Mr Yatomi-Clarke said.

Prescient was unchanged at 16.5 cents.

CLARITY PHARMACEUTICALS

Clarity says its annual general meeting will vote to issue 1,921,081 options to executive chair Dr Alan Taylor and managing director Dr Colin Biggin.

Clarity said shareholders would vote to issue 1,083,226 options to Dr Taylor and 837,855 options to Dr Biggin, exercisable at 50.8 cents, vesting in three tranches and expiring in five years, as part of their remuneration.

The company said the meeting would vote to re-electing directors Dr Chris Roberts and Dr Thomas Ramdahl and accept the remuneration report.

The meeting will be at the Ground Floor Seminar Room, National Innovation Centre, 4 Cornwallis Street, Eveleigh, Sydney on November 24, 2022 at 10am (AEDT).

Clarity was up half a cent or 0.8 percent to 60 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says the ASX has removed the "foreign ownership restricted US person prohibited tag" from its Chess depository interests (CDIs), effective from today.

Imricor said the designation was put in place at its initial public offering to comply with securities regulations, preventing CDIs being sold on the ASX to US investors.

The company said that the removal of the designation meant that US entities could acquire and trade its CDIs on the ASX, "either as brokers or market-makers and US individuals and corporations, including institutional investors".

Imricor was unchanged at 26 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested a trading halt "pending the release of 20-week data from its ongoing phase I/II clinical trial and the announcement of a capital raising".

Trading will resume on October 27, 2022 or on an earlier announcement.

Neurotech last traded at 13 cents.

MICROBA LIFE SCIENCES

Perennial Value Management says it has increased its substantial holding in Microba from 38,064,790 shares (13.87%) to 40,898,790 shares (14.91%).

The Sydney-based Perennial said on October 24, 2022 it bought 3,000,000 shares for \$420,924 or an average of 14.0 cents a share, and on September 28 and 29, it sold 166,000 shares for \$30,572 or an average of 18.4 cents a share.

Microba was up three cents or 21.4 percent to 17 cents.

NOXOPHARM

Founder and former chair Dr Graham Kelly says he has reduced his holding in Noxopharm from 36,162,294 shares (13.16%) to 34,762,294 shares (11.90%).

The Wildes Meadow, New South Wales-based Dr Kelly said that, through Milligene Pty Ltd the GE and PR Kelly Family Trust, he sold shares between September 23, and October 18, 2022, with the single largest sale on October 7 of 623,841 shares for \$112,116 or 18.0 cents a share.

Noxopharm fell one cent or 5.3 percent to 18 cents.

CORRECTION CANN GROUP

Last night's edition on Cann Group chief executive officer Peter Crock's intention to resign incorrectly said he was appointed chief executive officer in May 2017.

Mr Crock was appointed chief executive officer in April 2016, prior to the company's listing on the ASX in May 2017.

The mistake was made by the Monday medical marijuana editor who said she had a big weekend, and has been seconded to the Weed, Seed, Feed, Need & Greed publishing house for retraining.

OPTHEA

Opthea says it has appointed Timothy Morris as its US-based chief financial officer, effective from October 24, 2022.

Opthea said Mr Morris had more than 25 years of chief financial officer experience, leading financial teams of public and private biotechnology companies, including "raising over \$US2.5 billion in equity and convertible securities for seven companies and the completion of over 95 transactions".

The company said Mr Morris had most recently worked at Humanigen Inc as chief operating and financial officer and previously worked for Iovance Biotherapeutics, Acelrx Pharmaceuticals, Vivus Inc and Questcor Pharmaceuticals Inc, and was a director of a number of companies.

Opthea said Mr Morris held a Bachelor of Science in Business from California State University, Chico.

Opthea fell half a cent or 0.5 percent to 99.5 cents.