



Biotech Daily

Monday January 29, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PARADIGM UP 17%; NEXT SCIENCE DOWN 13%**
- * **VALE LANG WALKER**
- * **DIMERIX ADVANZ LICENCE MAIDEN H1 \$10.8m RECEIPTS**
- * **CARDIEX H1 RECEIPTS UP 174% TO \$8.5m**
- * **BIOXYNE MARIJUANA PUSHES H1 RECEIPTS UP 520% TO \$4.7m**
- * **CYCLOPHARM: YALE TO USE TECHNEGAS FOR ARDS STUDY**
- * **STARPHARMA VIRALEZE 'REDUCES SARS-COV-2 VIRAL LOAD'**
- * **EBR ON-TRACK FOR FDA FILING, APPROVAL**
- * **OSTEOPORE MILESTONE 100k IMPLANTS**
- * **PHARMAUST FDA 'MORE DATA FOR MONEPANTEL MND ORPHAN STATUS'**
- * **NEUROTECH APPROVED FOR MARIJUANA CEREBRAL PALSY TRIAL**
- * **RHINOMED SHARE PLAN RAISES \$42k; \$1.2m SHORTFALL**
- * **AROVELLA REQUESTS 'LICENCING AGREEMENT' TRADING HALT**
- * **RESPIRI APPOINTS JUSTIN MOUCHACCA, NOVA TAYLOR CO-CO SECS**

MARKET REPORT

The Australian stock market was up 0.3 percent on Monday January 29, 2024, with the ASX200 up 23.0 points to 7,578.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and one was unchanged.

Paradigm was the best, up six cents or 17.4 percent to 40.5 cents, with 1.8 million shares traded. Both Actinogen and Starpharma climbed 10.3 percent; Proteomics was up 8.15 percent; 4D Medical and Avita were up more than three percent; Clarity, Dimerix and Resonance rose two percent or more; Alcidion, Amplia, Cochlear, Nova Eye, Polynovo and Telix were up one percent or more; with CSL, Pro Medicus and SDI up by less than one percent.

Next Science led the falls, down 4.5 cents or 13.0 percent to 30 cents, with 151,406 shares traded. Cynata and Orthocell lost more than six percent; Medical Developments was down 5.4 percent; Atomo, Curvebeam, Emvision and Imugene fell four percent or more; Compumedics, Cyclopharm, Genetic Signatures and Percheron (Antisense) were down three percent or more; Nanosonics and Opthea shed two percent or more; Clinuvel, Immutep and Neuren were down more than one percent; with Resmed and Volpara down by less than one percent.

[VALE LANGLEY ALEXANDER WALKER \(5.7.1945 – 27.1.2024\)](#)

Biotech Daily is saddened to learn of the death of major biotechnology investor Lang Walker of the Walker Corporation and Auckland Trust Co.

Mr Walker invested in a number of companies including Acrux, Atomo, BTC Health, Medical Australia, Neuren and QRX Pharma.

[Next Science](#)

Next Science said it paid “tribute to long-standing supporter of the company, Lang Walker, who passed away on Saturday, January 27, 2024”.

Next Science chair Aileen Stockburger said: “It is with deep sadness that the board has learned of the passing of Mr Walker who has been a dedicated advocate of Next Science and its unique X-Bio technology”.

“We are grateful for the important contribution he made to our company and offer our sincere condolences to Mr Walker’s family and friends,” Ms Stockburger said.

[Neuren Pharmaceuticals, BTC Health](#)

Former Neuren chair and current BTC Health chair Dr Richard Treagus said: “Lang was an intrepid investor, who had the belief to back technologies and management teams he felt could make a real difference to patients.”

“He was prepared to cornerstone a company, providing patient capital even when others lacked the courage or the vision to do so,” Dr Treagus said.

“He was always straight to the point, had a very practical approach to solving problems, and seemed to understand better than most that ‘great things take time to build’,” Dr Tragus said. “Such investors are rare in our sector nowadays, and his unique approach and contribution will be sorely missed.”

[Walker Corporation](#)

The Walker Corporation said Mr Walker formed the company more than 50 years ago “and built a world class business shaping the group into Australia’s largest privately owned property company”.

“Lang made the strategically defining decision some time ago to hold a substantial property portfolio encompassing over \$9 billion of prime assets in Sydney, Melbourne and Adelaide,” the Corporation said.

Walker Corp managing-director David Gallant said Lang was “recognized and regarded as a great visionary, an inspirational leader and the first to creatively tackle the challenge of urban transformation”.

“With his team, he has delivered exceptional placemaking concepts that can be seen in iconic developments such as Broadway Shopping Centre, Rhodes Peninsula, Woolloomooloo Wharf, King Street Wharf, Hope Island Resort, Collins Square and Parramatta Square,” the company said.

A statement on the Walker Corp website said that “Lang Walker’s family are mourning the loss of a devoted and loving husband, father and grandfather, after he passed away peacefully at his home in Sydney on Saturday evening”.

“Lang loved creating incredible places where people can live and work, but he loved his family more than anything else in the world and his generosity and affection had no boundaries ... his zest for life and his relentless pursuit of perfection lives on within everyone in the Walker family.”

The website said that Lang Walker was survived by wife Sue, children Blake, Chad, Georgia and their spouses, and his 10 grandchildren.

DIMERIX

Dimerix says the payment of EUR6.5 million (\$A10.8 million) from Advanz has provided customer receipts for the six months to December 31, 2023 of \$10,872,000.

Dimerix said the up-front payment from Advanz Pharma was part of its licence agreement for DMX-200 for focal segmental glomerulosclerosis (FSGS).

Last year, the company said Advanz would pay up-to \$229.8 million for the rights to DMX-200 for FSGS in Europe, the UK, Canada, Australia and New Zealand through \$10.8 million upfront and up-to \$219 million in potential milestones (BD: Oct 5, 2023).

Today, Dimerix said it had a positive cash flow of \$9,290,000 for the six months and had cash and cash equivalents of \$14,810,000 at December 31, 2023, compared to \$5,714,000 at December 31, 2022.

Dimerix was up half a cent or 2.9 percent to 17.5 cents with six million shares traded.

CARDIEX

Cardiex says receipts from customers for the six months to December 31, 2023 were up 174.1 percent to \$8,524,000, compared to the previous corresponding period.

Cardiex said receipts for its vital signs wearable sensors for the three months to December 31, 2023, were up 204.3 percent to \$7,439,000, compared to the prior period.

Cardiex chief executive officer Craig Cooper said the company was working with the "ASX towards relisting and expected to satisfy the ASX's conditions for relisting "very shortly".

Earlier this month, Cardiex said that the ASX had agreed to progress discussions on lifting its voluntary suspension (BD: Oct 4, Dec 7, 2023 and Jan 2, 2024).

The company said that it had a positive cash flow of \$3,438,000 for the three months, with cash and cash equivalents of \$4,296,000 at December 31, 2023 compared to \$2,482,000 at December 31, 2022.

Cardiex was in a suspension and last traded at 13.5 cents.

BIOXYNE

Bioxyne says receipts from customers for the six months to December 31, 2023 were up 520.2 percent to \$4,676,000, compared to the previous corresponding period.

Bioxyne said receipts from customers for its probiotic and marijuana products for the three months to December 31, 2023 were up 276.7 percent to \$2,369,000.

The company said its probiotics business had underperformed for the three-month period due to its major customer being under market pressure from competitor probiotic products, and that it was "in the process of winding it down and divesting its interest in this division".

Bioxyne said its medical marijuana business was the key revenue driver during the quarter, with the recently acquired Breathe Life Sciences' marijuana products in the UK, Europe, and Japan continuing to "perform consistently, and Australia ... achieving rapid growth in wholesale of medicinal cannabis starting material".

Last year, the company said it had completed the acquisition of the Gold Coast, Queensland-based Breathe Life Sciences, which operated in Australia, the UK, Japan and Europe and manufactured, sold and distributed plant-based products and supplements, including cannabidiol, marijuana extracts, vitamins, manuka honey, skin care products and mushroom extract products (BD: Mar 20, May 22, 2023).

Today, Bioxyne said it had a cash burn of \$706,000 for the three months, with cash and cash equivalents of \$1,525,000 at December 31, 2023 compared with \$3,793,000 at December 31, 2022.

Bioxyne was up 0.1 cents or 7.1 percent to 1.5 cents.

CYCLOPHARM

Cyclopharm says Connecticut's Yale University will use its Technegas lung ventilation imaging agent for research on acute respiratory distress syndrome (ARDS).

Cyclopharm said the Yale Translational Research Imaging Center would use its Technegas pulmonary imaging system in the study of ARDS as well as "other debilitating conditions like pulmonary hypertension and heart failure".

The company said it would install Technegas at Yale University "later this week ... under commercial terms" but did not state the terms.

Yale's Prof Albert Sinusas said he had "been intrigued by the potential of Technegas for our ongoing research for several years".

"Following [US Food and Drug Administration] approval, I am pleased to see that this advanced imaging agent is now available in the US," Prof Sinusas said.

Cyclopharm said that it expected the collaboration "will not only elevate the profile of Technegas but also solidify Cyclopharm's position as an innovator in nuclear medicine".

Last year, Cyclopharm said the FDA had approved Technegas for pulmonary embolism imaging - opening a \$US180 million a year market (BD: Oct 2, 2023).

Cyclopharm fell seven cents or 3.8 percent to \$1.78.

STARPHARMA HOLDINGS

Starpharma says a 197-patient post-market study showed Viraleze reduced "Sars-Cov-2 viral load compared with placebo, but "was not statistically significant".

In 2022, Starpharma said it had begun a 160-patient, randomized, double-blinded, post-market UK study to assess the anti-viral performance of its Viraleze nasal spray on Covid19 (BD: Dec 8, 2022).

Today, the company said that for the 118 patients aged more than 45 years the study showed Viraleze "achieved a statistically significant reduction in Sars-Cov-2 viral load, the primary endpoint of the study ($p = 0.017$).

Starpharma said that "less than 24 hours after dosing, Viraleze reduced Sars-Cov-2 viral load in the nose by 80 percent from baseline in participants aged 65 [years] and over" ($p = 0.008$), while viral load in the placebo arm was unchanged from baseline to day-2.

The company said the study showed a statistically significant reduction in viral load compared with placebo in the 101 participants aged more than 50 years ($p = 0.018$), in the 84 participants more than 55 years old ($p = 0.024$) and in the 50 participants more than 60 years old ($p = 0.005$).

Starpharma said participants were randomized to self-administer Viraleze or a placebo nasal spray four times daily for seven days, with "treatment compliance and vaccination rates ... lowest in participants aged under 40".

"The magnitude of the reduction in viral load by Viraleze compared with placebo increased with age," the company said.

Principal investigator Dr Stephen Winchester said "based on these data, Viraleze, which is a broad-spectrum nasal spray, could have clinical benefit for protection against infection and treatment of individuals, as well as infection control of populations".

Starpharma chief executive officer Cheryl Maley said the study showed "positive anti-viral efficacy in participants with Covid-19".

"These results are consistent with Starpharma's non-clinical studies, which also demonstrated that Viraleze protected against infection in a humanized mouse challenge model of Covid-19," Ms Maley said.

Starpharma was up 1.5 cents or 10.3 percent to 16 cents.

EBR SYSTEMS INC

EBR chief executive officer John McCutcheon says the company is on-track to file the final Wise application module to the US Food and Drug Administration by October.

Mr McCutcheon told Biotech Daily that he was in Australia to see institutional and retail investors and said that he was hoping for FDA approval “early in 2025”.

Mr McCutcheon said the final module included technical specifications and rigorous testing data including the ability of the Wise (wireless stimulation endocardially) device to withstand shocks, heat, cold and other potentially damaging conditions.

Mr McCutcheon said the randomized subset of the Solve-CRT (cardiac re-synchronization therapy) trial of its Wise device showed efficacy for heart failure, along with the 183-patient pivotal trial which met its efficacy and safety endpoints with statistically significant improvement (BD: May 22, Sep 5, 2023).

The company previously said that the Wise technology was “the world’s only wireless, endocardial, inside the heart, pacing system in clinical use for stimulating the heart’s left ventricle”.

EBR said its Wise technology enabled “cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice ... [with] the need for a pacing wire on the outside of the heart’s left ventricle, and the attendant problems, [were] potentially eliminated”.

EBR fell two cents or 2.7 percent to 71 cents.

OSTEOPORE

Osteopore says its three-dimensional printed, bio-resorbable bone implants have been used in 100,000 procedures, with 80 percent in the last four years.

Previously, Osteopore said its product range consisted of Osteoplug for post-neurosurgery ‘burr holes’, Osteomesh for cranio-facial surgery to repair skull, neck and jaw fractures, and Osteostrip skull filler after craniotomy (BD: Oct 2, 2020).

Today, the company said it had been commercializing its technology since September 2019, and had increased its product adoption steadily despite “headwinds such as the pandemic, poor macroeconomic conditions and a major overhaul in the European regulatory environment”.

Osteopore chief executive officer Jing Lim said the 100,000-implant milestone “demonstrated the commercial viability of our product and technology”.

“Our organization is humbled and motivated to accelerate our commercialization process so that more surgeons and patients around the world can have access to technology that improves outcomes,” Mr Lim said.

Osteopore was up 0.1 cents or 2.9 percent to 3.5 cents.

PHARMAUST

Pharmaust says the US Food and Drug Administration has requested further data for its monepantel orphan drug designation application for motor neuron disease (MND)

Pharmaust said the FDA’s request was made “due to the absence of pre-clinical or clinical data to establish the potential for the drug to be effective in MND [and, or amyotrophic lateral sclerosis]”.

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

NEUROTECH INTERNATIONAL

Neurotech says it has ethics and Therapeutic Goods Administration approval for a phase I/II clinical trial of its marijuana-based NTI164 in 14 children with cerebral palsy.

Neurotech said the single-arm, open-label trial in children with spastic diplegia cerebral palsy would study the efficacy and safety of NTI164 from baseline to 12 weeks of treatment and it intended to conduct the study at Melbourne's Monash Medical Centre.

Neurotech said the primary endpoint would be the Caregiver priorities and Child Health Index of Life with Disabilities Questionnaire, which evaluated caregivers' perceptions of health-related quality of life and caregiver impact in children with cerebral palsy.

The company said secondary endpoints included safety and the effect of NTI164 on pain, sleep, seizure frequency, involuntary muscle contraction and spasticity.

Neurotech said it expected the trial to begin by July, 2024.

Neurotech was up half a cent or 5.9 percent to nine cents with 9.3 million shares traded.

RHINOMED

Rhinomed says it has raised \$42,206 of a hoped-for \$1.25 million in a share purchase plan at four cents a share, leaving a shortfall of \$1,205,794.

Last year, Rhinomed said it hoped to raise up-to \$1.25 million in a share plan at four cents a share for its delisting from the ASX (BD: Dec 11, 2023).

At that time, the company said delisting was in investors' best interests because the register was "insufficient to maintain an orderly and liquid market for trading", raising capital was dilutive and delisting would reduce costs and time spent on ASX matters.

Earlier this month, Rhinomed said its extraordinary general meeting voted 98.79 percent to delist from the ASX, which it expected to do on February 16, 2024 (BD: Jan 21, 2023).

Rhinomed was up 0.2 cents or 9.5 percent to 2.3 cents.

AROVELLA THERAPEUTICS

Arovella says it has requested a trading halt "pending the release of an announcement regarding a licencing agreement".

Trading will resume on January 31, 2024, or on an earlier announcement.

Arovella last traded at 13 cents.

RESPIRI

Respiri says it has appointed Justin Mouchacca and Nova Taylor as joint company secretaries replacing Andrew Metcalfe, effective immediately.

Respiri said Mr Mouchacca had more than 17 years' experience, was principal of JM Corporate Services and a company secretary and financial officer for a number of companies.

The company said Ms Taylor had about seven years of experience as a company secretary and held a Bachelor of Laws from Melbourne's Deakin University.

Respiri was unchanged at 2.3 cents.