



Biotech Daily

Thursday January 23, 2025

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: PRESCIENT UP 13.5%; CURVEBEAM DOWN 8%**
- * **NANOSONICS EXPECTS H1 REVENUE UP 18% TO \$94m; PROFIT \$11m**
- * **NEXT SCIENCE RECEIPTS UP 13% TO \$36m**
- * **BIOXYNE EXPECTS 2024-'25 REVENUE UP 168% TO \$25m**
- * **CYCLOPHARM US HCA TECHNEGAS DEAL**
- * **VAXXAS, CEPI CONTINUE mRNA MICRO-ARRAY VACCINE PROGRAM**
- * **HYDRIX SIGNS \$2.8m PAUL HARTMANN EXTENSION**
- * **ENA DOSES 'OLDER ADULT' PHASE Ib INNA-051 POWDER TRIAL**
- * **PRESCIENT 'RESOLVES OMNICAR CHALLENGES'; NEW VARIANTS**
- * **CARDIEX LAUNCHES CONNEQT IN US; PULSE DELIVERIES BEGIN**
- * **UNIVERSAL BIOSENSORS US PETRACKR GLUCOSE MONITORS DEALS**
- * **QBIOTICS: PROF VICTORIA ELEGANT CMO; PROF AURELIEN MARABELLE**

MARKET REPORT

The Australian stock market fell 0.61 percent on Thursday January 23, 2025, with the ASX200 down 51.1 points to 8,378.7 points. Nineteen of the Biotech Daily Top 40 companies were up, 14 fell, six traded unchanged and one was untraded.

Prescient was the best, up 0.7 cents or 13.5 percent to 5.9 cents, with 3.15 million shares traded. Cyclopharm climbed 11.8 percent; Orthocell was up 7.3 percent; Nova Eye improved 6.1 percent; Actinogen was up four percent; Compumedics, EBR, Emvision, Neuren and Opthea were up three percent or more; Aroa, Clarity, Genetic Signatures and Paradigm rose two percent or more; Dimerix, Immutep and Micro-X were up more than one percent; with Mesoblast, Pro Medicus and Telix up by less than one percent.

Curvebeam led the falls, down one cent or 8.3 percent to 11 cents, with 116,447 shares traded. Cynata and Starpharma fell more than four percent; Alcidion, Amplia, Imugene and Proteomics shed more than two percent; Avita, Impedimed, Medical Developments and Syntara were down more than one percent; with 4D Medical, Clinuvel, Cochlear, CSL, Resmed and SDI down by less than one percent.

NANOSONICS

Nanosonics says it expects revenue for the six months to December 31, 2024 to be up 17.6 percent to \$93.6 million, with profit before tax up 122.4 percent to \$10.9 million. Nanosonics said the increased unaudited revenue from sales of its Trophon ultrasound probe disinfectants and products was “primarily driven by 20 percent growth in our consumables and service annuity revenue streams”.

The company said that gross margin for the six months was expected to be about 78.5 percent compared with 79.7 percent in the previous corresponding period and 76.3 percent in the six months to June 30, 2024.

Nanosonics said that operating expenses for the six months to December 31, 2024 were expected to be about \$66.7 million, up 10 percent from the six months to December 31, 2023 and up three percent on the six months to June 30, 2024.

Nanosonics chief executive officer Michael Kavanagh said “the total number of Trophon units sold in the first half was broadly in line with internal forecasts and was similar to the total number sold in the [prior corresponding period]”.

The company said full results would be released on February 20, 2025.

Nanosonics was unchanged at \$3.75 with 1.6 million shares traded.

NEXT SCIENCE

Next Science says customer receipts for the year to December 31, 2024 were up 13.0 percent to \$US22,733,000 (\$A36,224,000) compared to the prior corresponding period.

Next Science said that receipts from sales of its wound treatments including Xperience for the three months to December 31, 2024 were up 24.6 percent to \$US7,228,000.

Next Science chief executive officer Harry Hall said the increased sales were a result of the saline shortage in the US “which provided opportunities to significantly expand our Xperience footprint”.

“This contributed to a tripling of Xperience sales in [the three months to December 31, 2024] on [previous corresponding period] as new customers were introduced to the surgical solution,” Mr Hall said.

The company said it had a cash burn for the three months of \$US645,000, with cash and cash equivalents of \$US1,674,000 at December 31, 2024 compared to \$US9,239,000 at December 31, 2023.

Next Science fell one cent or 6.9 percent to 13.5 cents.

BIOXYNE

Bioxyne says it expects revenue for the 12 months to June 30, 2025 to be up 168.1 percent to \$25,000,000, compared to the previous corresponding period.

Last year Bioxyne said that revenue for the year to June 30, 2024 was \$9,325,020, with net loss after tax of \$13,500,723 (BD: Sep 2, 2024).

Today, the company said revenue for the six months to December 31, 2024 was up 267 percent on the previous six-month period as a result of “several major contracts, a growing customer base and an expanding product range”.

Last year, Bioxyne said subsidiary Breathe Life Sciences had an agreement with the Melbourne and Berlin-based Montu Group Pty Ltd to supply up-to \$28 million worth of marijuana gummies (BD: Aug 21, Sep 18, 2024).

Today, the company said it expected a positive cash-flow to June 30, 2025 as well as positive earnings before interest, taxation, depreciation and amortization (Ebitda).

Bioxyne was up 0.3 cents or 10.7 percent to 3.1 cents with 13.1 million shares traded.

CYCLOPHARM

Cyclopharm says it will supply its Technegas lung imaging system to the Nashville, Tennessee-based Hospital Corporation of America (HCA) Healthcare.

In 2023, the company said that the US Food and Drug Administration had approved the Technegas system for pulmonary embolism imaging (BD: Oct 2, 2023).

Today, Cyclopharm said the three-year agreement was “a significant milestone for the company which will allow the deployment of Technegas in up-to 169 nuclear medicine departments across HCA’s extensive network”.

Cyclopharm said HCA Healthcare operated “one of the most comprehensive hospital networks in the US, encompassing over 180 hospitals and approximately 2,400 sites of care in 20 states”.

The company said the national contract followed multiple HCA sites entering into “independent discussions with Cyclopharm regarding Technegas”.

Cyclopharm said it would engage directly with individual HCA locations, clinical leaders and divisional directors to implement Technegas, prioritizing those sites which had already entered preliminary discussions with Cyclopharm.

The company said the deal opened discussions with HCA’s group purchasing organization, the Healthtrust Purchasing Group, which was the contracting and purchasing arm for a network of more than 1,800 hospitals in the US.

Cyclopharm did not disclose the commercial terms of the agreement.

Cyclopharm managing-director James McBrayer said the company was “thrilled to partner with HCA Healthcare, a leader in delivering quality care to millions of patients annually”.

“This three-year agreement will allow for the accelerated availability of Technegas across the US and reinforces our commitment to improving outcomes for patients with respiratory conditions,” Mr McBrayer said. “This agreement not only extends the footprint of Technegas in the US market but also sets the stage for its broader adoption within Healthtrust’s extensive network.”

Cyclopharm was up 24 cents or 11.8 percent to \$2.27 with one million shares traded.

VAXXAS PTY LTD

Vaxxas says it the Coalition for Epidemic Preparedness Innovations has approved it to continue its program assessing mRNA thermo-stability on its micro-array vaccines.

In 2023, Vaxxas said it had \$6.4 million from the Oslo, Norway-based Coalition for Epidemic Preparedness Innovations to assess the thermo-stability of mRNA vaccines when printed in a dried-formulation on its high-density micro-array patch (HD-MAP), which delivers vaccines when pressed on the skin for 10 seconds (BD: Jan 22, 2023).

Today, the company said the approval followed pre-clinical results which showed mRNA lipid nano-particles loaded onto its micro-array patch had “the potential to maintain stability at 2.0°C to 8.0°C and 25°C for at least 12 months, and 40°C for at least one month”.

Vaxxas said it would partner with the Seoul, South Korea’s vaccine developer SK Bioscience in the next stage of the program to study SK’s mRNA vaccine for Japanese encephalitis virus on its HD-MAP technology in a phase I clinical study.

The company said it planned to begin the stage two program from April 2025.

Vaxxas chief executive officer David Hoey said the HD-MAP technology offered “a potential solution to the growing need to significantly expand global access to innovative mRNA vaccines by eliminating the current ultra-cold storage requirements”.

“With compelling proof-of-concept results in hand, we’re excited to have CEPI’s commitment to advance to the next stage of development,” Mr Hoey said.

Vaxxas is a private company.

HYDRIX

Hydrix says it has a \$2.8 million extension to its product development services contract with Paul Hartmann AG, with the contract expected to be completed by October 2025.

Last year, Hydrix said it had a \$2.3 million product development services contract with Heidenheim, Germany's Paul Hartmann AG (BD: May 27, 2024).

Today, the company said it expected the work to be completed and revenue to be recognized "by the end of September 2025, adding to the \$3.7 million cumulative revenue from previous contract stages".

Hydrix marketing director Alan Morris said that "winning this project stage highlights our dedication to excellence and innovation, strengthens our growing reputation in international markets, and advances our strategy of pursuing global opportunities."

Hydrix was up 1.7 cents or 170 percent to 2.7 cents with 68.2 million shares traded.

ENA RESPIRATORY

ENA says it has completed dosing of the 32 older adult participants in its phase Ib study of intra-nasally dosed, dry powder INNA-051 for viral respiratory infections.

Last year, ENA said it had dosed 16 of up-to 40 volunteers in its phase Ib study of its INNA-051 immuno-modulator for respiratory viral infections (BD: Aug 28, 2024).

Today, the company said the study was designed to test the safety, tolerability, pharmacodynamics, and pharmacokinetics of INNA-051 as an intra-nasal dry powder, which had an expected shelf life of more than two years at room temperature.

ENA said intra-nasal administration of the new, more stable formulation of INNA-051 was "well-tolerated and led to local activation of innate immune pathways gene expression".

The company said participants in the multiple ascending dose cohorts were dosed weekly on three occasions, with a maximum dose of 900 micrograms, three times the maximum dose amount in the previous trial with liquid formulation.

ENA said drug-related adverse events were mild, short in duration and limited to the upper respiratory tract, with the tolerability observed at higher doses "similar to the profile observed in previous trials with the liquid nasal spray".

The company said biomarker analysis confirmed that treatment led "to a significant local activation of the innate immune pathways, including anti-viral host defense pathways, consistent with previous observations in the clinic".

ENA said the US Department of Defense-funded study extension into younger adults aged 18-to-45 years would complete dosing this month and that the first cohort dosed with 300 micrograms showed the formulation's safety and tolerability profile was "consistent with observations in the older adults".

Last year, the company said it had a \$US3.18 million (\$A4.72 million) grant from the US Department of Defense, adding to a previous \$US8.18 million (BD: Sep 6, 2024).

Today, ENA said a final report was expected by July 2025 and it was planning a phase II community infection study by the end of 2025 to assess the safety and potential efficacy of INNA-051 in reducing the incidence and duration of symptomatic infections caused by common respiratory viruses.

ENA chief executive officer Dr Christophe Demaison said the results provided "an excellent foundation for our planned phase II proof-of-concept community infection study and reinforce INNA-051's potential as a convenient, commercially attractive, seasonally-delivered product that minimizes the impact of common viral respiratory infections and prevents serious complications".

Ena is a private company.

PRESCIENT THERAPEUTICS

Prescient says it has resolved “technical challenges” with its Omnicar program and will study a “new generation of improved Omnicar variants” this year.

In 2021, Prescient said Omnicar was “a universal immune receptor technology platform that offers a number of potential benefits over existing Car-T therapies, including control, safety, flexibility and efficacy” (BD: Jan 18, 2021).

Later that year, the company said it would work with Melbourne’s Peter MacCallum Cancer Centre to develop its Omnicar chimeric antigen receptor (Car) cell therapy platform for three different types of cancer (BD: May 10, 2021).

Today, Prescient said it had “previously observed that Omnicar T-cells unarmed with antigen binders were demonstrating unexpected activity”.

Biotech Daily could not find previous disclosures of these issues, and had not received a reply from the company at the time of publication.

Prescient said the unexpected activity was “counter to the modular, controllable thesis of Omnicar and needed to be resolved before undertaking further development”, but did not disclose the specifics of the unexpected activity.

The company said it had worked with the Peter McCallum Cancer Centre and the Commonwealth Scientific and Industrial Research Organisation to resolve the issues and had designed several Omnicar variants that were observed to overcome the problem in preliminary in-vitro and in-vivo testing, including improved safety.

The company said that when armed with binders the “new Omnicar variants demonstrated highly effective tumor-killing activity in mice with HER2 [human epithelial growth factor receptor 2] positive tumors with duration of efficacy exceeding that of the previous version of Omnicar”.

Prescient said it would conduct further validation studies in the next 12 months and provide guidance on the Omnicar development plan at the appropriate time.

Prescient chief executive officer James McDonnell said the company was “pleased that these technical issues have been resolved, and the Omnicar program can once again move forward”.

“Omnicar has the potential to offer flexibility and optionality for cell therapies, and we are pleased that we are again on a path forward with this platform,” Mr McDonnell said.

Prescient was up 0.7 cents or 13.5 percent to 5.9 cents with 3.15 million shares traded.

CARDIEX

Cardiex says it is delivering first orders of 8,000 Pulse arterial health monitors and has launched its Conneqt application on the Apple software store and Google Play store.

Cardiex said it had begun delivering Pulse units to US customers, with the first order of 3,000 units received from its Tianjin, China-based manufacturing partner, Andon Health Co Ltd, and the remaining 5,000 units of the company’s initial order “currently in transit and due to arrive at the company’s fulfilment facility shortly”.

The company said it was “in the process of executing on its sales strategy to convert the current waitlist customers into orders including multiple online marketing and sales programs as part of the broader US market launch”.

Cardiex said the Conneqt application was part of the “digital ecosystem developed to support the Pulse” and was available for download in the US.

Cardiex chief executive officer Craig Cooper said the company was “off to a great start in 2025 with the launch of Pulse deliveries and the introduction of the Conneqt [application] across the mobile ecosystem”.

Cardiex was up 4.1 cents or 41.4 percent to 14 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it will sell its Petrackr blood glucose monitoring system for cats and dogs through the Miami, Florida-based pet retailer Chewy Inc and Amazon. In 2023, Universal Biosensors said it had five distribution deals for its Petrackr blood-glucose monitor for diabetic dogs and cats, bringing the total to eight deals worth \$480,000 (BD: Aug 8, 2023).

Today, the company said it had worked with Chewy for more than nine months to build its electronic commerce capability and could “now execute these agreements and begin to make sales on the Chewy and Amazon platforms”.

Universal Biosensors managing-director John Sharman said the company’s “initial focus for the launch of Petrackr was to the professional [veterinary] network and we have made progress raising the profile of Petrackr in this segment”.

“But it is apparent that whilst we have a much better product than the competition, the majority of sales for vet blood glucose monitoring systems are online,” Mr Sharman said.

“Chewy and Amazon are collectively the largest retailers of veterinary products in North America and Universal Biosensors expects the completion of these deals to have a material impact on Petrackr sales moving forward,” Mr Sharman said.

Universal Biosensors was unchanged at 9.3 cents.

QBIOTICS

Qbiotics says it has appointed Prof Victoria Elegant as part-time chief medical officer and clinical advisory board member Prof Aurelien Marabelle as an oncology consultant.

Qbiotics said Prof Elegant had been Amgen regional medical head of Asia Pacific and head of its Shanghai, China research site as well as Baxter Healthcare head of regulatory and medical affairs Asia Pacific and Shire head of medical affairs Asia.

According to her LinkedIn profile, Prof Elegant held a Bachelor of Medicine and Bachelor of Surgery from the University of London.

Qbiotics said Prof Elegant would “provide ongoing clinical guidance, leadership and counsel to the Qbiotics board and human clinical development team”, effective from January 28, 2025.

The company said Prof Marabelle would “be collaborating with Qbiotics on the development and strategic direction of the company’s human oncology drug development and commercialization program”.

Qbiotics is a public unlisted company.