

Biotech Daily

Friday May 2, 2025

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: GENETIC SIGNATURES UP 15.5%; RESONANCE DOWN 8%
- * DR BOREHAM'S CRUCIBLE: MICRO-X
- * VIVAZOME 'EXTRACELLULAR VESICLES IMPROVE FUNCTION, IN MICE'
- * OPYL PLACEMENT RAISES \$1.5m
- * INVION DOSES 6 PHASE I/II INV043 SKIN CANCER PATIENTS
- * NOXOPHARM FILES PHASE I SOF-SKN ETHICS APPROVAL
- * NYRADA TO DOSE 3rd PHASE I NYR-BI03 COHORT; DATA IN OCTOBER
- * REGAL FUNDS TAKES 13% OF IMMUTEP
- * CHIMERIC CHAIR PAUL HOPPER INCREASES, DILUTED TO 11%
- * UNISUPER TAKES 5% OF BOTANIX
- * NEUREN APPOINTS DARYL DEKARSKE CHIEF REGULATORY OFFICER
- * BTC LOSES DIRECTOR BRENDAN YORK
- * MARCELO MORA REPLACES BIOTRON CO SEC PETER NIGHTINGALE

MARKET REPORT

The Australian stock market was up 1.13 percent on Friday May 2, 2025, with the ASX200 up 92.4 points to 8,238.0 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and one was untraded. All four Big Caps were up.

Genetic Signatures was the best, up 6.5 cents or 15.5 percent to 48.5 cents, with 185,566 shares traded. Clarity climbed 14.0 percent; Medical Developments was up 12.3 percent; Dimerix rose 11.0 percent; Syntara was up 9.1 percent; Impedimed improved 8.3 percent; EBR was up 7.7 percent; Atomo and Neuren were up more than five percent; Polynovo and Telix were up more than four percent; Alcidion, Cyclopharm, Immutep, Micro-X and Optiscan were up three percent or more; Botanix and CSL rose more than two percent; Amplia, Orthocell, Pro Medicus and Resmed were up one percent or more; with Cochlear and Emvision up by less than one percent.

Resonance led the falls, down 0.3 cents or 7.7 percent to 3.6 cents, with 2.7 million shares traded. Curvebeam fell 4.8 percent; 4D Medical, Actinogen and Compumedics lost more than three percent; Cynata and Starpharma shed more than two percent; Avita, Mesoblast and Paradigm were down more than one percent; with Clinuvel and SDI down by less than one percent.

DR BOREHAM'S CRUCIBLE: MICRO-X

By TIM BOREHAM

ASX code: MX1

Share price: 5.9 cents; Shares on issue: 664,173,290; Market cap: \$39.2 million

Chief executive officer: Kingsley Hall

Board: Patrick O'Brien (chair), Jim McDowell, Ilona Meyer, Andrew Hartmann (Dr Alexander Gosling left in November 2024 and David Knox left January 2025)

Financials (December 2024 half year): revenue \$3.96 million (down 51.7%), net loss \$8.68 million (\$7.66 million deficit previously), 1.59 quarters cash at March 31, 2025

Identifiable major holders: Perennial Value Management 12.9%, Acorn Capital 10.85%, Varex Imaging 8.15%, Tiga/Thorney 6.8%, Billion Prima 4.02%, Peter Rowland 2.4%

Many life science companies stress the virtue of diversity: multiple programs to protect against one of them failing.

Diversity can be helpful: after its failed phase III eye disease programs, Opthea would be wishing it had another drug candidate up its sleeve.

But chasing too much stuff can spread resources too thinly and create investor confusion.

Just last week Clarity Pharmaceuticals ditched neuroblastoma and some prostate cancer programs from its crowded radiotherapy rota and Clinuvel has paused its stroke program.

In the case of Micro-X, as part of a "strategy re-set" the x-ray imaging house has decided to focus on medical applications, rather than security and defence uses such as bomb and baggage screening.

"The tech we have developed has fantastic applications in medical, security and defence," CEO Kingsley Hall says.

"We have decided that while our technology enables applications in all those fields, we can impact medical the quickest and the best. While the security industry is quite large, it tends to be slowest to move and has some significant incumbents."

About Micro-X

Micro-X has commercialized two mobile digital radiology (DR) devices: the first-generation Nano and a sturdier iteration called Rover.

Based in Adelaide, Micro-X listed on December 21, 2015, having raised \$20 million at 50 cents apiece.

Along the way, Micro-X entered several alliances and distributorships, including with Carestream Health Inc (formerly Kodak Medical Imaging), MXR Imaging Inc and listed French x-ray equipment manufacturer DMS Imaging SA.

EG Capital co-founder Alison Coutts says she co-founded Micro-X in 2011 with Ko Koike, and appointed Peter Rowland as CEO to oversee commercialization of the company's revolutionary cold-cathode x-ray technology. Mr Rowland says he founded the company.

Amid investor frustration about slow progress, in May 2023 Mr Rowland stepped down in favor of chief financial officer Kingsley Hall.

In September 2022, Micro-X inked a deal with Nasdaq listed x-ray component supplier Varex Imaging Corp, by which Varex took a 9.9 percent equity stake for a \$15 million outlay.

Hot to trot on cold cathodes

In a century-old process, x-rays are generated with a heated filament cathode that generates electrons in a vacuum tube. But the process is inefficient because of wasted heat and the electrons don't all move in the right direction.

Micro-X's cold cathode technique is based on four-nanometre wide carbon tubes, under an electrified fine mesh structure.

While standard computed tomography (CT), scanners use only one x-ray source to rotate around an object. Micro-X's tubes enable x-ray beams to be fired from different angles with no moving parts.

The tubes are substantially smaller and lighter and are controlled electronically - rather than via heat - and can be turned on and off instantly.

Rover runs well in the field

A lightweight 'ruggedized' version of the Nano, Rover is proving its mettle in the Ukraine conflict.

Initially funded by two US-based charities, Micro-X delivered 13 Rovers to the Ukraine in late 2022, followed by 16 more Australian government-funded units last year.

"The feedback from surgeons using them on the frontline has been phenomenally positive," Mr Hall says.

"One of them was used 6,000 times in its first month."

In toto, Micro-X has sold 400 Rovers in 39 countries, with the US comprising the biggest market.

The company also has Conformité Européenne (CE) mark approval for Rover, but it's a "large and difficult market."

The company is awaiting formal feedback to undergo a large formal trial in the US, with an unnamed hospital group.

... and he's a good sport

Another Rover application is on the sporting field rather than battlefield, with about one third of US Major Baseball League teams deploying the units to examine player injuries.

Rover was also the mobile digital radiology units of choice for the recent National Collegiate Athletics Association's US basketball championships.

Rover has also been used in driver's pits at grand prix events.

"It's found a really nice niche among professional sporting teams and associations," Mr Hall says.

Baseball and basketball may not be contact sports, but hand and feet injuries abound.

Rover means teams may not have to send players to hospital for an x-ray and may be able to get them back on the field.

'World first' full body CT: image-in that?

In early December last year, the US Advanced Research Projects Agency for Health (ARPA-H) awarded the company up to \$US25 million over five years to develop the world's first portable full-body computed tomography (CT) scanner.

The first \$US8 million is in the bank and the rest depends on meeting "technical objectives" and US Food and Drug Administration approval.

Th compact is part of the US government's 'Paradigm' program, to take hospital-grade computed tomography into regional America.

Mr Hall says that to be selected, the unit needed to be at least 80 percent lighter than a traditional computed tomography device, which typically weighs a tonne.

And for anyone wondering about the security of the funding, it helps that regional America is Donald Trump's voting heartland.

Stroke me, stroke me

Micro-X is building three prototype versions of its portable stroke units, which will be used in three planned local hospital trials.

Current stroke detection CT scanners weigh 600 kilograms and need a crew of five.

Oh - and they cost \$1.5 million.

Micro-X's so-called ring scanner weights 75kg, is much cheaper and emits 85 percent less radiation.

In December, the first stroke patient was successfully imaged.

The trials will entail suspected stroke victims being subject to standard CT imaging, then overlaid with the Micro-X scan.

Aiming for "several hundred" scans, the studies only need to prove that the Micro-X tech is just as good as the conventional ones.

In essence, the scans aim to distinguish clot strokes, the most common, from bleeds.

This is crucial because a clot can be treated with blood thinning drugs, but for a bleed patient, that could be fatal.

The program is backed by the Australian Stroke Alliance (ASA) and the Australian Medical Research Future Fund (MRFF).

Shedding the baggage

Initially funded by the US Department of Homeland Security to the tune of \$US29 million, Micro-X's self-service baggage scanning program has been far from wasted.

In February, the company struck a deal with Malaysian logistics company Billion Prima Sdn Bhd to develop the technology.

The compact involves Billion Prima taking a \$2.4 million equity stake in Micro-X – just under four percent of the company - at nine cents a share (a 15 percent premium).

Prima will pay Micro-X up to \$3.2 million to develop a baggage scanner for them, over the next 12 months.

If successful, the units would be distributed to up-to nine South East Asian countries.

"I think they will be very good partners," Mr Hall says. "But we have also had other good ongoing conversations bout monetizing other parts of our security assets ... in the short to medium term."

Bombs away

Micro-X won't spend any more money on its Argus bomb detection program, but that doesn't mean it's been detonated altogether. A lightweight self-contained camera carried by a robot, Argus can detect a suspicious object in 10 seconds - at up-to 1,500 metres.

The Australian Defence Force provided initial seed funding for Argus, which was launched in early 2024. But the company quickly realized there wasn't enough demand.

"The product was well engineered and well-resourced, and it did what it set out to do," Mr Hall said. "While the product was being developed, the environment changed".

The 'problem' is that terrorist activity has lessened, meaning bomb threats aren't as prevalent.

"We still think the technology is of great value and well will seek to commercialize it, outside of Argus as a product," Mr Hall says. "But we are not actively marketing it."

Finances and performance

Micro-X recorded revenue for the six months to December 31, 2024 of \$3.96 million, 51.7 percent lower year-on-year. Partly explaining the decline, the previous period included a \$2.8 million government Rover contract.

The company lost \$8.68 million, compared with a \$7.66 million deficit previously.

The revenue included \$995,000 from Rover sales and \$2.96 million of "engineering service income": \$300,000 from the ASA and \$2.666 million from the US DHS.

In March, the company completed a placement and rights offer that raised \$6.4 million at seven cents a share, a 10 discount.

This was over and above the \$2.4 million placement to Prima. The retail rights stanza raised only \$620,000 of the maximum \$2.74 million.

In December, the company pocketed a \$6.4 million Federal Research and Development Tax Incentive. The accounts record a \$1.5 million loan, which is an advance on this year's expected refund.

In February, the company also received \$1 million from Prima as the first instalment in the development deal.

Over the last 12 months Micro-X shares have traded between a low of 5.0 cents (mid-September last year) and 9.7 cents in early December.

The latter reflects a 70 percent share surge after the ARPH funding announcement.

Not tariff-ic, but we can live with it

Micro-X makes its goods - tubes, generators and high voltage - in Adelaide, with more than 90 percent of its input materials sourced from Australia.

Mr Hall says of the presumed 10 percent tariff: "It's difficult. But it's not as bad as [the US tariff on] our European and Asian trading partners. Our cost position relative our competitors is good, so ... it is not a game stopper."

What's your favorite?

Rather than nominating his favorite program, Mr Hall says the real hero is the company's underlying technology.

Over time, the company has evolved from making and refining the tubes, to making the high voltage generators and switching between the tubes

"We have three tubes but are developing a fourth one," he says. "They are different in size and shape and what they do ... but the underlying tech and applications are the same."

While the head (stroke) CT has 21 tubes, the full-body scanner has more than 100.

"Also, the majority of our software is constructed in-house," Mr Hall says. "We are really focused on the technology platform and how that transforms into medical products."

Dr Boreham's diagnosis:

Mr Hall says the company is looking for "positive and profitable" applications for its technology. Who could argue with that?

"Our goal is to make great imaging products that are better than our competitor," he says. "We think all three of our current medical products will be strong for us and the demand will grow as each one enhances our position in the market."

Micro-X has done well to attract non-dilutive funding from various sources.

But as is almost the case in the medical device game, progress to profitability has been slower than expected,

"There's a lot going on, but we have to get on with it and demonstrate some real positive results," Mr Hall says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has a lot going on and hopes to demonstrate some positive results in the not-too-distant future.

VIVAZOME THERAPEUTICS PTY LTD

Vivazome says its extracellular vesicles "improved motor function, enhanced exploratory behavior and promoted balance" in mice with traumatic brain injury.

In 2022, Vivazome said that with the University of Queensland it would study exosome treatments for traumatic brain injury and post-traumatic brain injury epilepsy (BD: May 19, 2022).

Today, the company said the "promising results" showed that its human cell line-derived extracellular vesicles improved function, exploratory behavior and balance 24 hours after moderate traumatic brain injury.

Vivazome said the data suggested extracellular vesicles had the "potential to reduce susceptibility to epileptic seizures".

The company said that post-traumatic epilepsy was a recurrent seizure disorder that developed after traumatic brain injury in one in 50 cases.

Vivazome said post-traumatic epilepsy could "manifest as seizures occurring weeks, months or even years after the initial injury".

The company said the data was presented in a poster, titled 'Vivazome Proprietary Human Cell-Derived Extracellular Vesicles Enhance Recovery After Moderate Traumatic Brain Injury in a Preclinical Model', at the International Society of Extracellular Vesicles in Vienna and was available at: <u>https://bit.ly/439VANH</u>.

Vivazome chief scientific officer Prof David Haylock said that it was "well established that inflammatory mechanisms play a crucial role in the outcomes of [traumatic brain injury]". "These results provide evidence that the Vivazome's [extracellular vesicles] are

dampening the initial inflammatory response, promoting functional recovery," Prof Haylock said.

"We already know that Vivazome's [extracellular vesicles] contain micro-RNAs that modulate inflammation, and we have demonstrated powerful anti-inflammatory activity invitro and in other in-vivo animal models," Prof Haylock said.

Vivazome managing-director Xenia Sango said traumatic brain injury and the associated post-traumatic epilepsy were "devastating conditions with limited treatment options".

"Over 700,000 Australians have a brain injury," Ms Sango said.

"These results are encouraging as Vivazome pushes on with further preclinical studies and ultimately into clinical trials," Ms Sango said.

Vivazome is a private company.

<u>OPYL</u>

Opyl says it has "firm commitments" to raise \$1,500,000 at 2.1 cents a share in an institutional placement, with one attaching option for every two shares issued.

Opyl said the issue price was a 23.4 percent discount to the 15-day volume weighted average price of 2.7 cents and a 19.2 percent discount to the last closing price on April 29, 2025 of 2.6 cents.

The company said the options were exercisable at 3.0 cents each within four years. Opyl said the placement was "notably supported" by director Antanas Guoga.

The company said funds would be used for sales, marketing and its Trialkey drug discovery platform, as well as development and infrastructure and working capital. Opyl said the options and 29,428,572 shares under the placement were subject to shareholder approval at an extraordinary general meeting to be held in June 2025. The company said Sandton Capital Advisory and GBA Capital were joint lead managers to the placement.

Opyl was unchanged at 2.6 cents.

<u>INVION</u>

Invion says it has dosed the first six patients in its at least 18-patient, phase I/II trial of topical INV043 for non-melanoma skin cancer, triggering a safety committee review. In December, the company said it had dosed the first of at least 18 patients in its phase I/II trial of topical INV043 for non-melanoma skin cancer at Brisbane's Veracity Clinical Research (BD: Dec 3, 2024).

Today, Invion said its safety review committee would review patient safety with treatment of INV043, which would clear the way for the next stage of the trial following appraisal of the six dosed patients in the coming weeks.

The company said the six patients came from two, three-patient cohorts and were part of a "light" dose-escalation study, in which INV043 dosage remained constant while two different light intensity doses were evaluated.

Invion said the safety review committee would determine if there was a need to adjust the dose-light interval and/or expand the trial to include superficial basal cell carcinoma instead of only cutaneous squamous cell carcinoma.

Invion was up 0.2 cents or two percent to 10 cents.

<u>NOXOPHARM</u>

Noxopharm says it has applied for human research ethics committee approval for its first in-human, phase I 'Heracles' trial of SOF-SKN for autoimmune disease.

In March, the company said it appointed Doherty Clinical Trials for its 'Heracles' trial, but did not disclose the commercial details nor protocol (BD: Mar 12, 2025).

Today, Noxopharm said Sofra was "initially targeted at cutaneous lupus erythematosus" as a proof-of-concept before potential further development for autoimmune-related skin diseases like psoriasis and atopic dermatitis.

The company said the trial would evaluate the safety profile of SOF-SKN at four different concentrations, but did not disclose the number of patients to be enrolled.

Noxopharm said its Sofra technology "could also be developed for rheumatoid arthritis,

type 1 diabetes, inflammatory bowel disease and other diseases linked to the dysregulation of the immune system, such as dementia".

The company said an ethics committee decision was expected in "several weeks". Noxopharm fell 0.2 cents or 2.6 percent to 7.5 cents.

<u>NYRADA</u>

Nyrada says the safety committee review of its 40-patient, phase I trial of NYR-BI03 for traumatic brain injury has raised no issues, enabling it to dose the third cohort. In February, Nyrada said the dose-escalation trial would dose participants, with intravenous doses over three hours of either NYR-BI03 or placebo (BD: Feb 7, 2025). Today, the company said the final phase I trial readout was expected by October 2025. Nyrada was up half a cent or 4.8 percent to 11 cents.

IMMUTEP

Sydney's Regal Funds Management says it has increased its substantial shareholding in Immutep from 171,522,666 shares (11.79%) to 187,082,505 shares (12.81%). Regal said it traded shares between November 15, 2024 and April 29, 2025, with the largest purchase on April 7 34,000,000 shares for \$7,990,000, or 23.5 cents a share. Immutep was up one cent or 3.85 percent to 27 cents with three million shares traded.

CHIMERIC THERAPEUTICS

Chimeric chair Paul Hopper says he has increased and been diluted from 194,994,574 shares (12.4%) to 204,994,574 shares (11.3%).

Mr Hopper said he acquired 10,000,000 shares in a rights offer at 0.5 cents a share. Last week, Chimeric said it had raised \$986,015 in its two-for-five rights offer at 0.5 cents a share, leaving a \$2.2 million shortfall (BD: Apr 24, 2025).

Chimeric was up 0.1 cents or 20 percent to 0.6 cents with 3.9 million shares traded.

BOTANIX PHARMACEUTICALS

Melbourne's Unisuper says it has become a substantial shareholder in Botanix with 100,455,466 shares, or 5.14 percent.

Unisuper said it bought and sold shares between January 23 and April 24, 2025, with the single-largest purchase 1,705,193 shares on April 9 for \$595,826 or 34.9 cents a share. Botanix was up one cent or 2.25 percent to 45.5 cents with 13.8 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has appointed Daryl Dekarske as its chief regulatory officer. Neuren said Mr Dekarske had regulatory experience in both non-clinical and clinical product development and management of research and development, having worked for Shire, Horizon Therapeutics and the company's North America trofinetide, or Daybue, partner, Acadia Pharmaceuticals.

The company said that while working for Acadia, Mr Dekarske played "an important role in the phase III development and new drug application for trofinetide".

According to his Linkedin page, Mr Dekarske held a Bachelor of Science and a Master of Science from Ann Arbor's University of Michigan.

Neuren was up 64 cents or 5.4 percent to \$12.44 with 727,672 shares traded.

BTC HEALTH

BTC says that Brendan York has submitted his resignation as a non-executive director, effective from June 11, 2025.

BTC said Mr York had been a director since October 2022 and was a nominee director of Naos Asset Management.

The company said Naos would "seek to appoint a new nominee in due course" and that it had commenced the process of appointing a replacement director.

BTC was up half a cent or 9.3 percent to 5.9 cents.

BIOTRON

Biotron says Marcelo Mora has been appointed as its company secretary following the resignation of Peter Nightingale.

Biotron was unchanged at 0.3 cents with 3.4 million shares traded.

Biotech Daily can be contacted at: PO Box 500, Flemington, Victoria, Australia, 3031 email: <u>editor@biotechdaily.com.au</u>; <u>www.biotechdaily.com.au</u>