Biotech Daily

Friday July 4, 2025

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: AMPLIA UP 25.5%; MEDADVISOR DOWN 15%**

*** DR BOREHAM'S CRUCIBLE: TETRATHERIX**

*** PETER MAC: 'CAR T-CELLS KILL SOLID TUMORS, IN MICE'**

*** AEGROS FOUNDERS PROF HARI NAIR, JOHN MANUSU 'NON-EXECUTIVE'**

*** ENLITIC $3m GE HEALTHCARE PAYMENT, $50m DEAL**

*** ONCOSIL 'PANCOSIL' PANCREATIC CANCER TRIAL ENROLED**

*** IMUGENE RECEIVES $5.9m FEDERAL R&D TAX INCENTIVE**

*** CLARITY CHAIR DR ALAN TAYLOR TAKES 5%**

*** MCRAE REDUCES, DILUTED TO 7% OF NEUROSCIENTIFIC**

*** FIL (FIDELITY) TAKES 7% OF RHYTHM**

*** MARK AZZI TAKES 15% OF NYRADA**

*** DORSAVI LOSES DIRECTOR MICHAEL WINLO; TECH STAFF WANTED**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Friday July 4, 2025, with the ASX200 up 7.2 points to 8,603.0 points. Twenty-three of the Biotech Daily Top 40 companies were up, 12 fell, four traded unchanged and one was untraded.

Amplia was the best, up six cents or 25.5 percent to 29.5 cents, with 19.9 million shares traded. Cyclopharm climbed 16.15 percent; Botanix was up 9.7 percent; Actinogen, Nova Eye and Orthocell were up more than eight percent; EBR was up 7.6 percent; Clarity and Medical Developments climbed more than six percent; Curvebeam improved 4.2 percent; Atomo and Proteomics were up more than three percent; 4D Medical, Aroa, Avita, Compumedics, Emvision, Imugene, Paradigm and Polynovo rose two percent or more; Resmed and Telix were up one percent or more; with CSL, Mesoblast, Neuren and Pro Medicus up by less than one percent.

Medadvisor led the falls, down one cent or 15.4 percent to 5.5 cents, with 4.4 million shares traded. Impedimed lost 7.7 percent; Optiscan and Universal Biosensors fell more than four percent; Syntara was down 3.85 percent; Genetic Signatures, Immutep, Prescient and SDI shed two percent or more; Clinuvel, Nanosonics and Starpharma were down more than one percent; with Cochlear down by 0.1 percent.

DR BOREHAM'S CRUCIBLE: TETRATHERIX

By TIM BOREHAM

ASX Code: TTX

Share price: $4.30

Shares on issue: 50,331,637 (8.7 million issued in IPO)

Market cap: $216.4 million

Chief executive officer: Will Knox (co-founder)

Board: Emma Cleary (chair) Ali Fathi (co-founder), Mr Knox, Gillian Shea, David Bottomley, Atlanta Daniel, John Kelly (Atomo), Maurizio Vecchione

Financials (half year to December 31, 2024): revenue nil, R&D Tax Incentive $459,000, net loss after tax $2.63 million, cash of $31 million (post IPO)

Major identifiable shareholders: Ali Fathi 28%, Radar Ventures (Atlanta Daniel and Rod Drury) 13.3%, David Bottomley and Ryder Capital 11.1%, Will Knox 6.7%. Abrams family 4.95%, Marsden Pty Ltd 4.95%, Aspirate Investments 4.16%

By taking the 'less is more' approach to funding, the backers of the first ASX life sciences initial public offer (IPO) in seven months have been rewarded with a robust share price over the first few trading days.

The developer of the world's first "bio-stealth fluid matrix" wound management house, Tetratherix listed on Monday after reducing its raising from $35 million to $25 million.

"This IPO is not an endpoint or an exit strategy, rather a foundation upon which we will accelerate product development, expand our global clinical footprint and scale manufacturing and commercial operations," CEO Will Knox declared.

The company's Tetramatrix platform has nothing to do with stealth fighters or furtive FBI agents, but is the basis of novel tools for applications including tissue healing, bone regeneration and surgical spacing.

"Bio-stealth refers to the ability to quietly enter the body through minimally invasive means," Mr Knox says.

"It tricks the body, so it doesn't know it has been in there and done the things it needs to do before being reabsorbed.

"That's important because the product doesn't elicit any inflammatory or foreign body response."

Mr Knox dubs the platform as ‘medical Lego’, in that the products are built from the same polymer structure.

“That means you can use the same underlying biological performance and safety data in all regulatory applications,” he says. “Our path to market is a lot faster and simpler because the data is interchangeable across the different applications.”

‘Intelligent chemistry’

The technology combines four liquid monomers in ready-to-use syringes.

The “intelligent chemistry” means it sets to a chewing-gum consistency at body temperature, causing minimal damage to other tissue. The material avoids the fibrotic response associated with healing.

“The ethos is to have something everyone can use, without changing clinical workflows,” says Dr Ali Fathi, the company’s co- founder.

“Even a first-year [medical] school student can use it.”

The material can be easily moulded to suit the application and is not rejected by the body.

Eventually, the material breaks down into water and carbon dioxide.

These qualities make it suitable for day surgeries, which are increasingly common.

Tetratherix currently does not have an approved product.

Pending expected US Food and Drug Administration approval, the company hopes to launch products for dental applications, bone regeneration and orthopaedic uses next year.

This thesis was more than theory

Academic theses tend to be derided as esoteric or theoretical - or both.

That’s not the case with University of Sydney researcher and chemical engineer Dr Fathi, whose thesis spawned the Tetra-tech.

The topic? ‘Injectable Hydrogels with Tunable Physico-chemical Characteristics and Cell-interactive Behaviour for Musculo-skeletal Tissue Regeneration’.

Dr Fathi and Terence Abrams formed the company, then known as Trimph Holdings, in 2025.

In 2018, a dental clinical study established the technology’s street cred.

The company adopted its current moniker in 2020 and carried out its first private fund-raising (series A round) for $2.5 million of preference shares. This was followed by two convertible note raisings, totalling $8.45 million.

The company then converted to an unlisted public company structure.

Mr Knox has extensive experience on commercializing regenerative therapies including at Cochlear. The board includes John Kelly, co-founder of the ASX-listed Atomo Diagnostics.

With an initial focus on dermal repair and orthopaedic bone regeneration, Tetratherix expanded into surgical spacing and tissue healing (preventing scars forming in surgery)

The company also plans to commercialize a ‘spacer’ to protect surrounding tissue (such as the rectum) during prostate cancer radiation therapy.

Tegenix …

First off the commercialization rank is the company’s dental bone regeneration tool, Tegenix. Clinicians mix the material for a bone graft. The putty is then pressed into the bone defect, providing flexibility.

“It also means general dentists can carry out some of these more complex procedures,” Mr Knox says.

Tetratherix has carried out two clinical trials that show Tegenix supports natural bone healing, and expects to bring Tegenix to market by July 2026, following expected FDA clearance. Identical in chemistry to Tegenix, fast follower Tegeneous is intended for orthopaedic uses, enabling minimally invasive treatment of trauma and spinal injuries.

Tutelix …

Under a joint venture with the local Koda Health, Tetratherix is developing Tutelix for prostate spacing.

The material is injected through a long needle between the prostate and the rectum, which protects the latter from radiation during prostate procedures.

“We make cancer radiation therapy safer and simpler. It provides clinicians with optionality in that they can inject it at the pace they want,” Mr Knox says. “It’s visible under a [computer tomography] scan and ultrasound, enabling precision.”

The joint venture has ethics approval for a human trial, expected to start within weeks.

On the ophthalmic front, the Tetratherix ‘eyes’ a product called Optelex, to maintain the volume and shape of peepers during surgery.

… and Tetraderm

Tetraderm prevents scar formation after procedures such as caesarean sections and breast augmentation and reductions.

The product forms a gel between layers of the dermal tissue, reducing ‘dead space’ and providing cushioning to prevent scar formation.

Carried out on the Gold Coast, a trial has passed the first safety and efficacy hurdles.

The company expects a pre-submission meeting with the FDA by the end of 2026.

In the fast lane

Mr Knox says Tetratherix is taking the relatively easy FDA 510(k) path to market.

“We are not a drug, so don’t need phase I to III style programs,” he says. “The average time for an FDA response is 124 calendar days, rather than months or years.”

The company’s regulatory team sifted through 300 510(k) applications and discovered a 95 percent success rate.

“It is a much lower risk profile from a market access perspective.”

Take your partners

Management describes a dual revenue model, by which the technology is licenced to partners in a specific field. This approach means the company does not have to set up a large marketing team: “an expensive and arduous process”.

The partners have the right to self-fund expanded indications, with Tetratherix providing the material.

For Tegenix, the company has an agreement with Henry Schein, the world’s biggest dental supplier.

Tetratherix has teamed up New York’s Bio-Optix Inc to develop and commercialise a novel ophthalmic visco-elastic device (for cataract surgery).

Mr Knox describes the partnerships as distinct and long term.

“We try to avoid the difficult two-to-three-year distribution arrangement,” he says. “Over many years I have found that doesn’t provide enough long-term stability.

“Our partnerships are more a co-development agreement over 15 to 20 years.”

Made in Australia

US tariffs aside - and such imposts shouldn't overly affect the company - Tetratherix is intent at keeping its manufacturing and development on local shores.

"We are setting ourselves up to be an Australian leader in advanced material manufacturing in the biological and medical device space," Mr Knox says.

The polymers are made at the company's facility at Alexandria, near Sydney Airport.

About $10 million IPO proceeds are earmarked for a new plant around the corner, with 10 times the capacity.

Mr Knox says the products are made from widely available raw materials, using "catalogue' equipment.

"The smarts are how you combine and cook those ingredients and how the parts of the process are put in place."

Finances and performance

The IPO consisted of an institutional round and limited retail offering, raising $25 million at $2.88 a pop.

The shares jumped 15 percent after listing on Monday and by Wednesday were a lusty 33 percent to the good.

Mr Knox says the company could have raised the $35 million but wanted to avoid "fast money" subscribers unlikely to stick around.

The company now has cash on hand of circa $30 million.

This funding provides a runway to mid-2027. It factors in two FDA approvals, one further submission and "multiple clinical trial readouts".

Mr Knox says the company has spent about $15 million in research and development over the last decade, with little extra spending required.

Currently, US reimbursement depends on the product.

With bone regeneration, the patient pays out of pocket in what's a low-cost, high-volume game.

But prostate spacing has a well-defined US reimbursement model.

Tetratherix expects milestone licencing payments, as well as on-going annuity-style revenue from licencing and manufacturing margins.

The register includes Rod Drury, who founded small to middle sized enterprize (SME) ‘software as a service’ (SaaS) accounting pioneer Xero.

Mr Drury says he was attracted to Tetratherix because the company applies “SaaS platform thinking” to smart medical devices.

Dr Boreham’s diagnosis:

Mr Knox says the IPO coincides with the company maturing from research and development stage to a commercially-focused entity.

The company cites a combined addressable market for bone regeneration, tissue spacing and tissue healing at $US6.8 billion and forecast to grow to $US9.5 billion by 2023.

“We have five very distinct products across three franchises, built on a platform opportunity,” Mr Knox says.

Still, wound-care newbies need to prove they have the superior - or cheaper - mousetrap.

That often doesn’t work.

This week, the struggling ASX-listed Next Science said it would sell most of its assets to an Italian acquiror for $US50 million ($A75.9 million).

Mr Knox says, typically, the company won’t compete with ASX peers such as Aroa Biosurgery, Avita, Orthocell and Polynovo.

“Instead, we try to disrupt markets, such as in bone regeneration in dental and orthopaedic procedures.

Tetratherix management is most excited about Tutelix and Tetraderm, given their potential to displace incumbent products from sector giants like Teleflex and Boston Scientific

First thing’s first, though: Tetratherix needs to win the two initial FDA approvals and start to accrue that annuity revenue.

But Mr Knox says Tetratherix will take it slowly, wooing the top opinion-leading clinicians before tackling the others,

“There is a very deliberate and strategic way of launching these products,” he says.

“Going too hard, too fast can be the death knell because if [the product is] used in the wrong hands, the messaging is not controlled.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His key to longevity is not going too hard or too fast

PETER MACCALLUM CANCER CENTRE

The Peter MacCallum Cancer Centre says a study shows that chimeric antigen receptor (CAR) T-cell therapy is effective against solid tumors, in mice.

The Peter MacCallum Cancer Centre said CAR T-cells were “an emerging immuno-therapy which can cure patients with aggressive blood cancers who have exhausted all other treatment options”.

The Centre said its scientists used gene-editing techniques “to 'armor' CAR T-cells to produce additional proteins, enabling them to target cancer cells in solid tumors successfully”, with solid tumors accounting for 90 percent of all cancers.

The Peter MacCallum Cancer Centre said the study suggested “these modified CAR T-cells have the potential to treat many common types of cancer, including breast, colon and ovarian cancer”.

The Peter MacCallum Centre said the research, titled ‘Rewiring endogenous genes in CAR T cells for tumor-restricted payload delivery’ was published in the journal Nature, with the full article available at: https://www.nature.com/articles/s41586-025-09212-7.

The Peter MacCallum Cancer Centre research paper said that the efficacy of chimeric antigen receptor (CAR) T-cell therapy in solid tumors was limited by immune-suppression and antigen heterogeneity.

“To overcome these barriers, ‘armored’ CAR T-cells, which secrete pro-inflammatory cytokines, have been developed,” the research paper said.

“However, their clinical application has been limited because of toxicity related to peripheral expression of the armoring transgene,” the study said.

“We have developed a [clustered regularly interspaced short palindromic repeats or CRISPR] knock-in strategy that leverages the regulatory mechanisms of endogenous genes to drive transgene expression in a tumor-localized manner,” the study said.

“By screening endogenous genes with tumor-restricted expression, we have identified the NR4A2 and RGS16 promoters as promising candidates to support the delivery of cytokines such as [interleukin-12] and IL-2 directly to the tumor site, leading to enhanced anti-tumor efficacy and long-term survival of mice in both syngeneic and xenogeneic models,” the study reported.

“This effect was concomitant with improved CAR T-cell poly-functionality, activation of endogenous anti-tumor immunity and a favorable safety profile, and was applicable in CAR T cells from patients,” the study said.

The Peter MacCallum Cancer Centre said the study showed the modified CAR T-cells led to cure rates in mice with solid tumors “close to 100 percent”.

The Centre said its researchers had “overcome two major hurdles preventing CAR T-cells from being an effective treatment for solid tumors”.

The Peter MacCallum Cancer Centre said “previously, armored CAR T-cells damaged healthy body cells as well as tumor cells”.

The Centre said targeting CAR T-cells “to attack cells in tumors also proved tricky because, unlike blood cancer cells, cells in solid tumors lack uniformity, meaning there is no common target”.

The Peter MacCallum Cancer Centre said it overcame these issues “by identifying two areas of DNA that were activated in CAR T-cells once inside a tumor”.

The Peter MacCallum Cancer Centre said the study used the two areas of DNA “to program the CAR T-cells to release anti-cancer proteins, called cytokines, only inside the tumor”.

The Centre said that the study was “a critical first step to enabling CAR T-cell therapy to revolutionize treatment of solid cancers, as it has for blood cancer”.

AEGROS

Former Aegros executive chair Prof Hari Nair has told Biotech Daily that he and former managing-director John Manusu have stepped down to non-executive directors.

Last year, then Aegros chief executive officer Mr Manusu said that the plasma fractionator hoped to raised $100 million at $18.00 a share “in the near term” with the funds to complete the $65 million Sydney manufacturing plant for its hyperimmune products, including its first intended product for Covid-19 (BD: Apr 2, 2024).

Mr Manusu said at that time that he and founding chair Hari Nair and “friends and family” held about 60 percent of the company, which had 720 individual shareholders.

According to STK Markets at that time: “Aegros has developed the Haemafrac machine and process which will disrupt the industry … it produces higher yields, from smaller batch sizes, and is significantly faster”.

The company said Haemafrac significantly reduces cost of goods, with double the yield.

Biotech Daily wrote to Prof Nair and Mr Manusu following a newspaper article alleging the company suspended operations in November 2024 and failed to pay staff entitlements.

Prof Nair said the he and Mr Manusu were non- executive directors, and referred Biotech Daily to chair Ray Nolan and interim chief executive officer Damian Thornton.

An Aegros spokesman told Biotech Daily that, last year, the company “operated at a reduced capacity and was back on track, now”.

The spokesman said Aegros raised $37 million at $1.00 a share, with Mr Nolan providing $20 million and clients of STK Markets providing the $17 million balance, while Daniel Phillips' Fresh Start Australia and Mark Garkawe's L39 Capital remained shareholders.

In 2022, the Queensland Government said it had invested in Aegros’ $352 million facility in Brisbane for blood fractionation and plasma therapeutic use, but did not quantify the amount (BD: Nov 25, 2022).

Prof Nair told Biotech Daily at that time that, with Mr Manusu, the company expected to have the same blood fractionation output in Australia as CSL.

Prof Nair and Mr Manusu were formerly the managing-director and executive chair, respectively, of Nusep, which later became Memphasys (BD: Nov 30, 2012; Dec 2, 2013).

Aegros is a public unlisted company

ENLITIC

Enlitic says it has a $US2 million ($A3 million) advance payment following the signing of its up-to $50 million GE Healthcare medical imaging “migration services” contract.

Earlier this year, Enlitic said Chicago’s General Electric (GE) Healthcare’s Genesis imaging program would include its artificial intelligence (A.I.)-based Ensight Suite program for medical imaging migrations and imaging data transfer (BD: Mar 5, 2025).

Later, the company said it had an up-to $50 million, five-year “migration services” deal with GE Precision Healthcare, subject to raising at least $10 million (BD: May 5, 2025).

Today, Enlitic said it had received an initial payment of $US2 million which would further support the operational roll-out of its Ensight Suite program with GE Healthcare.

The company said subsidiary Laitek would work to deliver between $US3 million and $US6 million a year of annual migration capacity to GE Healthcare for the next five years.

Enlitic said the agreement was “an opportunity for revenue to Enlitic of up-to $46 million over the next five years”.

Enlitic managing-director Michael Sistenich said the company was “delighted to formally complete the financial requirements … with GE Healthcare, laying the foundations for our long-term strategic collaboration”.

Enlitic was up half a cent or 16.7 percent to 3.5 cents with 3.2 million shares traded.

ONCOSIL MEDICAL

Oncosil says all 20 patients have been enrolled in an investigator-led, phase I/II study of its radio-therapy device, percutaneously administered for pancreatic cancer.
In 2023, Oncosil said the first patients had been treated at the Amsterdam University Medical Center (BD: Jun 5, Nov 29, 2023).
Today, the company said the trial's primary objective was "to assess a novel delivery method for the Oncosil device via a [computed tomography]-guided percutaneous approach", that is, through the skin.
Oncosil said the approach had "the potential to simplify administration and lower barriers to adoption, supporting wider market penetration and real-world clinical use".
The company said it expected preliminary data from study to be available in late 2025.
Oncosil managing-director Nigel Lange said the completion of recruitment was "a critical milestone in the clinical development of the Oncosil device".
"The study's importance to our device's development process cannot be overestimated, with it representing a major opportunity to unlock new pathways for delivering our therapy and accelerating its adoption in clinical practice," Mr Lange said.
"We now look forward to the results from the … study and expect that they will make an invaluable contribution to our efforts to make the Oncosil device a go-to treatment for patients with unresectable locally advanced pancreatic cancer," Mr Lange said.
Oncosil was up 8.5 cents or 7.1 percent to $1.28.

IMUGENE

Imugene says it has received $5,872,248 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.
Imugene said the funds would be used for development of its immuno-oncology pipeline.
Imugene was up one cent or 2.4 percent to 42.5 cents.

CLARITY PHARMACEUTICALS

Clarity executive chair Dr Alan Taylor says he has become a substantial shareholder in the company with 16,285,811 shares, or 5.036 percent.
Dr Taylor said that he acquired 592,373 shares on July 1, 2025 through the "exercise of options on a cashless basis applying a share price of $2.2999 a share, being the five-day [volume weighted average price] prior to instruction to exercise".
Clarity was up 19 cents or 6.9 percent to $2.94 with 5.2 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

McRae Technology Pty Ltd says it has reduced and been diluted in Neuroscientific from 25,255,263 shares (17.6%) to 24,107,921 shares (7.25%).
The Perth-based McRae said that it sold 1,147,341 shares between April 5 and 15, 2024 for $77,438, or 6.75 cents a share and was diluted on June 27, 2025.
Earlier this year, Neuroscientific said it would acquire Perth's Isopogen WA through the issue of 85,714,286 shares and 57,142,857 performance shares and had "firm commitments" for an up-to $3.5 million placement and 3.5 cents a share to fund the development of Isopogen's technology (BD: Apr 16, 2025).
Last month, the company said it had completed its acquisition of Isopogen WA and its Stemsmart mesenchymal stem cells for scrip (BD: Jun 27, 2025).
Neuroscientific was up one cent or 7.7 percent to 14 cents.

RHYTHM BIOSCIENCES

FIL Limited (Fidelity Investment Management) says it has increased its substantial shareholding in Rhythm from 17,511,734 shares (6.04%) to 20,645,216 shares (7.11%).
The Sydney and Hong Kong-based Fidelity said that it bought shares between April 9 and July 1, 2025 at prices ranging from 8.00 cents a share to 5.18 cents a share.
Rhythm was up 0.8 cents or 15.4 percent to six cents.

NYRADA

Nyrada says Mark Azzi has increased his substantial shareholding from 30,427,243 Chess depository interests (CDIs) (14.43%) to 32,583,494 shares (15.45%).
Nyrada was up one cent or 3.7 percent to 28 cents.

DORSAVI

Dorsavi says Michael Winlo “has tendered his resignation as non-executive director to focus on his other business commitments”.
Earlier this year, Emyria said managing-director Dr Winlo was appointed chief scientific officer and remained a director (BD: Jan 22, 2025).
Today, Dorsavi said it extended its “sincere thanks to Mr Winlo for his insights and contributions during his time on the board”.
The company said it was “actively looking to hire executives and advisers with strong expertise in [resistive random-access memory] and semi-conductor technologies”.
Last month, Dorsavi said it would pay $S1,100,000 ($A1,320,000) for the Singapore Nanyang Technological University’s resistive random-access memory (RRAM) technology to be used to extend the battery life of its wearable sensors, minimizing recharge cycles and improving usability in continuous monitoring (BD: Jun 12, 2025).
Today, the company said it was “particularly interested in candidates with proven experience in advanced memory architectures, semiconductor design, and related commercialization pathways”.
“These appointments will play a critical role in guiding the company's next phase of innovation and growth,” Dorsavi said.
Dorsavi was up 0.2 cents or 11.8 percent to 1.9 cents with 11.2 million shares traded.