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Daily news on ASX-listed biotechnology companies

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 the size of 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.

The company 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