ASX RELEASE

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TUTELIX FAST TRACKS PIVOTAL TRIAL PROGRAM FOLLOWING SERIES A CAPITAL RAISE

HIGHLIGHTS:

- Tetratherix Limited (ASX:TTX) (**Tetratherix**) is pleased to announce the progression of its prostate spacing clinical trial with promising indications of performance on patients undergoing radiation therapy.
- The trial has been designed to investigate the ability of Tutelix to be safely injected between the prostate and rectum to create and maintain space around the prostate.
- The results from this human study showed that Tutelix is simple to use and optimises the delivery of radiation during treatment for prostate cancer. Specifically, it:
  - maintained its shape and form;
  - did not migrate from where it was injected and importantly;
  - did not cause any safety issues.
- Following these promising results we are rapidly **moving into the international pivotal study** in the US and Australia.
- On the back of this, our joint venture (**JV**) partner (Tutelix Pty Ltd) has successfully completed Series A funding round from key investors in the space. Led by a dedicated MedTech VC, with strong support from a syndicate of key opinion leaders in the space bringing total funds raised by the JV to ~ **$5 million**.

CONTEXT

Why this capital raise is important?

The JV independently funds its activities and growth; this capital raise allows the JV to fast-track the clinical trial to move towards an international pivotal study in the Australia and the US. More than half of the JV shareholders are US-based key opinion leaders (**KOLs**) in the segment of the market which the JV operates, validating the technology's differentiation and clinical significance. The engagement of the KOLs will also provide immediate in-market presence and strong commercial momentum for rapid US adoption of the product as a spacer after FDA approval.

Why do patients need spacers for their prostate cancer radiation therapy?

A rectal spacer is a soft, absorbable gel injected around the prostate to space the rectum away from tissue being radiated. This lowers the amount of radiation that the rectum receives, reducing the risk of short and long-term side effects. By doing this patients can complete their radiation treatment with higher doses in shorter time frames, for example in 4-6 weeks.

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CONTEXT (CONTINUED)

How these spacers are administered?

When inserting spacers clinicians use transperineal ultrasound to visualise the location that spacers are needed. Some clinicians then inject saline to open the tissue plane between the prostate and rectum – this is called hydrodissection.

There are currently two prostate spacer options in the market, one is a solidifying plastic (**Product A**) and the other is a gel that is normally used as an injectable face filler (**Product B**). Both products are injected through a long needle (>15 cm) into the site of the prostate.

Product A is provided in a kit, consisting of multiple syringes and solutions that need to be mixed before insertion and must be injected within 30 seconds otherwise the product crystalises and blocks the insertion needle which can cause clinical problems and wastage. Product A also blocks the ultrasound signal extruded from the inserting needle, this means that clinicians cannot see or control the sharp tip of the inserting needle which is very close to the delicate rectal wall.

Product B is provided in ready-to-use syringes, this format is faster and more convenient for clinicians. However, hydrodissection cannot be used for Product B as the saline at the injection site will dilute the face filler and make it less cohesive.

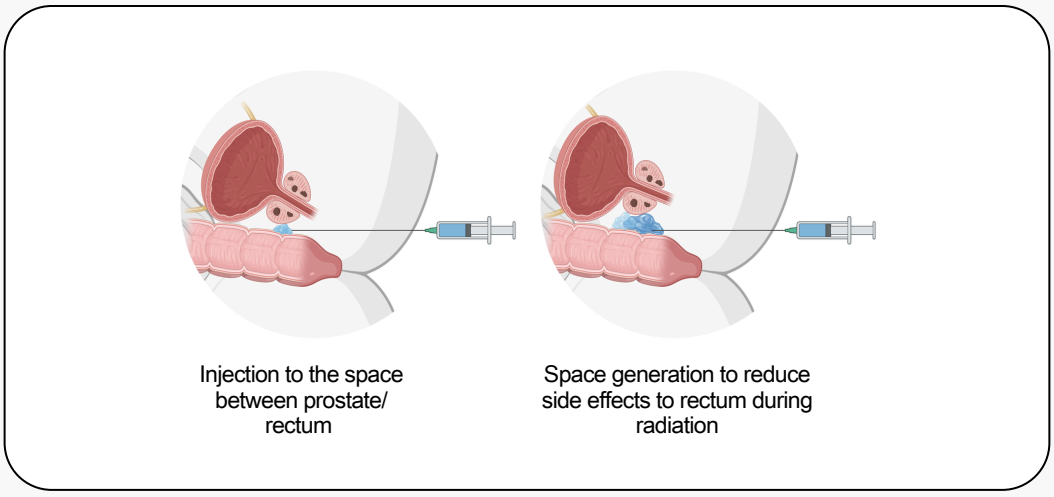

Figure 1. Application of Tutelix

To read more about our partnership strategy, the value of our JV model and how we think about approaching markets head to our Medium page via this link to learn more:

Medium

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CONTEXT (CONTINUED)

The Tutelix product difference

The Tutelix spacer, similarly to Product A and B, is inserted in a quick outpatient setting under an ultrasound guided procedure. The Tutelix product is ready-to-use, does not need preparation before insertion and does not block the inserting needle. Uniquely, Tutelix can be used with or without hydrodissection to provide flexibility to clinicians and their preferences. Importantly, ultrasound visibility is not impacted by the Tutelix so clinicians can safely see the location of the needle while Tutelix forms a cohesive space at the site to push the rectum away from the prostate for optimised radiation dosing.

Why it is a good commercial opportunity?

Urology outpatient procedures are growing. More men are being screened and treated with radiotherapy increasing the demand for efficient, clinic-based spacers. In the US, the proportion of prostate cancer patients receiving rectal spacers during radiation therapy has surged, growing at a compound annual growth rate of ~11% in recent years. This trajectory suggests a rapidly expanding standard of care with the prostate spacing market estimated to be US$1.3 billion[1]. Product A and Product B can be expensive, require extra steps like hydrodissection or specialised training adding time and complexity to busy outpatient workflows limiting adoption. Tutelix offers a clinician-friendly spacer designed for quick, reproducible insertion with minimal added steps and supply advantages. This positions Tutelix attractively for both rapid uptake in established markets and a future focused rollout into developing and emerging markets where cost-effective, easy-to-use solutions can meet rising demand.

What have we seen in the clinical study and how do we measure success?

To date the primary objective of the study has been achieved for each recruited patient. 12 patients have included Tutelix in their treatment and the space generated by the technology reduced the radiation dose received by the rectum in each patient. All 12 participants have completed or are in the process of completing their radiation treatment plan. There have been no safety concerns or adverse events related to Tutelix at any follow up time points up to 6 months post-insertion. Tutelix has illustrated its efficacy facilitating simple and safe radiation therapy.

What are the next technical and commercial steps?

Consistent with our prospectus disclosures, the JV continues to progress as planned, on cost and within the communicated time frame. The remaining 3 patients in the pilot trial are being recruited in March 2026. The details for the pivotal trial for US-FDA 510(k) clearance of Tutelix have been confirmed with the regulator and Human Research Ethics Committee approval in Australia is imminent. For the pivotal trial 50% of patients will be enrolled in Australia (expected to be initiated before July 2026) and the remainder will be in the US within the next 12 months. These milestones support the timely trial completion and regulatory submission, keeping us on schedule for an exciting product clearance by CY 2028.

SEE OVER FOR COMMERCIALISATION PATHWAY

[1] Based on Tetratherix's internal modelling.

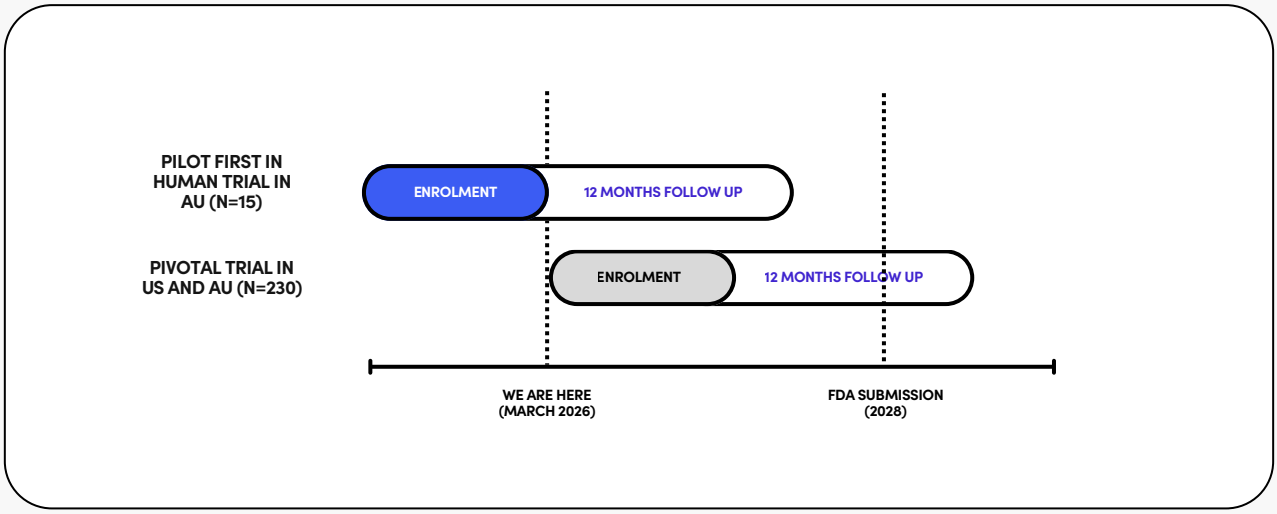

Figure 2. Commercialisation pathway.

Will Knox, CEO of Tetratherix, said:

"We are incredibly proud to hit yet another exciting milestone for our Tutelix spacer technology. What makes this moment particularly compelling for our shareholders over and above the quantum raised is securing backing from elite US interventional physicians - the key opinion leaders who will drive adoption in the world's largest healthcare market - is a massive vote of confidence.

We are not just introducing a new product, we are displacing outdated technologies that are often difficult to administer or prone to sub-optimal patient outcomes. Tutelix offers a superior patient experience by allowing for higher radiation doses in significantly shorter timeframes, moving treatment from months to just weeks. With this fresh capital and strong clinical momentum we are perfectly positioned to capture a significant share of the global prostate spacer market."

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For any questions regarding this announcement, to receive regular Tetratherix announcements & updates and to engage with management join the TTX Investor Hub or for more information visit:

TTX Investor Hub

This announcement was authorised for ASX release by the CEO.

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