



## Telix Reports \$204M Revenue, Up 63% YOY

22 Jul 2025

MELBOURNE, Australia and INDIANAPOLIS, July 22, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today provides an update on its commercial and operational performance for the quarter ended 30 June 2025 (Q2 2025). All figures are in USD unless stated otherwise.

### Q2 2025 Highlights

- Q2 2025 unaudited group revenue of approximately \$204 million, up 63% year-over-year.
- FY 2025 revenue guidance of \$770 million to \$800 million is reaffirmed.
- Gozellix® launched in the U.S. and commercial dose deliveries commenced.
- Gozellix has been assigned a Level II HCPCS code<sup>1</sup> (effective 1 October 2025), a prerequisite for receiving Transitional Pass-Through payment status.
- ProstACT™ Global Phase 3 trial milestone – all 30 patients consented for Part 1. Global expansion with regulatory approvals to expand the trial into China, Japan and Canada.

### Q2 2025 Revenue (Unaudited)

Revenue\$M	Q2 2025	Q2 2024	Variation	Q1 2025	Variation
Group revenue	204	125	63%	186	10%
Global Illuccix® revenue	154	123	25%	151	2%
RLS revenue <sup>1</sup>	46	-	-	33 <sup>2</sup>	39%

### Commentary and business highlights

Dr. Christian Behrenbruch, Managing Director and Group CEO, Telix, stated, "Dose volumes for Illuccix rose 7% quarter-on-quarter in the U.S., reinforcing the strength of our market position and continued customer demand. Despite emerging competitive pricing pressure, we have effective strategies in place to manage impact to average selling price. This includes the recent launch of Gozellix which has been assigned a HCPCS code, a crucial reimbursement milestone towards pass-through status. We continue to show positive momentum across multiple assets in our therapeutic pipeline, including achievement of a key recruitment milestone in our ProstACT Global Phase 3 trial."

### Therapeutics business

- **TLX591 (<sup>177</sup>Lu-rosopatamab tetraxetan):** Telix has consented all 30 patients required to complete Part 1 of ProstACT Global, the Phase 3 trial of its lead prostate cancer therapy candidate. Patients in two of the three arms (abiraterone and enzalutamide as standard of care) have completed dosing. An interim readout of safety and dosimetry will follow the completion of patient dosing, monitoring and data analysis. The trial is proceeding seamlessly into Part 2 at existing ex-U.S. sites and additional regulatory approvals have been obtained to commence the trial in China, Canada and Japan<sup>4</sup>.
- **TLX592 (<sup>225</sup>Ac-PSMA-RADmAb):** Telix has submitted a Human Research Ethics Committee (HREC) application in Australia for a Phase 1, first-in-human therapeutic study of a targeted alpha therapy in advanced metastatic castration resistant prostate cancer.
- **TLX101 (<sup>131</sup>I-iodofalan, or <sup>131</sup>I-IPA):** Telix received HREC approval in Australia to commence IPAX BrIGHT, an international pivotal trial. An IPAX BrIGHT Clinical Trial Application (CTA) has also been submitted in Europe.
- **TLX250 (<sup>177</sup>Lu-DOTA-girentuximab):** STARLITE-1<sup>5</sup> is enrolling patients. This Phase 1b/2 clinical trial is investigating the use of TLX250 in combination with cabozantinib and

nivolumab, in clear cell renal cell carcinoma (ccRCC). Trial submission is in preparation for a pivotal trial of TLX250 as a monotherapy in advanced metastatic ccRCC, initially launching ex-U.S.

- **TLX090 (<sup>153</sup>Sm-DOTMP):** In July, Telix submitted an Investigational New Drug (IND) application for a Phase 1 bridging study for Telix's therapeutic candidate for the palliation of bone pain in patients with osteoblastic metastatic disease to the bone.

#### Precision Medicine business

##### *PSMA portfolio (Illuccix and Gozellix):*

- Telix received country-level approvals for Illuccix in France, Finland, Ireland, Sweden, Germany, Portugal, Greece, the Czech Republic, Belgium and Italy in Q2 and is launching on a market-by-market basis, as reimbursement is secured.
- Telix has completed enrolment of the Illuccix China Phase 3 study<sup>6</sup>, which will be used to file a marketing authorization in China in Q4 2025.
- Telix has received HREC approval in Australia and filed an IND with the FDA in the U.S. for a Phase 3 clinical trial aimed at expanding the label indication for Illuccix and Gozellix. The BiPASS study<sup>7</sup> will evaluate the performance of MRI<sup>8</sup> combined with PSMA PET<sup>9</sup> imaging for detection and diagnosis of prostate cancer, which is designed to reduce the need for invasive biopsies.
- Telix has submitted a Prior Approval Supplement (PAS) to update the U.S. Prescribing Information for Illuccix. The proposed label expansion includes patient selection for radioligand therapy (RLT) in the pre-taxane setting. The prescribing information is expected to be updated, following FDA's review of the submission<sup>10</sup>.
- As part of product lifecycle management strategy, Telix announced a novel PET<sup>11</sup> radiochemistry solution based on fluorine-18 (<sup>18</sup>F)-aluminium fluoride (AIF), branded AIFluor<sup>TM</sup><sup>12</sup>. The platform technology enables flexible radiolabeling of PSMA<sup>13</sup> with either AIF or gallium-68 (<sup>68</sup>Ga). As part of the platform's development, Telix signed a strategic agreement with University Hospital Ghent and Ghent University for a novel [<sup>18</sup>F]AIF-PSMA-11 targeting agent, including extensive clinical data to enable a U.S. registration trial.

**Pixclara**<sup>14</sup> (TLX101-CDx, <sup>18</sup>F-floretyrosine or <sup>18</sup>F-FET): A successful Type A meeting was held with the FDA on 24 June 2025, to agree on a path forward for resubmitting the New Drug Application (NDA) for Telix's brain cancer imaging candidate.

**Zircaix**<sup>15</sup> (TLX250-CDx, <sup>89</sup>Zr-DFO-girentuximab): The Company continues to progress a Biologics License Application (BLA) with the FDA for its kidney cancer PET imaging candidate. The PDUFA<sup>16</sup> date remains 27 August 2025.

##### **Telix Manufacturing Solutions (TMS)**

- Telix announced its Good Manufacturing Practice (GMP) manufacturing facility in Yokohama, Japan. Telix's first cyclotron facility in the Asia Pacific region represents a significant milestone in the Company's global manufacturing strategy. It will serve as a hub for commercial and clinical drug product supply, and future research and development in the region.
- The TMS facility in Brussels South (Seneffe), Belgium, produced its first GMP commercial radiopharmaceutical doses, marking the formal launch of Telix's radiopharmaceutical manufacturing capability in Europe.

## Corporate update

Telix has received a subpoena from the U.S. Securities and Exchange Commission (SEC) seeking various documents and information primarily relating to the Company's disclosures regarding the development of the Company's prostate cancer therapeutic candidates.

The Company is fully cooperating with the SEC and is in the process of responding to the information request. At this stage, this matter is a fact-finding request. The Company has elected to notify the Australian Securities and Investments Commission of the SEC's information request. Telix's policy is not to discuss any details of an ongoing regulatory inquiry.

The information request from the SEC does not mean that Telix or anyone else has violated United States federal securities laws or that the SEC has a negative opinion of any person, entity or security. We cannot predict when this matter will be resolved or what (if any) action the SEC may take following the conclusion of this investigation.

While the matter is ongoing, Telix will continue with its clinical development programs relating to its prostate cancer therapy candidates, in the ordinary course of business. The information request does not extend to Telix's commercial and late-stage precision medicine products including Illuccix, Gozellix, Zircaix, Pixclara and Scintimun®.

## FY 2025 guidance

- Telix confirms FY 2025 revenue guidance of \$770 million to \$800 million<sup>17</sup>.
- Guidance reflects revenue from Illuccix sales in jurisdictions with a marketing authorization, and 11 months of revenue contribution from RLS<sup>18</sup>.
- Telix confirms research and development (R&D) expenditure guidance, expecting a year-over-year increased investment range for FY 2025 of 20% to 25% compared to FY 2024.

## Guidance disclaimer

The stated revenue guidance is based on expected global and domestic economic conditions and is subject to known and unknown risks, uncertainties and other factors that may cause our actual results to differ materially. As such, investors are cautioned not to place undue reliance on this guidance and in particular Telix cannot guarantee a particular result. In compiling financial forecasts, a number of key variables that may have a significant impact on guidance have been identified and are listed below.

Key variables that could cause actual results to differ materially include: the success and timing of research and development activities; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; competitive developments affecting our products; the ability to successfully market new and existing products; difficulties or delays in manufacturing; trade buying patterns and fluctuations in interest and currency exchange rates; legislation, regulation, or policy that affects product production, distribution, pricing, reimbursement, access or tax; acquisitions and divestitures; research collaborations; litigation or government investigations; and Telix's ability to protect its patents and other intellectual property. See the Legal Notices section below for additional information, risks and assumptions.

## About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, Brazil, Canada, United Kingdom, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Telix's prostate imaging product, gallium-68 (<sup>68</sup>Ga) gozetotide injection (also known as <sup>68</sup>Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the FDA<sup>19</sup>, and in multiple markets globally. Gozellix® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection) has been approved by the FDA<sup>20</sup>.

Telix's osteomyelitis (bone infection) imaging agent, technetium-99m (<sup>99m</sup>Tc) besilesomab, marketed under the brand name Scintimun®, is approved in 32 European countries and Mexico. Telix's miniaturized surgical gamma probe, SENSEI®, for minimally invasive and robotic-assisted surgery, is registered with the FDA for use in the U.S. and has attained a Conformité Européenne (CE) Mark for use in the European Economic Area. No other Telix product has received a marketing authorization in any jurisdiction.

Visit [www.telixpharma.com](http://www.telixpharma.com) for further information about Telix, including details of the latest share price, ASX and U.S. Securities and Exchange Commission (SEC) filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on [LinkedIn](#), [X](#) and [Facebook](#).

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*This announcement has been authorized for release by the Telix Pharmaceuticals Limited Board of Directors.*

## Legal Notices

### *Cautionary Statement Regarding Forward-Looking Statements.*

*You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.*

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<sup>1</sup> Healthcare Common Procedure Coding System, refer to ASX disclosure 9 July 2025.

<sup>2</sup> Excludes revenue contribution from Illuccix sales.

<sup>3</sup> Revenue from date of RLS acquisition 27 January 2025.

<sup>4</sup> IND approved in China 22 July 2025; Clinical Trial Notification (CTN) approved in Japan 20 June 2025; Clinical Trial Application for Part 2 approved in Canada 22 May 2025.

<sup>5</sup> ClinicalTrials.gov ID: NCT05663710.

<sup>6</sup> Refer to disclosure 13 May 2025.

<sup>7</sup> ClinicalTrials.gov ID: NCT07052214.

<sup>8</sup> Magnetic resonance imaging.

<sup>9</sup> Imaging of prostate-specific membrane antigen with positron emission tomography.

<sup>10</sup> Subsequent to Telix disclosure on 23 June 2025, the FDA reclassified the submission to a PAS. The submission was made 5 June 2025.

<sup>11</sup> Positron Emission Tomography.

<sup>12</sup> Refer to ASX disclosure 20 June 2025.

<sup>13</sup> Prostate-specific membrane antigen.

<sup>14</sup> Brand name subject to final regulatory approval.

<sup>15</sup> Brand name subject to final regulatory approval.

<sup>16</sup> Prescription Drug User Fee Act.

<sup>17</sup> Refer to ASX disclosures 20 February 2025.

<sup>18</sup> See Guidance Disclaimer for further information.

<sup>19</sup> Telix ASX disclosure 20 December 2021.

<sup>20</sup> Telix ASX disclosure 21 March 2025.