



## Telix Achieves FY 2025 Guidance with US\$804M (A\$1.2B) Revenue, Accelerates Growth with Gozellix Launch

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MELBOURNE, Australia and INDIANAPOLIS, Jan. 20, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") provides an update on its commercial and operational performance for the quarter ended 31 December 2025 (Q4 2025).

### Q4 2025 Highlights

- Full-year (FY) 2025 unaudited Group revenue of approximately US\$804 million (A\$1.2 billion<sup>1</sup>), in line with upgraded guidance of US\$800-\$820 million<sup>2</sup> (previously US\$770-800 million).
- Q4 2025 unaudited Group revenue of approximately US\$208 million, up 46% year-over-year.
- Precision Medicine business revenue of approximately US\$161 million, up 4% quarter-over-quarter, driven by the successful United States (U.S.) launch of Gozellix® following reimbursement by Centers for Medicare and Medicaid Services (CMS), effective from 1 October 2025<sup>3</sup>.
- First international patients treated in Part 2 (randomized expansion) of the ProstACT® Global Phase 3 study of TLX591-Tx in advanced prostate cancer<sup>4</sup>.
- First U.S. patients treated in the SOLACE Phase 1 study of TLX090-Tx in patients with pain from bone metastases<sup>5</sup>.
- Announced strategic collaboration with Varian, a Siemens Healthineers company, to explore the combination of Telix's radiopharmaceuticals with external beam radiation therapy (EBRT) <sup>6</sup>.

### Q4 2025 Revenue (Unaudited)

Revenue (US\$M)	Q4 2025	Q4 2024	Variation	Q3 2025	Variation
Group revenue	208	142	46%	206	1%
Precision Medicine revenue <sup>7</sup>	161	139	16%	155	4%
RLS third-party revenue <sup>8</sup>	45	—	—	47	(4)%

### Commentary and business highlights

Dr. Christian Behrenbruch, Managing Director and Group CEO, stated, "Telix's Precision Medicine business delivered excellent sequential growth in Q4 2025, driven in part by the successful U.S. launch of Gozellix. This revenue growth outpaced a 3% increase in dose volumes, demonstrating the positive impact of our two-product strategy on market share and pricing. With strong early uptake of Gozellix and a robust pipeline of key accounts integrating Gozellix and ARTMS technology, Telix is well positioned for sustained growth in 2026."

### Therapeutics business

- **TLX591-Tx (lutetium (<sup>177</sup>Lu) rosopatamab tetraxetan):** Telix is preparing for a readout of safety and dosimetry data from Part 1 of ProstACT Global, the Phase 3 trial of its lead prostate cancer therapy candidate. Part 2 (randomized treatment expansion) has commenced following data safety review and dosed first patients. The study is open for enrollment in Australia, New Zealand and Canada, with further sites to be opened in China, Singapore, South Korea, Türkiye, the United Kingdom and Japan<sup>9</sup>, where regulatory approvals have already been granted. Data from Part 1 will be presented to the U.S. Food and Drug Administration (FDA) to ascertain eligibility for U.S. patients to participate in Part 2.
- **TLX592-Tx (<sup>225</sup>Ac-PSMA-RADmAb):** Telix is preparing to activate sites for AlphaPRO, a first-

in-human (FIH) study of its targeted alpha therapy candidate for prostate cancer. The study will initially recruit ex-U.S.

- **TLX250-Tx (<sup>177</sup>Lu-DOTA-girentuximab)**: Telix is commencing site activations ahead of opening patient enrollment in LUTEON<sup>10</sup>, its pivotal trial of TLX250-Tx as a monotherapy in metastatic clear cell renal cell carcinoma (ccRCC). The study will initially recruit ex-U.S.
- **TLX252-Tx (<sup>225</sup>Ac-DOTA-girentuximab)**: Telix has received approval in Australia to commence ALPHIX, a Phase 1, FIH study of its targeted alpha therapy candidate for advanced metastatic kidney cancer and other cancers that express carbonic anhydrase IX (CAIX).
- **TLX101-Tx (<sup>131</sup>I-iodofalan)**: Telix is enrolling patients at Australian sites in IPAX-BriGHT, an international pivotal trial of TLX101-Tx in patients with recurrent glioblastoma<sup>11</sup>. European sites are expected to join the study in Q1 2026.
- **TLX102-Tx (<sup>211</sup>At astato-L-phenylalanine)**: Telix is preparing to commence a FIH study of TLX102-Tx, its alpha therapy candidate targeting L-type amino acid transporter 1 (LAT1), in patients with leptomeningeal disease (LMD). The FDA has acknowledged LMD as a significant unmet medical need and provided positive written feedback on a two-part study design (dose escalation and safety expansion), along with guidance on a combined protocol for imaging and therapy to enable a true theranostic evaluation, including potential future label expansion for TLX101-Px.
- **TLX090-Tx (<sup>153</sup>Sm-DOTMP)**: Telix has dosed the first U.S. patients in SOLACE<sup>12</sup>, a Phase 1 study of its therapeutic candidate for treating pain in patients with osteoblastic bone metastases from prostate and breast cancers.

#### Precision Medicine business

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

- Following approval of Illuccix® in Spain<sup>13</sup>, Telix now holds marketing authorizations for all 19 European countries that were included in its decentralized procedure (DCP) submission. Commercial launches have commenced in 12 European countries including France, Germany, Spain and the United Kingdom as reimbursement is secured on a market-by-market basis.
- Australian hospitals and imaging centers continue to effectively transition from in-house production of <sup>68</sup>Ga-PSMA-11 to Illuccix®, with Telix's approved agent now the leading PSMA-PET<sup>14</sup> tracer nationally (approximately 55% market share at 31 December 2025)<sup>15</sup>.
- The Chinese National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE) has accepted the New Drug Application (NDA) filing for TLX591-Px (Illuccix)<sup>16</sup>. This follows positive top-line results from the Illuccix China Pivotal Phase 3 registration study<sup>17</sup>, which reported an overall patient-level positive predictive value (PPV) of 94.8% for detecting tumors in patients with biochemical recurrence (BCR) of prostate cancer<sup>18</sup>.
- Telix has dosed the first U.S. patients in its BiPASS™ Phase 3 study<sup>19</sup> to evaluate magnetic resonance imaging (MRI) combined with its commercial PSMA-PET imaging agents, Illuccix and Gozellix, in the initial prostate cancer diagnosis setting. The trial is recruiting in Australia and the U.S.
- Telix has dosed the first patient in its Phase 3 registration study of TLX591-Px in Japan<sup>20</sup>. The

study will enroll up to 105 Japanese men at 11 sites with data intended to support a future marketing authorization application for Illuccix in Japan.

**Pixclara®<sup>21</sup> (TLX101-Px, Floretyrosine F18):**

- Telix has engaged in collaborative discussions with the FDA on additional clinical data and a revised statistical analysis plan, following a productive Type A meeting to review the basis of the Complete Response Letter (CRL). Telix is finalizing its resubmission package and will provide an update upon acceptance of the refiling.
- The approved Expanded Access Program (EAP) for TLX101-Px remains active, reflective of Telix's commitment to patients <sup>22</sup>.

**Zircaix®<sup>21</sup> (TLX250-Px, <sup>89</sup>Zr-DFO-girentuximab):**

- In December 2025, Telix participated in a Type A meeting to discuss chemistry, manufacturing, and controls (CMC) deficiencies identified in the CRL for its Biologics License Application (BLA) for this ccRCC PET imaging candidate<sup>23</sup>. In January 2026, Telix participated in an additional Type A meeting to address clinical comparability between the drug product used in the ZIRCON Phase 3 clinical trial<sup>24</sup> and the product from scaled-up manufacturing intended for commercial use. Following this meeting, Telix believes it has alignment with the Agency on all key resubmission aspects. Telix will provide a further update on receipt of official FDA minutes from both meetings.
- TLX250-Px is now included in updated international guidelines from the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM) and The American College of Nuclear Medicine (ACNM) for molecular imaging of renal masses, reflecting a shift toward precision medicine in renal cancer<sup>25</sup>.
- Data from ZIRCON-X, a non-interventional, prospective, study – using imaging data from Telix's pivotal Phase 3 ZIRCON study – were presented at the 26th Annual Meeting of the Society of Urologic Oncology (SUO). The study evaluated the impact of TLX250-Px imaging on clinical decision-making versus standard contrast-enhanced imaging in 294 patients with indeterminate renal masses (IRMs). Outcomes demonstrated that 48.6% of patients (143) would have experienced a change in management if imaged with TLX250-Px, with over 20% of these (31 patients) potentially avoiding invasive biopsy<sup>26</sup>.
- The approved EAP for TLX250-Px remains active, reflective of Telix's commitment to patients<sup>27</sup>.

**Telix Manufacturing Solutions (TMS)**

In line with its stated strategy to invest in supply chain and production capabilities to meet future demand for radiopharmaceuticals, Telix is progressing several key projects:

- Upgrades to select RLS Radiopharmacies network sites for cyclotron installations to enable in-house production of critical therapeutic and diagnostic isotopes, along with enhanced manufacturing capabilities.
- A major upgrade of Good Manufacturing Practice (GMP) production facilities and clean rooms at the Angleton, Texas site for IsoTherapeutics, a Telix Company.
- Opening of a TMS site in Yokohama, Japan<sup>28</sup>. This is Telix's first cyclotron facility in the Asia Pacific region to support future product launch in Japan and regional clinical trials.

- Construction of a TMS-led translational research hub in North Melbourne, Australia, is in completion. The facility incorporates radiochemistry hot labs for clinical dose production and a patient dosing and imaging suite, including in-house SPECT/CT<sup>29</sup>.

These investments support vertical integration, supply chain control, and global centers of excellence for advancing Telix's next-generation therapeutic radiopharmaceutical portfolio.

#### Corporate updates

##### **Strategic clinical collaboration with Varian**

Telix announced a strategic clinical collaboration with Varian, a Siemens Healthineers company and global leader in radiation oncology. The collaboration focuses on developing novel clinical applications that combine Telix's theranostic products with EBRT, starting with PSMA-PET imaging for prostate cancer. This framework supports future co-development opportunities, including with other PET imaging candidates in Telix's pipeline (TLX250-Px and TLX101-Px) and potential future therapeutic radiopharmaceuticals.

##### **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, United Kingdom, Brazil, Canada, 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).

Illuccix has been approved by the FDA<sup>30</sup>, and in multiple markets globally. Gozellix has been approved by the FDA<sup>31</sup>. No other Telix product mentioned in this announcement 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.*

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<sup>1</sup> Converted at the full year 2025 average US\$:A\$ exchange rate of 1.55:1

<sup>2</sup> Telix ASX disclosure 14 October 2025.

<sup>3</sup> Telix ASX disclosure 23 September 2025.

<sup>4</sup> Telix media release 8 December 2025. ClinicalTrials.gov ID: [NCT066520345](#).

<sup>5</sup> Telix media release 23 October 2025. ClinicalTrials.gov ID: [NCT07197645](#).

<sup>6</sup> Telix media release 10 December 2025.

<sup>7</sup> Primarily sales of Illuccix and Gozellix in our Precision Medicine business.

<sup>8</sup> RLS Radiopharmacies revenue excludes revenue contribution from Illuccix and Gozellix sales.

<sup>9</sup> Japanese regulator Pharmaceuticals and Medical Devices Agency (PMDA) has granted approval for a Japan-specific Part 1 in nine patients, prior to commencing Part 2.

<sup>10</sup> ClinicalTrials.gov ID: [NCT07197580](#).

<sup>11</sup> ClinicalTrials.gov ID: [NCT07100730](#).

<sup>12</sup> Telix media release 23 October 2025.

<sup>13</sup> Telix media release 29 August 2025.

<sup>14</sup> Imaging of prostate-specific membrane antigen.

<sup>15</sup> Management estimate based on Medicare Benefit Schedule statistics, available at: [medicarestatistics.humanservices.gov.au/](#)

<sup>16</sup> Telix ASX disclosure 20 January 2026.

<sup>17</sup> ClinicalTrials.gov ID: [NCT05847348](#).

<sup>18</sup> Telix ASX disclosure 22 December 2025, Telix data on file. Illuccix China Clinical Study Report, December 2025.

<sup>19</sup> Biopsy of the Prostate Avoidance Stratification Study; ClinicalTrials.gov ID: [NCT07052214](#). Telix media release 16 January 2026.

<sup>20</sup> Japan Registry of Clinical Trials identifier: JRCT2031250473

<sup>21</sup> Brand name subject to final regulatory approval.

<sup>22</sup> ClinicalTrials.gov ID: [NCT06743100](#).

<sup>23</sup> Telix ASX disclosure 22 December 2025.

<sup>24</sup> ClinicalTrials.gov ID: [NCT03849118](#).

<sup>25</sup> Rowe et al. *J Nucl Med*. 2025. Telix media release 23 October 2025.

<sup>26</sup> Telix ZIRCON-X SUO 2025 abstract, available at: <https://suo-abstracts.secure-platform.com/a/gallery/rounds/24/details/4869>

<sup>27</sup> ClinicalTrials.gov ID: [NCT06090331](#).

<sup>28</sup> Telix media release 21 November 2025.

<sup>29</sup> Single-photon emission computed tomography combined with computed tomography.

<sup>30</sup> Telix ASX disclosure 20 December 2021.

<sup>31</sup> Telix ASX disclosure 21 March 2025.