



Telix Reports US\$206M Revenue, FY 2025 Guidance Upgraded

14 Oct 2025

MELBOURNE, Australia and INDIANAPOLIS, Oct. 14, 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 September 2025 (Q3 2025). All figures are in USD unless stated otherwise.

Q3 2025 Highlights

- Q3 2025 unaudited group revenue of approximately \$206 million, up 53% year-over-year.
- FY 2025 revenue guidance increased to \$800 million to \$820 million¹.
- Gozellix® now fully reimbursed by Centers for Medicare and Medicaid Services (CMS): Level II HCPCS² code and Transitional Pass-Through (TPT) payment status effective 1 October 2025³.
- Illuccix® now approved in 19 European markets⁴ and the United Kingdom (UK); commercial launch has commenced in the UK, Germany, France, Finland, Sweden, Norway and Denmark.
- First patients dosed in the BiPASS™ trial of MRI + PSMA-PE⁵ for the diagnosis and detection of prostate cancer.
- ProstACT® Global Phase 3 trial – Part 2 open for enrollment in Australia, New Zealand and Canada and study approved to commence in China, Singapore, Türkiye and Japan. Part 1 preliminary readout of safety profile and dosimetry to follow completion of patient monitoring and data analysis.

Q3 2025 Revenue (Unaudited)

Revenue US\$M	Q3 2025	Q3 2024	Variation	Q2 2025	Variation
Group revenue	206	135	53%	204	1%
PSMA imaging revenue ⁶	155	132	17%	154	1%
RLS third-party revenue ⁷	47	—	—	46	2%

Commentary and business highlights

Dr. Christian Behrenbruch, Managing Director and Group CEO, stated, "We believe this is a solid result, particularly in light of the reimbursement dynamics during the quarter. Moreover, a 3% increase in dose volumes suggests competitive pricing pressures are beginning to stabilize. Telix has entered Q4 in a position of strength, supported by a growing customer base, two FDA- approved PSMA imaging agents and CMS reimbursement for Gozellix effective from 1 October in the U.S. This differentiated two-product strategy enables us to expand market share across all customer segments, with Gozellix enhancing our production flexibility and providing customer choice based on patient reimbursement pathways."

Therapeutics business

- **TLX591 (¹⁷⁷Lu-rosopatamab tetraxetan):** Telix has closed enrollment into Part 1 of ProstACT Global⁸, the Phase 3 trial of its lead prostate cancer therapy candidate. A preliminary readout of safety and dosimetry will follow the completion of patient treatment (with standard of care), monitoring and data analysis. Part 2 (randomized treatment expansion) has opened for enrollment in Australia, New Zealand and Canada, and with further sites to be opened in China, Singapore, Türkiye and Japan, where the study has regulatory approval.
- **TLX250 (¹⁷⁷Lu-DOTA-girentuximab):** Telix received ethics approval in Australia to commence LUTEON⁹, a pivotal trial of TLX250 as a monotherapy in advanced metastatic

clear cell renal cell carcinoma (ccRCC). STARLITE-1¹⁰ - a Phase 1b/2 clinical trial investigating the use of TLX250 in combination with cabozantinib and nivolumab, in ccRCC, has commenced dosing patients.

- **TLX101 (¹³¹I-iodofalan, or ¹³¹I-IPA):** Telix received approval¹¹ to commence IPAX-BrIGHT in Europe. This international pivotal trial of TLX101 in patients with recurrent glioblastoma is currently activating its first site in Australia, following receipt of ethics approval in Q2 2025¹².
- **TLX090 (¹⁵³Sm-DOTMP):** Telix is preparing to dose the first patient in SOLACE, a Phase 1 study of Telix's therapeutic candidate for treating bone pain in patients with osteoblastic metastatic cancer.
- **TLX400 (¹⁷⁷Lu-DOTAGA.Glu.(FAPi)₂):** A study of Telix's Fibroblast Activation Protein (FAP)-targeting therapy candidate, TLX400, was published in the *Journal of Nuclear Medicine*, demonstrating clinical antitumor activity with an encouraging safety profile in subjects with advanced sarcoma¹³.

Precision Medicine business

PSMA portfolio (Illuccix and Gozellix):

- Gozellix is now a fully reimbursed product in the U.S., having been granted a Level II HCPCS code¹⁴ and TPT payment status (effective 1 October 2025)¹⁵. Telix is the only company with two U.S. Food and Drug Administration (FDA)-approved PSMA imaging products.
- Following country-level approval for Illuccix in Spain¹⁶, Telix now has approvals for all 19 markets in the Company's decentralized procedure (DCP) submission in Europe. Commercial launch has commenced in the UK, Germany, France, Finland, Sweden, Norway and Denmark, as Illuccix is rolled out on a market-by-market basis when reimbursement is secured.
- Telix dosed the first patients in the BiPASSTM study¹⁷ to evaluate the performance of MRI combined with PSMA-PET imaging in diagnosing prostate cancer, with the aim of reducing the need for invasive biopsies. This Phase 3 registration-enabling trial aims to expand the indications for Illuccix and Gozellix. Telix has commenced the study in Melbourne, Australia and has filed an investigational new drug application (IND) with the FDA to commence the study in the U.S.
- Telix successfully received a Prior Approval Supplement (PAS) to update the U.S. Prescribing Information for Illuccix. The Illuccix label now includes patient selection for radioligand therapy (RLT) in the pre-taxane setting.

Pixclara®¹⁸ (TLX101-CDx, ¹⁸F-floretyrosine or ¹⁸F-FET): Telix reached agreement with the FDA on a pathway for resubmission of the New Drug Application (NDA) for Telix's brain cancer imaging candidate, confirming it plans to resubmit the NDA during Q4 2025¹⁹.

Zircaix®¹⁸ (TLX250-CDx, ⁸⁹Zr-DFO-girentuximab): Following the receipt of a Complete Response Letter from the FDA in August 2025²⁰, Telix is requesting a Type A meeting, ahead of the resubmission of the Biologics License Application (BLA) for its kidney cancer imaging agent.

Telix Manufacturing Solutions (TMS)

Telix has been granted radiation licenses for its TMS North Melbourne (Australia) and Yokohama (Japan) facilities - for a broad range of clinically and commercially important medical isotopes. Both facilities are in the final stages of fit-out and preparing for operational readiness.

Corporate updates

Final royalty payment to ANMI

In 2018, Telix acquired Advanced Nuclear Medicine Ingredients (ANMI), the developer of the underlying Illuccix technology. The acquisition agreement included contingent consideration (variable payments) based on Illuccix global sales for five years following marketing authorization of Illuccix, with an option to buy out remaining payments in the third year following marketing authorization if agreed sales thresholds were met. As a result of strong sales performance, Telix has successfully exercised its option to buy-out the remaining variable payments. The final payment of \$51.7 million comprising the option payment and third and final annual variable payment was made in July 2025, and will be reflected in the cash flows for H2 2025, included in the Company's full year financial results.

FY 2025 guidance

- Telix increases FY 2025 revenue guidance to \$800 million to \$820 million²¹.
- Guidance reflects revenue from PSMA imaging (Illuccix and Gozellix) product sales in jurisdictions with a marketing authorization, and 11 months of revenue contribution from RLS²².
- 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, 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).

Telix's prostate imaging product, gallium-68 (⁶⁸Ga) gozetotide injection (also known as ⁶⁸Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the FDA²³, and in multiple markets globally. Gozellix® (kit for the preparation of gallium-68 (⁶⁸Ga) gozetotide injection) has been approved by the FDA²⁴.

Telix's osteomyelitis (bone infection) imaging agent, technetium-99m (^{99m}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 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](#).

¹ Previous FY 2025 revenue guidance: \$770 million to \$800 million.

² Healthcare Common Procedure Coding System.

³ Telix ASX disclosure 23 September 2025.

⁴ All European countries included in Telix's European Economic Area submission.

⁵ Magnetic resonance imaging; imaging of prostate-specific membrane antigen with positron emission tomography.

⁶ PSMA imaging revenue represents sales of Illuccix® and Gozellix® in our Precision Medicine business.

⁷ RLS Radiopharmacies revenue excludes revenue contribution from Illuccix and Gozellix sales.

⁸ ClinicalTrials.gov ID: [NCT06520345](https://clinicaltrials.gov/ct2/show/study/NCT06520345).

⁹ ClinicalTrials.gov ID: [NCT07197580](https://clinicaltrials.gov/ct2/show/study/NCT07197580).

¹⁰ ClinicalTrials.gov ID: [NCT05663710](https://clinicaltrials.gov/ct2/show/study/NCT05663710).

¹¹ Approved with conditions.

¹² Telix ASX disclosure 22 July 2025. ClinicalTrials.gov ID: [NCT07100730](https://clinicaltrials.gov/ct2/show/study/NCT07100730).

¹³ Telix media release 6 October 2025. Ballal et al. *J Nucl Med*. 2025.

¹⁴ Telix ASX disclosure 9 July 2025.

¹⁵ Telix ASX disclosure 23 September 2025.

¹⁶ Telix media release 29 August 2025.

¹⁷ Biopsy of the Prostate Avoidance Stratification Study; ClinicalTrials.gov ID: [NCT07052214](https://clinicaltrials.gov/ct2/show/study/NCT07052214). Telix media release 9 September 2025.

¹⁸ Brand name subject to final regulatory approval.

¹⁹ Telix ASX disclosure 9 September 2025

²⁰ Telix ASX disclosure 28 August 2025.

²¹ Telix ASX disclosure 20 February 2025.

²² See Guidance disclaimer for further information.

²³ Telix ASX disclosure 20 December 2021.

²⁴ Telix ASX disclosure 21 March 2025.

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

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