

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 6-K**

REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the month of September, 2025

Commission File Number: **001-42128**

**Telix Pharmaceuticals Limited**

(Translation of registrant's name into English)

**55 Flemington Road**  
**North Melbourne, Victoria 3051, Australia**  
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F  Form 40-F

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INFORMATION CONTAINED IN THIS FORM 6-K REPORT

On September 23, 2025 (Melbourne, Australia), Telex Pharmaceuticals Limited filed an announcement with the Australian Securities Exchange titled "CMS Grants Transitional Pass-Through Status for Gozellix," a copy of which is attached to this Form 6-K as Exhibit 99.1.

[99.1](#)

Press release – September 23, 2025

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Telix Pharmaceuticals Limited**

Date: September 23, 2025

By: /s/ Genevieve Ryan  
Name: Genevieve Ryan  
Title: Company Secretary

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**ASX ANNOUNCEMENT**

**CMS Grants Transitional Pass-Through Status for Gozellix**

*Melbourne (Australia) and Indianapolis, IN (U.S.) – 23 September 2025.* Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today announces that the United States (U.S.) Centers for Medicare & Medicaid Services (CMS) has granted Transitional Pass-Through (TPT) payment status for Gozellix® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection), Telix’s next-generation PSMA-PET<sup>1</sup> imaging agent for prostate cancer.

This designation enables separate reimbursement for Gozellix® under the Hospital Outpatient Prospective Payment System (HOPPS), effective 1 October 2025, and marks a significant milestone in Telix’s U.S. commercial strategy. Gozellix® has already been assigned a permanent Healthcare Common Procedure Coding System (HCPCS) Level II code A9616 to be recognized by CMS and commercial health insurers, effective 1 October 2025<sup>2</sup>. Additionally, patients are not subject to the 20% patient coinsurance under TPT.

After radiolabelling with <sup>68</sup>Ga, Gozellix® is indicated for PET scanning of PSMA positive lesions in men with prostate cancer who have suspected metastasis and are candidates for initial definitive therapy, and those with suspected biochemical recurrence (BCR) based on elevated serum prostate-specific antigen (PSA) level<sup>3</sup>.

Gozellix® is a novel imaging agent offering a longer shelf life of up to six hours and an extended distribution radius compared to existing gallium-based products, helping to overcome many of the logistical barriers that have historically limited access to PSMA-PET imaging<sup>4</sup>. Its innovative formulation enables scalable production, with preparation possible via gallium generators (50mCi and 100mCi) or cyclotron-based methods. This flexibility has the potential to significantly improve efficiency, scheduling flexibility, and throughput for scanning clinics<sup>5</sup>. Cyclotron production of Gozellix® is supported by the GE FASTlab™<sup>6</sup> solid and liquid target production system and Telix’s ARTMS QUANTM Irradiation System® (QIS®), the market-leading cyclotron solid target technology, enabling large-scale production across both commercial networks and academic centers.

Kevin Richardson, Chief Executive Officer, Precision Medicine, Telix, said, “Granting TPT status for Gozellix is a strong endorsement of the clinical value of our next-generation imaging agent. Gozellix is already available nationally, and this reimbursement milestone will reduce the out-of-pocket burden for patients, enhance patient access to advanced prostate cancer imaging and simplify payment for providers. As the only provider with two FDA-approved and reimbursed products in this class, we are pleased to make PSMA-PET/CT imaging accessible to more patients and providers across the U.S.”

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<sup>1</sup> Imaging of prostate-specific membrane antigen with positron emission tomography.

<sup>2</sup> Telix ASX disclosure 9 July 2025.

<sup>3</sup> Gozellix® prescribing information.

<sup>4</sup> Data on file.

<sup>5</sup> Gozellix® prescribing information. Data on file.

<sup>6</sup> FASTlab is a trademark of GE Healthcare and its affiliates.

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## 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® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved in multiple markets globally. Gozellix® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection) has been approved by the U.S. FDA<sup>7</sup>.

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 Disclosure Committee on behalf of the Board.*

### 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>7</sup> Telix ASX disclosure 21 March 2025.

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*This announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as “may”, “expect”, “intend”, “plan”, “estimate”, “anticipate”, “believe”, “outlook”, “forecast” and “guidance”, or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on Telix’s good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect Telix’s business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix’s business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress, completion and results of Telix’s preclinical and clinical trials, and Telix’s research and development programs; Telix’s ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix’s product candidates, manufacturing activities and product marketing activities; Telix’s sales, marketing and distribution and manufacturing capabilities and strategies; the commercialization of Telix’s product candidates, if or when they have been approved; Telix’s ability to obtain an adequate supply of raw materials at reasonable costs for its products and product candidates; estimates of Telix’s expenses, future revenues and capital requirements; Telix’s financial performance; developments relating to Telix’s competitors and industry; the anticipated impact of U.S. and foreign tariffs and other macroeconomic conditions on Telix’s business; and the pricing and reimbursement of Telix’s product candidates, if and after they have been approved. Telix’s actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements.*

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