

**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 January, 2025

Commission File Number: **001-42128**

Telex 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

INFORMATION CONTAINED IN THIS FORM 6-K REPORT

On January 17, 2025, Telix Pharmaceuticals Limited (the “Company”) filed with the Australian Securities Exchange (the “ASX”) an announcement captioned “Illucix® Receives European Approval,” a copy of which is attached to this Form 6-K as Exhibit 99.1.

[99.1](#)

Press release – January 17, 2025

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: January 17, 2025

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

ASX ANNOUNCEMENT

Illuccix® Receives European Approval

Melbourne (Australia) and Liège (Belgium) – 17 January 2025. Telix Pharmaceuticals Limited (ASX: TLX, Nasdaq: TLX, Telix, the Company) today announces that it has received a positive decision on the Marketing Authorization Application (MAA) for its prostate cancer PET¹ imaging agent Illuccix® (kit for the preparation of gallium-68 gozetotide injection), which was submitted in Europe via a decentralized procedure (DCP).

This significant milestone follows the issuance of the Final Assessment Report from the German Competent Authority BfArM² as Reference Member State (RMS). Through the DCP, the RMS and all 18 European Economic Area (EEA) Concerned Member States (CMS)³ agree that Illuccix should receive marketing authorization. The DCP regulatory process will now transition into an administrative national phase to implement authorizations to facilitate commercial launch in each country⁴.

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine commented, “We are delighted by this positive outcome, setting the stage for a European commercial launch of Illuccix. This clinically important prostate cancer imaging modality is currently recommended in international clinical practice guidelines including European Association of Urology (EAU) and European Society for Medical Oncology (ESMO).”

PSMA-PET imaging⁵ represents a major advancement in prostate cancer management, largely replacing conventional imaging methods (bone scan, CT⁶ scan) as the standard of care after initial diagnosis and biochemical recurrence (BCR). European guidelines highlight the superior accuracy of PSMA-PET for the staging of primary disease⁷ and evaluation of BCR/biochemical persistence (BCP)⁸.

About Illuccix®

Telix’s lead 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 U.S. Food and Drug Administration (FDA)⁹, by the Australian Therapeutic Goods Administration (TGA)¹⁰, and by Health Canada¹¹.

¹ Positron emission tomography.

² The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte).

³ Germany serves as the Reference Member State in the Decentralised Procedure. The other 18 Concerned Member States are Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, and Sweden.

⁴ Regulatory approval timeframe from EEA CMSs may vary considerably.

⁵ Imaging of prostate-specific membrane antigen with positron emission tomography.

⁶ Computed tomography.

⁷ EAU, ESMO.

⁸ EAU.

⁹ Telix ASX disclosure 20 December 2021.

¹⁰ Telix ASX disclosure 2 November 2021.

¹¹ Telix ASX disclosure 14 October 2022.

In Europe, Illucix, after radiolabelling with gallium-68, will be indicated for detection of PSMA-positive lesions with PET in adults with prostate cancer (PCa) in the following clinical settings:

- Primary staging of patients with high-risk PCa prior to primary curative therapy
- Suspected recurrent PCa in patients with increasing levels of serum prostate-specific antigen (PSA) after primary curative therapy
- Identification of patients with PSMA-positive progressive metastatic castration-resistant prostate cancer (mCRPC) for whom PSMA-targeted therapy is indicated.

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, 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).

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

Telix Investor Relations

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This announcement has been authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

Legal Notices

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 registration statement on Form 20-F filed with the SEC, or on our website.

The information contained in this announcement is not intended to be an offer for subscription, invitation or recommendation with respect to securities of Telix Pharmaceuticals Limited (Telix) in any jurisdiction, including the United States. The information and opinions contained in this announcement are subject to change without notification. To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to update or revise any information or opinions contained in this announcement, including any forward-looking statements (as referred to below), whether as a result of new information, future developments, a change in expectations or assumptions, or otherwise. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained or opinions expressed in the course of this announcement.

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 and results of Telix’s preclinical and clinical trials, and Telix’s research and development programs; Telix’s ability to advance product candidates into, enrol 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 commercialisation 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; 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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