### 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 November, 2024

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  $\boxtimes$  Form 40-F  $\square$ 

#### INFORMATION CONTAINED IN THIS FORM 6-K REPORT

On November 19, 2024, Telix Pharmaceuticals Limited (the "Company") filed with the Australian Securities Exchange ("ASX") an announcement (the "Announcement") captioned "Telix to Add FAP-Targeting Candidates to Theranostic Pipeline", a copy of which Announcement is attached to this Form 6-K as Exhibit 99.1.

 $Attached \ as \ Exhibit \ 99.2 \ is \ a \ presentation \ the \ Company \ filed \ with \ the \ ASX \ on \ November \ 19, 2024 \ in \ connection \ with \ the \ Announcement.$ 

99.1 Press release dated November 19, 2024 99.2 Presentation dated November 19, 2024 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: November 19, 2024

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



Telix Pharmaceuticals Limited ACN 616 620 369 55 Flemington Road North Melbourne Victoria, 3051 Australia

ASX ANNOUNCEMENT

#### Telix to Add FAP-Targeting Candidates to Theranostic Pipeline

Melbourne (Australia) – 19 November 2024. Telix Pharmaceuticals Limited (ASX: TLX; Nasdaq: TLX; Telix, the Company) today announces it will expand its theranostic pipeline with new assets targeting Fibroblast Activation Protein (FAP), one of the most promising pan-cancer targets in nuclear medicine. Telix's development program will initially focus on the treatment of bladder cancer, rounding out its urology franchise, which includes late-stage therapeutic programs for kidney and prostate cancers.

FAP is a pan-cancer marker expressed in the tumour microenvironment of epithelial cancers and on the surface of some specific cancer types, including sarcomas and mesotheliomas.

Telix has entered into asset purchase and exclusive worldwide in-licence agreements for a suite of clinically validated FAP-targeting therapeutic and precision medicine (diagnostic) radiopharmaceutical candidates developed by Professor Frank Roesch and his collaborators at the Institute of Nuclear Chemistry at the Johannes Gutenberg-Universität Mainz, Germany. The next-generation therapeutic assets are differentiated by a novel structure that drives extended tumour retention while minimising off-target uptake, potentially overcoming the limitations seen with first-generation compounds. The diagnostic and therapeutic compounds have been clinically validated in over 500 patients across a variety of solid tumours and are the subject of multiple peer-review publications!

Richard Valeix, Chief Executive Officer, Telix Therapeutics, said, "We are delighted to partner with Professor Roesch and his team on this exciting frontier of radiopharmaceuticals. Telix will gain access to assets that are already significantly de-risked, with clinically demonstrated safety profile and efficacy. We will develop these assets in bladder cancer as a primary indication, in line with our focus on urological cancers, and explore the potential of FAP as a pan-cancer target, adding significant value to our pipeline."

Frank Roesch, professor emeritus, said, "Over the past two years, our FAP inhibitor-based theranostic candidates have seen extensive preclinical and clinical evaluation. Collaboration has been very important, and I am grateful to many colleagues around the world who have contributed to advancing the molecules to this point. We are excited to be working with Telix as a leader in radiopharmaceutical innovation, development and commercialisation, to further develop and bring these drug candidates to regulatory approval. The ultimate goal is to improve the diagnostic precision and therapeutic outcomes of cancer patients in need."

#### Deal terms and condition

Under an exclusive worldwide licence agreement with a German company controlled by Professor Roesch, SCV GmbH, and a concurrently-signed asset purchase agreement with German company Medianezia GmbH, which collectively hold the intellectual property rights to the FAP assets, Telix will pay  $\epsilon$ 7 million in cash as of closing (inclusive of  $\epsilon$ 700,000 paid at or prior to the signing of the agreements) and a further  $\epsilon$ 3 million in 12 months' time subject to any potential indemnity setoff.

<sup>1</sup> Ballal et al. Pharmaceuticals. 2021; Ballal et al. JNM. 2022; Ballal et al. JNM. 2023; Bal et al. JNM. 2024.

Page

Telix will pay up to a further  $\varepsilon$ 132 million contingent upon achievement of certain clinical development and regulatory milestones related to both the diagnostic and therapeutic products under both agreements. An additional  $\varepsilon$ 20 million will be payable under the licence agreement on achievement of certain commercial milestones related to the diagnostic product; as well as royalties on net sales in the low to mid-single digits on the diagnostic product and an earlier formulation of the therapeutic product, if used.

Closing of the licence agreement and asset purchase agreement is expected to occur simultaneously and is subject to customary closing conditions including, with respect to the acquisition of assets, assignment of patents rights and foreign direct investment (FDI) approval of Germany's Ministry for Economic Affairs and Climate Action. Telix cannot guarantee these transactions will close in any specific timeframe or upon the terms summarised herein, if at all.

Telix is a biopharmaceutical company focused on the development and commercialisation of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, 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 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)<sup>2</sup>, by the Australian Therapeutic Goods Administration (TGA) 3, and by Health Canada4. No other Telix product has received a marketing authorisation in any jurisdiction.

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, announcements made to the ASX, 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

Ms. Kvahn Williamson Telix Pharmaceuticals Limited SVP Investor Relations and Corporate Communications Email: kvahn.williamson@telixpharma.com

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.

<sup>&</sup>lt;sup>2</sup> Telix ASX disclosure 20 December 2021.

<sup>&</sup>lt;sup>3</sup> Telix ASX disclosure 2 November 2021 <sup>4</sup> Telix ASX disclosure 14 October 2022.

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 to differ materially from any future results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements 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 adout: the initiation, timing, progress and results of Telix's preclinical and clinical trials; the fitting of Telix's preclinical and clinical trials; the timing of Telix's preclinical and clinical trials; the timing of Telix's preclinical and clinical trials; the timing of Telix's product candidates, manufacturing activities and product marketing activities; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialis

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### **Disclaimer**

This presentation should be read 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 presentation is not intended to be an offer for subscription, invitation or recommendation with respect to shares of Telix Pharmaceuticals Limited (Telix) in any jurisdiction, including the United States. The information and opinions contained in this presentation 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 presentation, 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 this presentation.

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This presentation also contains estimates and other statistical data made by independent parties and by Telix relating to market size and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of Telix's future performance and the future performance of the markets in which it operates are necessarily subject to a high degree of uncertainty and risk.

Telix's lead imaging product, gallium-68 (\*SGa) gozetotide injection (also known as \*GGa PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA), by the Australian Therapeutic Goods Administration (TGA), and by Health Canada. No other Telix product has received a marketing authorisation in any jurisdiction.

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# Transaction to add clinically-validated FAP assets to pipeline

### A promising pan-cancer target with initial focus on bladder cancer

### Next generation of **FAP-targeting** theranostics

- · Fibroblast Activation Protein (FAP) is one of the most exciting targets in nuclear medicine - expressed in over 90% of epithelial cancers1
- · Next-generation assets have potential for imaging, and both alpha and beta therapy applications
- · Demonstrated safety and efficacy profile in extensive preclinical and clinical validation
- · Developed by renowned radiochemist Professor Frank Roesch and team

### Strategic acquisition • bolsters Telix's focus in urology

- Bolsters pipeline with a pan-cancer program complementing Telix's CAIX portfolio
- · Initial development program to focus on bladder cancer, which rounds out urology franchise

### Deal summary

- €7M cash (upfront) (AU\$11M)
- €3M cash (12 months' time) (AU\$5M)
- Up to €132M subject to (AU\$215M)
- Up to €20M subject to  $(AU$33M)^2$



- ( Telix 1. Rettig et al. Proc Natl Acad Sci USA. 1988.
  - Conversion to AUD\$ is at an average exchange rate of AU\$1 = EUR € 0.61

### FAP: The Achilles' heel of cancer?

### Targeting key players in the tumour microenvironment (TME)

Fibroblasts are cells which help to form connective tissue and promote the body's normal healing process

In cancer this forms part of a protective wall around the tumour called **stroma** protecting it from immune response

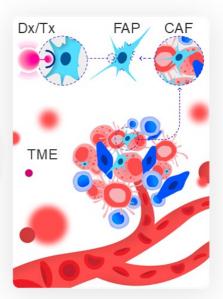
Stroma makes up >70% of solid tumour mass<sup>1</sup>

Cancer cells can 'manipulate' normal fibroblasts to promote tumour growth

Permanently activated fibroblasts are known as Cancer Associated Fibroblasts (CAF) CAFs are marked by significantly increased levels of Fibroblast Activation Protein (FAP)

FAP is expressed in CAFs as well as on some tumour cells, creating a potential double-hit to the tumour

**FAP** is a druggable target and therefore a potential Achilles' heel of cancer





1. Micke et al., EBioMedicine. 2021.

# The theranostic potential of FAP

Using radiation to image, damage or destroy cancer cells

# Overexpressed in cancer

FAP is highly expressed in the TME of epithelial cancers, and on the surface of some specific cancer types, including sarcomas and mesotheliomas<sup>1</sup>

# Powerful therapy potential

By delivering radiation to CAFs, targeted radionuclide therapy has the potential to damage or destroy the cancer stroma and cancer cells

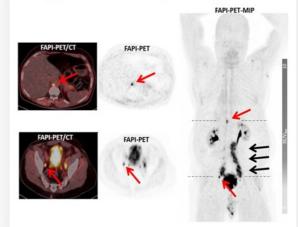
# Combined treatment options

Weakening of the cancer stroma may also improve the effectiveness of other therapies

# Demonstrated evidence in bladder cancer

FAP targeting for imaging patients<sup>2,3</sup> - superior to FDG - highlights its potential to address a significant unmet need through a theranostic approach

# FAP Imaging in bladder cancer exemplifies potential for therapeutic approach



<sup>68</sup>Ga-FAPI PET in 65-y-old patient with bladder cancer<sup>2</sup>

Patient representative scans - individual results may vary.



- 1. Zboralski et al., EJNMMI. 2022.
- Novruzov et al. Molecular Imaging and Biology. 2022.
- 3. Koshkin et al. JNM. 2024.

# Cracking therapeutics: A new way to target FAP

### New assets have potential to overcome key challenges

First-generation FAP-targeting candidates limited by short tumour residence

Telix's next generation candidates have a novel design enabling:

- Extended tumour retention
- ✓ Improved clearance
- Minimal off-target uptake
- ✓ Labelling with either <sup>177</sup>Lu (beta) or <sup>225</sup>Ac (alpha)
- Significant radiotherapeutic dose to tumour
- Potential for beta and alpha therapy

Clinically validated for safety profile and efficacy in several cancer types, under an extensive compassionate use program<sup>1-4</sup>



- 1. Yadav et al. EJNMMI. 2024.
- 2. Ballal et al. Pharmaceuticals (Basel). 2021.
- 3. Martin et al. Cancers. 2023.
- 4. AIMS, New Delhi, India.

# Clinical evidence for acquired next-gen compounds

### Proof-of-concept in-human study and extensive compassionate use

#### Extensive clinical data

Successful proof of concept across diagnostic, therapeutic, for multiple indications

### Safety profile established

FAP-targeting diagnostic has been used in >400 patients, establishing safety profile<sup>2</sup>

#### Pan-cancer uses

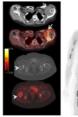
Used as therapy in >120 patients across sarcoma, breast, thyroid and medullary thyroid cancers to date<sup>1</sup>

#### Peer-reviewed data

Builds on extensive preclinical data, published in several peer-reviewed papers<sup>3</sup>

# Published data demonstrates therapeutic potential<sup>1</sup>

68Ga-DOTA SA. FAPi PET/CT

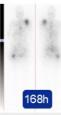




Intense accumulation of radiotracer in tumour mass (arrows) and multiple skeletal sites (right femurarrow head).

177Lu-DOTA (SA FAPi)<sub>2</sub> post-therapy serial whole-body scans





Radiotracer retention in metastatic sites at **168 hours** 

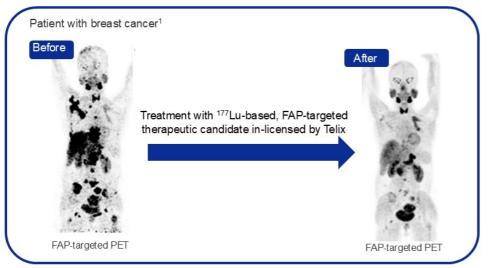
Patient representative scans - individual results may vary.

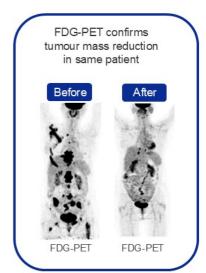


- 1. Ballal et al. Pharmaceuticals. 2021; Ballal et al. JNM. 2022; Ballal et al. JNM. 2023; Bal et al. JNM. 2024.
- 2. AIIMS, New Delhi, India. Data on file.
- 3. Laeppchen et al. Molecules. 2024.

# Compelling responses seen in late-stage cancer patients

Significant tumour mass reduction following treatment with therapeutic candidate





Clinical effect of <sup>177</sup>Lu-based, FAP-targeted therapeutic candidate in-licensed by Telix, in a patient with breast cancer. Response verified by FAP-targeted PET (above) and FDG-PET (right) using the diagnostic in-licensed by Telix.

Patient representative scans - individual results may vary.



1. AIIMS, New Delhi, India. Data on file.

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### Clinical development led by renowned KOLs

### **Broad community of supporters leading investigations**

#### Frank Roesch, PhD Mainz, DE

- Renowned radiochemist in nuclear medicine
- Invented the <sup>68</sup>Ga generator
- Chairs World Theranostics Conference

#### Ken Herrmann, MD, MBA Essen, DE

- Chair of Dept of Nuclear Medicine at University Hospital Essen
- Chair of EANM Oncology & Theranostics Committee
- Prolific commentator in nuclear medicine community

Chandrasekhar Bal, MD & Sanjana Ballal, PhD New Delhi, IN

- Extensive clinical experience with all Roesch compounds
- Widely published in both JNM and other nuclear medicine publications

### Frederik L. Giesel, MD, MBA Düsseldorf, DE

- Chair of Dept of Nuclear Medicine at Uni Düsseldorf
- Global leader in application of PSMA and FAP targeting in nuclear medicine



"FAP-targeting is very exciting.
In the past, we have been successful in treating primarily one cancer type with a certain asset or therapeutic agent. Here we have opened a new door to treat a variety of cancer subtypes – a pan tumour target and even beyond!"

- Prof. Dr. Frederik L. Giesel

(1) Telix

### Unmet need in bladder cancer

6th most common cancer in the U.S., significant unmet need

Large market opportunity

83K

new cases and 16K+ deaths per year in the U.S.<sup>1</sup>

29%

of patients develop metastatic disease<sup>2</sup> with 5-year survival rate of 8%<sup>3</sup> White space opportunity for TRT<sup>5</sup>, including FAP-targeting agents

No approved systemic radionuclide therapy Studies suggest FAP expressed in over 67% of cases<sup>6</sup>

\$5.6B

 $\rightarrow$ 

\$13.7B

in 2024

in 2029

Global market for bladder cancer therapies estimated to grow by over 20% per annum over next 5 years<sup>4</sup>





3. National Cancer Institute, Bladder Cancer Prognosis and Survival Rates, accessed October 2024.

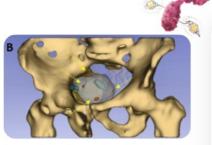
- 4. National Cancer Institute, Bladder Cancer Prognosis and Survival Rates, accessed October 2024.
- Targeted radionuclide therapy.
- 6. Hemida et al. J Immunoassay Immunochem. 2022.
- 7. NCCN Guidelines Version 4.2024, Bladder Cancer.





# Adding to the bladder cancer therapy toolbox

### Complements Telix's CAIX program, options for localised and disseminated disease



3D representation with superimposed bladder based on TLX250-CDx Pelvis PET/CT Fusion images

#### Trials of TLX250-CDx in bladder cancer

#### PERTINENCE (IIT)

Alpha candidate in non-muscle invasive bladder cancer

Phase I feasibility study of TLX250-CDx complete

Moving to first-inhuman therapeutic studies with 211At (alpha) via Telix partner ATONCO

#### ZiP-UP (IIT)

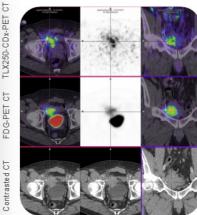
Exploring indication expansion for TLX250 in urothelial carcinoma or bladder cancer

TLX250-CDx-PET

FDG-PET

Phase I study of TLX250-CDx complete - awaiting readout



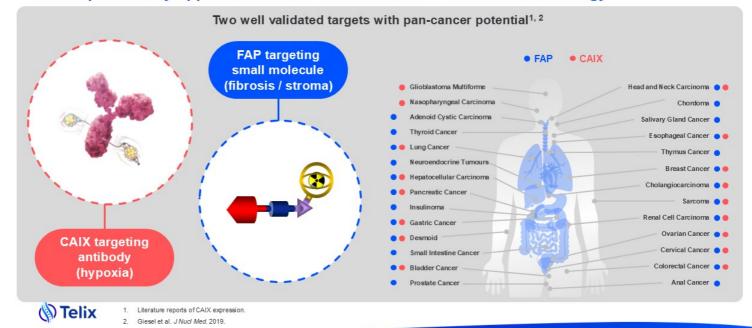


Comparison of TLX250-CDx PET-CT with FDG-PET CT. Patient representative scans - individual results may vary.



# Pan-cancer: "Double hit" at TME – targeting hypoxia and fibrosis

A complementary approach – and a "shot in the arm" to immuno-oncology



# In summary: An exciting asset with big potential

### Adds to urology pipeline with ability to expand to other cancer types

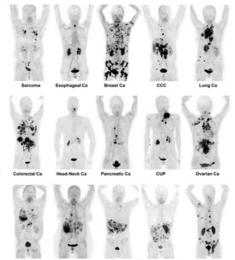
- Clinically validated theranostic drug candidates targeting FAP – a highly promising target
- Next-generation compounds with longer tumour retention than earlier versions
- Adds to Telix's urology development pipeline with novel candidates for bladder cancer, a major market opportunity
- Potential to generate further value from pancancer targeting
- Clinical data (safety profile and efficacy) reduce development risk, guide target indications and may expedite development
- Visit our website for more: <u>Attack on Stroma</u>

# of the Year 2019

**SNMMI** Image

<sup>68</sup>Ga-FAPI PET/CT: Tracer Uptake in 28 Different Kinds of Cancer<sup>1</sup>

Maximum-intensity projections of <sup>88</sup>Ga-FAPI PETI/CT in patients reflecting 15 different histologically proven tumour entities (sorted by uptake in descending order). Ca = cancer, CCC = cholangiocellular carcinoma; CUP = carcinoma of unknown primary; MTC = medullary thyroid cancer, NET = neuroendocrine tumour.





 Kratochwil et al. 2019. Journal of Nuclear Medicine June 2019, 60 (6) 801-805; DOI: https://doi.org/10.2967/jnumed.119.227967

Patient representative scans - individual results may vary.

