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ASX ANNOUNCEMENT

Telix Q3 2024 Business Update – Quarterly Revenue Exceeds AU$200M

Melbourne (Australia) – 17 October 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today provides an update on its revenue and operational performance for the quarter ended 30 September 2024 (Q3 2024).

Revenue update, full year guidance reaffirmed

- Unaudited total revenue of approximately US$135 million (AU$201 million[1]), primarily generated from sales of Telix's prostate cancer imaging product Illuccix® in the Precision Medicine (Px) business unit. This represents an increase of 55% on the prior corresponding quarter (Q3 2023: US$87 million or AU$133 million) and an increase of 9% on the prior quarter (Q2 2024: US$124 million or AU$189 million).
- Revenue generated from sales of Illuccix in the United States (U.S.) was approximately US$131 million (AU$195 million).
- Total revenue[2] generated for the year to date is US$374 million (AU$565 million).
- The Company reaffirms its full year 2024 revenue guidance of US$490 million to US$510 million (AU$745 million to AU$776 million), representing a ~48 to 54% increase on full year 2023.
- Guidance for full year 2024 R&D expenditure remains at an expected 40 to 50% increase compared with full year 2023, funded by earnings from product sales.
- Revenue guidance is based on approved products in jurisdictions with a marketing authorisation. (*See Guidance Disclaimer for further information*).

Q3 2024 Overview

Telix continued to deliver strong revenue growth from sales of Illuccix in the U.S. as the Company executed on its sales and marketing strategy to drive adoption, increase market share and reinforce its position in the urology market as a leading provider of PSMA[3] imaging, committed to innovation in imaging, surgical intervention and treatment of urological cancers.

The Company further strengthened its cash reserves, raising AU$650 million in convertible bonds with strong investor support[4]. The proceeds from the capital raise provide funding to accelerate key clinical development programs across the Company's diagnostic and therapeutic portfolio, pursue strategically significant M&A transactions, and invest in global supply chain and manufacturing capabilities.

In support of the Company's strategy to further expand its North American manufacturing footprint, Telix announced the acquisition of RLS (USA) Inc for US$230 million upfront[5], as detailed in the operational highlights for Telix Manufacturing Solutions.

[1] Conversion to AUD$ is at an average exchange rate realised during Q3 2024 of AUD$1 = US$0.672
[2] Total revenue year-to-date is provided on unaudited basis.
[3] Prostate-specific membrane antigen.
[4] Telix ASX disclosure 24 July 2024.
[5] Telix ASX disclosure 23 September 2024.

Dr Christian Behrenbruch, Managing Director and Group Chief Executive Officer, Telix, said, "Our achievements over the past quarter reinforce Telix's leadership in the radiopharmaceutical sector. We continue to make excellent progress across multiple late-stage assets in our therapeutic pipeline, while preparing to commercialise three new imaging agents within our precision medicine portfolio. Telix's strong cash position and earnings generation mean the business is well-positioned to pursue high-value opportunities across the pipeline and invest in the infrastructure that underpins commercial dose delivery and long-term value creation."

During the period, Telix announced a business reorganisation aligning operations across four business units to reflect its focus as a therapeutics-led radiopharmaceutical company committed to precision oncology. The updated business model comprises: Therapeutics, Precision Medicine (Diagnostics), Lightpoint (MedTech) and Telix Manufacturing Solutions (TMS). Full year 2024 financial results will be reported in line with this structure (with Lightpoint included under Precision Medicine for financial reporting purposes).

Operational highlights by business unit

Therapeutics

Therapeutics are at the core of Telix, as it seeks to improve and extend patient life through targeted radiopharmaceutical therapies.

- **Prostate cancer therapy, TLX591 (^{177}Lu rosopatamab tetraxetan):** Following allowance of an Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) in April 2024, the ProstACT GLOBAL Phase III trial[6] is now enrolling patients at its first U.S. sites, in addition to ongoing patient dosing at sites in the Asia Pacific region. Current enrolment is focused on recruiting Part 1 of the trial, a 30-patient safety and manufacturing/CMC[7] lead-in cohort.

  During the quarter, the Company participated in a multidisciplinary meeting with the FDA for alignment on Part 2 of ProstACT GLOBAL, the randomisation treatment expansion arm of the trial. This incorporated a positive consultation on the primary and secondary endpoints, patient enrolment strategy, and incorporation of key design learnings from other recently reported PSMA radionuclide therapy mCRPC[8] studies, with the goal of de-risking the trial.

- **Kidney cancer therapy, TLX250 (^{177}Lu-girentuximab):** The Phase II STARLITE-2 trial of TLX250 in patients with advanced clear cell renal cell carcinoma[9], established the maximum-tolerated dose (MTD) of TLX250 when administered in combination with nivolumab. Telix intends to shortly provide an update and interim data on these initial dosing cohorts. The trial is expected to proceed with an expansion cohort at the MTD before concluding.

- **Brain cancer therapy, TLX101 (^{131}I-iodofalan, or ^{131}I-IPA):** The Company's IPAX-1 Phase I trial was published in *Neuro-Oncology Advances,* confirming the safety and tolerability profile, and early efficacy of TLX101 therapy, in combination with external beam radiation therapy (EBRT), in recurrent glioblastoma (GBM), the most common and aggressive form of primary brain cancer[10]. The IPAX-2[11] and IPAX-Linz[12] trials in front-line and recurrent GBM continue to dose patients.

[6] ClinicalTrials.gov ID: NCT06520345.
[7] Chemistry manufacturing and controls.
[8] Metastatic castration-resistant prostate cancer.
[9] ClinicalTrials.gov ID: NCT05239533.
[10] Pichler et al. *Neuro Onc Adv.* 2024.
[11] ClinicalTrials.gov ID: NCT05450744.
[12] EudraCT Number: 2021-006426-43.

Precision Medicine (Px)

The Precision Medicine business is focused on the commercialisation of Telix's imaging agents, which are key to informing treatment decisions and selecting patients for therapy. Over the past quarter, the Company progressed regulatory filings for several products globally:

- **Prostate cancer imaging, TLX007-CDx:** The FDA accepted the filing of a New Drug Application (NDA) for a new and proprietary cold kit for the preparation of PSMA-PET[13] imaging for prostate cancer. The PDUFA[14] goal date is 24 March 2025. If approved, this will significantly transform patient access and production flexibility for PSMA-PET, as an additional option for prostate cancer imaging, alongside Illuccix.

- **Kidney cancer imaging, TLX250-CDx (Zircaix®[15], ^{89}Zr-girentuximab):** Telix is on track to resubmit the Biologics License Application (BLA) for its kidney cancer imaging agent in November 2024, consistent with prior guidance, and continues to target a full U.S. commercial launch in 2025[16].

  Telix has announced Cardinal Health, Inc. will be a commercial radiopharmaceutical distributor to supply finished unit doses of Zircaix for the U.S.[17], subject to regulatory approval. Concurrently the expanded access (EAP) and named patient (NPP) programs for TLX250-CDx continue to dose patients across the U.S., Australia and Europe in a significant area of unmet patient need. The EAP is active at 20 sites across the U.S. with additional site activations underway.

  Primary results from the **Phase III ZIRCON trial** were published in *The Lancet Oncology*, where TLX250-CDx, a first-in-class investigational PET agent, was found to be highly accurate in detecting and characterising clear cell renal cell carcinoma in patients with indeterminate renal masses[18].

- **Brain cancer imaging, TLX101-CDx, (Pixclara®[19], ^{18}F-floretyrosine or ^{18}F-FET):** An NDA was submitted to the FDA for a PET diagnostic agent for the characterisation of progressive or recurrent glioma (brain cancer) from treatment-related changes in both adult and pediatric patients. Telix is targeting a full U.S. commercial launch in 2025, subject to regulatory approval. TLX101-CDx is currently being used in the IPAX-2 and IPAX-Linz therapeutic studies as companion diagnostic. An EAP for TLX101-CDx has opened in the U.S. and is enrolling patients.

- **Illuccix global regulatory submissions:** After a protracted administrative review and delayed clockstop, the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM) has restarted the clock on the Company's marketing authorisation application for the **European Union** and provided guidance for an approval decision expected in January 2025.

  Applications for the **United Kingdom (UK) and Brazil** are progressing as expected with their respective regulators. In the UK, the Company has responded to all questions, no substantive issues have been raised and an approval decision is expected in the coming months. The Company still expects an ANVISA (Brazil) approval decision in the coming quarter.

[13] Imaging of prostate-specific membrane antigen with positron emission tomography.
[14] Prescription Drug User Fee Act (PDUFA) date – the date by which the FDA must respond to the application.
[15] Brand name subject to final regulatory approval.
[16] The FDA did not accept the initial BLA due to an issue in the CMC package. This is now being remediated. See Telix ASX disclosure 31 July 2024.
[17] Telix media release 17 September 2024.
[18] Shuch et al. *Lancet Oncol.* 2024.
[19] Brand name subject to final regulatory approval.

Telix Manufacturing Solutions (TMS)

TMS is a global network of facilities for the production and delivery of patient doses worldwide. It is focused on building manufacturing capacity and improving the technology and processes for producing precision medicines and therapies at scale. TMS works closely with key isotope supply chain and regional distribution partners to achieve this.

- **RLS (USA) Inc acquisition:** The Company announced an agreement to acquire RLS, America's only Joint Commission-accredited radiopharmacy network distributing PET, SPECT[20] and therapeutic radiopharmaceuticals. The acquisition will significantly expand Telix's North American manufacturing footprint and establish the basis of a next-generation radiometal production network to benefit Telix and select strategic commercial partners. The purchase price includes an upfront cash consideration of US$230 million and deferred cash consideration up to a maximum of US$20 million, contingent on achievement of certain milestones. The acquisition is expected to close in the first quarter of 2025.

- **Good Manufacturing Practice (GMP) and Wholesaler Distribution Authorisation (WDA) accreditation:** Site inspections were successfully completed for all three manufacturing facilities in Belgium. GMP accreditation for the Herstal and Liège facilities was renewed, with Herstal also granted a new WDA. GMP accreditation for the new Brussels South facility is expected in H1 2025, which paves the way to future commercial supply of doses starting in 2025.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of therapeutic and diagnostic radiopharmaceuticals and associated medical devices. 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).

Telix's lead imaging product, gallium-68 (^{68}Ga) gozetotide injection (also known as ^{68}Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA)[21], by the Australian Therapeutic Goods Administration (TGA)[22], and by Health Canada[23]. 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.

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[20] Single-photon emission computed tomography.
[21] Telix ASX disclosure 20 December 2021.
[22] Telix ASX disclosure 2 November 2021.
[23] Telix ASX disclosure 14 October 2022.

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 or regulations that affect 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.

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