



Telix Pharmaceuticals Limited

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ASX ANNOUNCEMENT

Q2 2024 Revenue and Business Highlights, Guidance Upgrade

Melbourne (Australia) – 18 July 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today provides an update on its revenue and operational performance for the quarter ended 30 June 2024 (Q2 2024).

Q2 2024 Financial Performance and Guidance Upgrade

The Company reports unaudited total revenue of approximately US\$124M¹ (AU\$189M) primarily generated from sales of Telix's prostate cancer imaging product Illuccix®. This represents an increase of 55% on the prior corresponding quarter (Q2 2023: US\$80M or AU\$120M) and an increase of 8% on the previous quarter (Q1 2024: US\$115M or AU\$175M). Revenue generated from sales of Illuccix® in the United States (U.S.) was approximately US\$121M (AU\$184M, Q2 2023: US\$78M or AU\$116M).

On the basis of these results, the Company has upgraded revenue guidance for FY2024 which is now expected to be in the range of US\$490M to US\$510M (AU\$745M to AU\$776M at current exchange rates). This represents an approximate increase of 48% to 54% on 2023 revenue. Prior guidance was ranged at US\$445M to US\$465M² (AU\$675M to AU\$705M).

Dr Christian Behrenbruch, Managing Director and Group Chief Executive Officer said, "We have continued to deliver excellent quarterly growth in both revenue and dose volume sales of Illuccix. We have leveraged our unrivalled scheduling flexibility and clinical differentiation, to increase our market share and minimise the impact of new entrants."

Revenue guidance is based on approved products in jurisdictions with a marketing authorisation³. Telix reaffirms guidance for R&D expenditure, which remains at an expected 40-50% increase compared with 2023, funded by earnings.

The above 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 included below as a footnote⁴.

The Company will release its interim report and Appendix 4D for the six months ended 30 June 2024 on 22 August 2024.

¹ Conversion to AUD\$ is at an average exchange rate realised during Q2 2024 of AUD\$1 = US\$0.658

² Telix ASX disclosures 22 February and 17 April 2024.

³ Illuccix® has received a marketing authorisation in Australia, Canada and the U.S.

⁴ 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.

Q2 2024 Operational Highlights

Telix continued to progress its extensive theranostic pipeline during the quarter. Highlights include positive data from prostate cancer therapy programs:

- **TLX591 (¹⁷⁷Lu rosopatamab tetraxetan):** Telix reported a positive efficacy signal from the ProstACT SELECT trial of TLX591, its lead investigational radio antibody-drug conjugate (rADC) in prostate cancer. The median radiographic progression-free survival (rPFS) of 8.8 months compares favourably to small molecule radioligand therapy (RLT) agents at a similar stage of development and builds on earlier results from ProstACT SELECT confirming the favourable safety profile and clinical utility of the short, two-dose treatment regimen. TLX591 is being further evaluated in the Phase III ProstACT GLOBAL trial. The study received Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration (FDA) during the quarter. Multiple sites across the U.S. are now being activated and preparing to dose first patients. Patient recruitment continues at sites in Asia Pacific.
- **TLX592 (²²⁵Ac-RADmAb®):** Successful proof-of-concept study completed for targeted alpha therapy in prostate cancer. The initial results demonstrated Telix's proprietary RADmAb engineered antibody is rapidly eliminated from the blood circulation and cleared via the liver, desirable characteristics for use with alpha emitting radioisotopes. Based on the outcomes of this trial, the program will progress to a Phase I/II therapeutic trial with Actinium 225.

Telix is progressing multiple marketing authorisation applications across its precision medicine (diagnostic) portfolio, including:

- **New Drug Application (NDA) submission for new prostate cancer imaging agent TLX007-CDx (PSMA-PET imaging⁵):** Telix submitted a NDA to the FDA for a new PSMA targeting prostate cancer imaging agent designed to expand the availability, distribution and scheduling flexibility for PSMA-PET imaging⁶. The FDA is expected to confirm by the end of July 2024 whether the submission is accepted for review. Confirmation of the PDUFA⁷ goal date (review timeframe) is expected in early August 2024, in line with FDA procedure.
- **Kidney cancer imaging agent TLX250-CDx (Zircaix®⁸, ⁸⁹Zr-DFO-girentuximab) regulatory filing completed:** The Biologics License Application (BLA) submission to the FDA for kidney cancer imaging has now been completed⁹. The Company is expecting confirmation of the PDUFA goal date from the FDA by end of July 2024. Concurrently the expanded access and compassionate use programs for TLX250-CDx continue to dose patients across the U.S., Australia and Europe in a significant area of unmet patient need. Separately, a manuscript reporting the final results from the pivotal Phase III ZIRCON study is in the late stages of peer-review for publication in a leading medical journal.
- **Brain cancer imaging agent TLX101-CDx (Pixclara™⁸, ¹⁸F-floretyrosine or ¹⁸F-FET) regulatory package:** Telix participated in a pre-NDA meeting with the FDA on 12 June 2024, with the purpose of consulting on the final package and likely scope of label indications, including alignment on the final clinical package. On the basis of this positive discussion the Company is now finalising its NDA for submission during Q3 2024.
- **European Union (EU), United Kingdom (UK) and Brazil regulatory filings for Illuccix®:** The marketing authorisation applications for the EU and the UK are continuing to progress. All regulator questions raised in the EU marketing authorisation application within the standard clock stop period have been addressed and no substantive issues have been

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

⁶ Telix ASX disclosure 27 May 2024.

⁷ Prescription Drug User Fee Act.

⁸ Brand name subject to final regulatory approval.

⁹ Telix ASX disclosure 3 June 2024.

identified. The Company will communicate the final decision date once set by the competent authority, the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). Telix is expecting to receive a regulator's assessment report by the end of July 2024 from the UK Medicines & Healthcare Products Regulatory Agency (MHRA), which is expected to include final questions and a timeline for the remainder of the review. The marketing authorisation application in Brazil with Telix's partner Grupo GSH is in the final stages of review with an approval decision anticipated from the Brazilian Health Regulatory Agency (Agencia Nacional de Vigilância Sanitária, ANVISA) during Q3 2024 based on current information.

Subsequent to the end of Q2 2024, the U.S. Centers for Medicare & Medicaid Services (CMS) announced proposed changes for the Hospital Outpatient Prospective Payment System (OPPS) rule, which would improve payments to Medicare patients for diagnostic radiopharmaceuticals in the U.S., including Illuccix® and future Telix diagnostic products, if approved¹⁰. Telix welcomes the proposal to keep the payment for the diagnostic radiopharmaceuticals separate from the nuclear medicine test (scan) after transitional pass-through payment status expires, which will facilitate continued patient access¹¹. The proposal is now in a 60-day comment period, with a final rule to be issued in early November 2024 and take effect 1 January 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 (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)¹², by the Australian Therapeutic Goods Administration (TGA)¹³, and by Health Canada¹⁴. 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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This announcement has been authorised for release by the Board of Telix Pharmaceuticals Limited.

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¹⁰ CMS Press Release 10 July 2024.

¹¹ Telix ASX disclosure 11 July 2024.

¹² Telix ASX disclosure 20 December 2021.

¹³ Telix ASX disclosure 2 November 2021.

¹⁴ Telix ASX disclosure 14 October 2022.

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This announcement may contain forward-looking statements 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”, “outlook”, “forecast” and “guidance”, or other similar words. 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 the Company’s good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect the Company’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 studies, 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, manufacturing activities and product marketing activities; the commercialisation of Telix’s product candidates, if or when they have been approved; 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. You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the ASX or on our website.

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