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## ASX RELEASE

### **Activities Report and Appendix 4C for June Quarter**

Melbourne (Australia) – 21 July 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today issues its Appendix 4C quarterly cash flow statement and accompanying Activities Report for the quarter ended 30 June 2022. All figures are in AUD\$ unless otherwise stated. All figures are provided on an unaudited basis.

#### Financial Summary

- Telix reports total revenue of \$22.5 million from global sales of Illuccix® in its first commercial quarter – more than a ten-fold increase on the previous quarter (\$1.9 million, Q1 2022). This includes USD\$13.6 million (AUD\$19.3 million) generated from sales of Illuccix in the United States in the ten weeks following first commercial sales.
- As of 30 June 2022, the Company held cash reserves of \$122.6 million.
- Cash inflows for the quarter included \$5.4 million in customer receipts, up from \$1.9 million in the previous quarter. Additional (non-product related) cash inflows include \$17.2 million in government tax incentives for eligible R&D activities undertaken for the year ended 31 December 2021 and \$1.1 million of proceeds from options exercised.
- Net operating outflows during the quarter were \$25.8 million, down from \$33.6 million in the previous quarter. Expenditure included a one-off upfront license fee payment to Eli Lilly and Company (Lilly) of USD\$5 million (AUD\$6.8 million) and \$2.1 million in build-out costs related to Telix's manufacturing facility in Brussels South (Seneffe).
- \$17.4 million was invested in R&D, manufacturing and clinical development activities during the quarter, primarily in relation to the Company's therapeutic programs.
- Per the accompanying Appendix 4C, the Company has 5.5 quarters runway based on net cash used in operations in the June 2022 quarter. The Company notes that the net operating outflows (used to calculate runway) include only \$3.8 million from U.S. customer cash receipts compared to the U.S. commercial revenue of \$19.3 million due to timing differences of revenue recognition and cash payment terms from distributors.

#### Operational Highlights

- Commercial launch of Illuccix in the U.S. and rapid expansion of the distribution network to 140 pharmacies across the Cardinal Health, PharmaLogic, United Pharmacy Partners (UPPI), Jubilant Radiopharma and Radioisotope Life Sciences (RLS) networks.
- U.S. reimbursement designations granted and effective from 1 July 2022: a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II code and transitional pass-through (TPT) payment status.
- ZIRCON Phase III kidney cancer imaging trial enrolment completed, with 300 patients dosed.
- Progress across core therapeutic clinical programs for prostate, kidney and brain cancer.
- In-licence agreement with Lilly to develop the antibody Olaratumab (formerly marketed as Lartruvo®) as a diagnostic and therapeutic radiopharmaceutical agent.
- Co-development and commercialisation agreement with RefleXion Medical to advance Illuccix for biology-guided radiation therapy (BgRT), a future market growth opportunity.
- TelixAI™ Artificial Intelligence platform being developed with Invicro; pilot showcased at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) annual meeting held in Vancouver in June 2022.
- Mr. Darren Smith appointed as Group Chief Financial Officer, effective 1 August 2022, and Mr. Kevin Richardson appointed as CEO of Telix Americas.

## Commercial Activity Report

### **Illuccix U.S. Commercial Launch**

During the quarter, Telix launched its lead prostate cancer imaging product, Illuccix® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide (also known as PSMA-11) injection) in the U.S., with first commercial doses being administered from 14 April 2022.<sup>1</sup>

Sales revenue from U.S. commercial sales between 14 April and 30 June 2022 was USD\$13.6 million (AUD\$19.3 million). Sales were primarily generated via Telix's nuclear pharmacy distribution partners to imaging centres and hospitals, but also included some luminary academic centres and Veterans' Affairs (VA) sites directly contracted with Telix.

During the quarter the Illuccix distribution network was progressively expanded from 117 to 140 radiopharmacies. Select Jubilant and RLS pharmacies have been added to the partnership network since launch, which initially comprised Cardinal Health, PharmaLogic and UPPI. The objective of the pharmacy network expansion is to provide broad geographic coverage, boosting capacity in both major metropolitan and regional markets to enable reliable access to PSMA-PET<sup>2</sup> imaging.

*Telix Managing Director and Group CEO Dr. Christian Behrenbruch, said, "The U.S. commercial launch of Illuccix is off to a strong start. This result reflects the efficacy of our differentiated business model in a large and growing market. We've delivered doses across the entire country, demonstrating the value of our nationwide pharmacy distribution partnerships and with industry-leading on-time delivery. We are meeting the needs of our customers and patients through reliable service delivery, flexible scheduling and wide accessibility to PSMA-PET imaging. With reimbursement effective 1 July, we expect to see Illuccix revenues grow considerably."*

During the quarter Telix announced it had been granted a Healthcare Common Procedure Coding System (HCPCS) Level II code, A9596 and Transitional Pass-Through Payment Status.<sup>3</sup> Both reimbursement designations were formally recognised by the U.S. Centers for Medicare and Medicaid Services (CMS) from 1 July 2022. Transitional pass-through status enables CMS to provide separate payments for the radiopharmaceutical and the PET-CT scan, when performed with Illuccix in the hospital outpatient setting, for a period of up to three years.

### **Illuccix (TLX591-CDx)<sup>4</sup> worldwide revenue and customer receipts**

A total of \$22.5 million in revenue was generated from sales of TLX591-CDx during the quarter. Of this \$3.2 million was generated from pre-commercial sales<sup>5</sup>, primarily in Europe and the United Kingdom, reflecting 166% growth on the previous corresponding quarter (\$1.2 million, June 2021).

Of the \$5.4 million in customer receipts, \$3.8 million (USD\$2.7 million) was from U.S. commercial sales. Revenue from commercial sales is recognised when a dose is administered. Payment terms average 45 days from invoicing.

Commercial sales of Illuccix in Australia and New Zealand is planned to commence in Q3, 2022.

<sup>1</sup> Media release 14 April 2022.

<sup>2</sup> Positron emission tomography

<sup>3</sup> ASX disclosure 30 May 2022.

<sup>4</sup> For regulatory reasons, Telix refers to its 68 Ga-gozetotide kit as Illuccix in markets where it has received regulatory approval, and TLX-591CDx when referring to its use in both approved and unapproved markets.

<sup>5</sup> Pre-commercial sales are from investigational, clinical trial, magisterial and compassionate use in accordance with local laws and regulations (not as a commercial diagnostic imaging product sold for routine clinical practice).

### ***Illuccix (TLX591-CDx) global regulatory and reimbursement updates***

Marketing authorisation applications for TLX591-CDx are under review and progressing in 17 countries (13 European Union Member States, United Kingdom, Canada, Brazil and South Korea). Telix currently has a temporary use (pre-approval) authorisation in the Czech Republic and Brazil.

In summary, the key regulatory updates for the quarter are:

- **U.S.:** On 17 May Telix filed a supplemental new drug application (sNDA) to the FDA, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Illuccix. The sNDA relates to an indication expansion for Illuccix for patient selection for radioligand (PSMA) therapy. The sNDA has been accepted for standard review with a Prescription Drug User Fee Act (PDUFA) user fee goal date of 17 March 2023.
- **EU:** The Company's Marketing Authorisation Application (MAA) is being evaluated by the Danish Medicines Agency (DKMA) in its capacity as a Reference Member State, on behalf of the 13 European countries selected by Telix. As previously reported, Telix has until 9 August 2022<sup>6</sup> to conclude the regulatory review process.
- **South Korea:** An imported New Drug Application (NDA) has been submitted by Telix's partner in South Korea, DuChemBio Co, Ltd. (DuChemBio), to the Ministry of Food and Drug Safety (MFDS).
- **New Zealand:** The drug safety regulator Medsafe has confirmed that Illuccix is an exempt product under the NZ Medicines Act 1981 and Radiation Safety Act 2016. Illuccix may now be supplied and used in New Zealand.

In addition, and subsequent to quarter end, on 1 July 2022, PSMA-PET imaging for prostate cancer was listed on the Medicare Benefits Schedule (MBS) in Australia. This means that MBS funding now covers the initial staging of intermediate to high-risk patients with prostate cancer and the restaging of patients with recurrent prostate cancer, commensurate with the broad clinical indications granted in Australia for Illuccix. Illuccix remains the only Therapeutic Goods Administration (TGA)-approved PET agent for the diagnostic imaging of men with prostate cancer available in Australia.

### ***Illuccix (TLX591-CDx) global distribution agreements***

Telix has continued to build out its global distribution network for TLX591-CDx in preparation for regulatory decision notification and commercial launch in countries beyond Australia and the United States. During the quarter, Telix entered into the following agreements:

- **Canada:** Isologic Innovative Pharmaceuticals (Isologic) and Telix signed a licence and distribution agreement, appointing Isologic as the commercial distributor for Illuccix in Canada, once approved.<sup>7</sup>
- **Saudi Arabia:** Abdulla Fouad for Medical Supplies and Services Company (AFMS) and Telix signed a licence and distribution agreement, appointing AFMS as the commercial distributor for Illuccix in the Kingdom of Saudi Arabia, once approved.

Telix now has commercial distribution agreements in place in all major European Union markets and the United Kingdom. In the APAC region, Telix has distribution agreements in place for Australia, New Zealand, Greater China (including Hong Kong, Taiwan, Macau) and South Korea. In the Americas region (ex-U.S.) Telix has agreements in place for Canada and Brazil.

<sup>6</sup> ASX disclosure 7 February 2022.

<sup>7</sup> ASX disclosure 23 June 2022.

## Clinical Programs Update

### **ZIRCON Phase III kidney cancer imaging study completed**

The Company announced recruitment completion of the ZIRCON Phase III study of TLX250-CDx (<sup>89</sup>Zr-DFO-girentuximab), an investigational product for the imaging of clear cell renal cell carcinoma (ccRCC) with PET.<sup>8</sup> A total of 300 patients were dosed in the study. The Company expects to report the outcome of the ZIRCON study in 2H 2022.

*“This is a major clinical milestone and an important validation point for the Company. If the study is successful in meeting its endpoints, it paves the way for us to seek regulatory approval and commercialise a follow-on imaging product for the urologic oncology field in an area of unmet need. Indeterminate renal masses (IDRMs) are being detected at an increasing rate and present a dilemma for physicians. While it is estimated that up to 80% of IDRMs will be malignant, currently the only way to confirm diagnosis is through an invasive biopsy or partial nephrectomy and these procedures are not always necessary and can lead to complications,<sup>1</sup>” stated Telix Chief Medical Officer, Dr. Colin Hayward.*

Following readout of the study, TLX250-CDx is expected to be available in selected countries to eligible patients under an Expanded Access Program (EAP) (also known as early access, pre-approval access or emergency use), in accordance with Telix’s Compassionate Use Policy and subject to jurisdictional regulatory requirements.<sup>9</sup>

### **Clinical Development Highlights**

Telix continues to progress its clinical pipeline, with a core focus on prostate cancer, kidney cancer, brain cancer (glioblastoma) and rare diseases (bone marrow conditioning). The Company has 20 clinical trials underway, including collaborative investigator-sponsored studies. Some key highlights include:

- Telix’s PSMA-targeting ProstACT therapeutic program is evaluating the efficacy of Telix’s lutetium-177 (<sup>177</sup>Lu)-labelled therapeutic antibody (TLX591) in various stages of prostate cancer, from first recurrence to advanced metastatic disease.<sup>10</sup> The Company continues to progress its global regulatory submissions for the ProstACT GLOBAL Phase III study.
- During the quarter, Human Research Ethics Committee (HREC) approval was granted and patient recruitment commenced in the Phase II ProstACT TARGET study of TLX591, in patients experiencing a first recurrence of prostate-specific antigen (PSA) after initial therapy for prostate cancer.<sup>11</sup>
- The ProstACT SELECT study, a “theranostic” (imaging and therapy) Phase I radiogenomics study to demonstrate the utility of Illuccix imaging to select TLX591 patients for therapy, is now approaching the halfway point of patient enrolment.
- The first patients have been dosed in the STARLITE 2 Phase II study of the Company’s investigational renal cancer therapy, TLX250 (<sup>177</sup>Lu-DOTA-girentuximab), at Memorial Sloan

<sup>8</sup> ASX disclosure 11 July 2022.

<sup>9</sup> Telix Compassionate Use Policy, accessible at: <https://telixpharma.com/wp-content/uploads/Policy-on-Offering-Compassionate-Use-to-Investigational-Medicines.pdf>

<sup>10</sup> ASX disclosure 27 January 2022.

<sup>11</sup> ASX disclosure 12 April 2022.

Kettering Cancer Center (MSK) in New York.<sup>12</sup> This study is assessing the efficacy of TLX250 targeted radiation in combination with immunotherapy for ccRCC the most common and aggressive form of kidney cancer. TLX250 targets carbonic anhydrase IX (CA9, a protein that is highly expressed in patients that are likely to be less responsive to cancer immunotherapy.<sup>13</sup> The clinical hypothesis is that low doses of targeted radiation can potentially overcome immune resistance or immunologically “prime” a tumour, making it more susceptible to cancer immunotherapy.

- The NOBLE (Nobody Left Behind) Registry continues to collect clinical data to inform the development of TLX599-CDx (<sup>99m</sup>Tc-iPSMA), an investigational prostate cancer imaging agent that targets PSMA using single photon emission computed tomography (SPECT) imaging.<sup>14</sup> SPECT is the predominant imaging modality in many countries, including remote and rural regions. The NOBLE registry aims to accelerate global access to advanced prostate cancer imaging where PET is not an option and is now active across eight sites globally.<sup>15</sup> The NOBLE Registry is funded in collaboration with the Oncidium Foundation.

## Research and Innovation Activity

### ***Olaratumab in-licence agreement with Eli Lilly and Company (Lilly)***

In April, Telix announced the signing of a licence agreement with Lilly granting Telix exclusive worldwide rights to develop and commercialise radiolabelled forms of Lilly’s Olaratumab antibody for the diagnosis and treatment of human cancers.<sup>16</sup> Olaratumab was originally developed by Lilly as a (non-radiolabelled) monoclonal antibody targeting Platelet Derived Growth Factor Receptor Alpha (PDGFR $\alpha$ ). Telix intends to develop radiolabelled Olaratumab initially for the diagnosis and treatment of soft tissue sarcoma, a debilitating cancer with a high unmet need for new treatment options.

### ***Expanded partnership with RefleXion Medical***

Following a successful preliminary collaboration, the Company announced that it has advanced to a co-development and commercialisation agreement with RefleXion Medical Inc (RefleXion) to evaluate the use of Illuccix as a biological guide in RefleXion’s BgRT<sup>17</sup> platform.<sup>18</sup> Illuccix will be the exclusive kit-based <sup>68</sup>Ga PSMA-PET imaging agent used with RefleXion’s BgRT platform.

BgRT is the first and only cancer treatment designed to integrate PET technology as part of external-beam radiotherapy delivery. It uses PET tracers as biological guides to signal the location of cancer and guide the delivery of radiotherapy to tumors in real-time. Telix and RefleXion will conduct and co-fund a BgRT clinical program using Illuccix as a biological guide, seek regulatory approval and jointly pursue commercialization, initially in the United States. If approved, Illuccix for BgRT could potentially open a broad new market opportunity for Illuccix as a therapy guidance agent.

### ***TelixAI™: Artificial Intelligence Platform***

Telix progressed its partnership with Invicro LLC (Invicro), a global, industry-leading imaging CRO, and part of REALM IDx, Inc., to develop an artificial intelligence (AI) platform to accompany Illuccix - dubbed TelixAI™.<sup>19</sup> TelixAI™ seeks to increase the efficiency and reproducibility of clinicians’

<sup>12</sup> Media release 5 May 2022.

<sup>13</sup> Giatromanolaki et al. *British Journal of Cancer*. 2020.

<sup>14</sup> See: [www.nobleregistry.org](http://www.nobleregistry.org).

<sup>15</sup> The NOBLE Registry is being conducted at eight sites globally in Australia, Azerbaijan, Egypt, Indonesia, Mexico, Nigeria, South Africa, and the United Arab Emirates.

<sup>16</sup> ASX disclosure 11 April 2022.

<sup>17</sup> The RefleXion® X1 is cleared for SBRT/SRS/IMRT. BgRT is pending regulatory review and is not commercially available.

<sup>18</sup> ASX disclosure 10 June 2022.

<sup>19</sup> Media release 14 June 2022.

imaging assessments using advanced analysis capabilities with an initial focus on prostate cancer but with the eventual goal of supporting Telix's entire diagnostic imaging pipeline.

The commercial objective of the development partnership is the submission to the United States Food and Drug Administration (FDA) 510(K) approval for software as a medical device. A demonstration of the TelixAI™ was presented to key opinion leaders at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, which took place in Vancouver (Canada) in June of this year.

### Advanced Manufacturing

Following the completion of project financing for Telix's Brussels South (Seneffe) manufacturing facility in Q1, 2022,<sup>20</sup> the Company has completed major building and infrastructure works to prepare for the commencement of clean room and hot cell installation for nine GMP manufacturing lines for isotope processing and radiopharmaceutical manufacturing. The Company is currently on track to complete the build-out and commence regulatory inspections by end-2022.

During the quarter, Telix was part of a consortium awarded \$23.0 million in Federal Government funding to establish the \$71.2 million Australian Precision Medicine Enterprise Project (APME).<sup>21</sup> At the heart of APME – a collaboration with Global Medical Solutions Australia (GMSA) and Monash University – a new high energy cyclotron will become a source of critical radioisotopes, many of which are currently imported into Australia at high cost and variable accessibility. For Telix this will mean increased capacity to develop and manufacture theranostic radiopharmaceuticals in Australia, strengthening its global supply chain for both clinical and commercial products.

### Notable Executive Appointments

On 1 June 2022, the Company announced it had appointed Mr. Darren Smith as Group Chief Financial Officer (CFO), effective from 1 August 2022. Darren joined the Company in February 2022 as part of succession planning for Mr. Douglas Cubbin.<sup>22</sup> Darren brings over 20 years of executive finance and general management experience, including in the nuclear medicine industry. Darren previously served as Global CFO and Company Secretary at Sirtex Medical Limited, acquired by China GrandPharma in 2018.

Mr. Kevin Richardson has been appointed to the role of CEO of Telix Americas (U.S./Canada/Latin America), and commenced employment on 11 July 2022.<sup>23</sup> Kevin brings 25 years of commercial experience in the healthcare industry including senior leadership and sales roles at Sirtex Medical, St Jude Medical, Boston Scientific and most recently as Chief Operating Officer of UroShape Medical.

### Payments to Related Parties

Telix confirms that payments noted under section 6.1 of the accompanying Appendix 4C include payments of \$0.7 million to ABX-CRO advanced pharmaceutical services (of which non-executive director Dr. Andreas Kluge is Managing Director) for the provision of clinical and analytical services for the Company's development programs.

Payments of \$0.3 million to Directors were for director fees and Managing Director salary.

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<sup>20</sup> ASX disclosure 22 March 2022.

<sup>21</sup> ASX disclosure 4 April 2022.

<sup>22</sup> ASX disclosure 1 June 2022.

<sup>23</sup> ASX disclosure 11 July 2022.

## About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan, Switzerland, and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical need in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit [www.telixpharma.com](http://www.telixpharma.com) and follow Telix on [Twitter](https://twitter.com/TelixPharma) (@TelixPharma) and [LinkedIn](https://www.linkedin.com/company/telix-pharmaceuticals).

Telix's lead product, Illuccix<sup>®</sup> (kit for preparation of gallium-68 (<sup>68</sup>Ga) gozetotide (also known as <sup>68</sup>Ga PSMA-11) injection) for prostate cancer imaging, has been approved by the U.S. Food and Drug Administration (FDA),<sup>24</sup> and by the Australian Therapeutic Goods Administration (TGA).<sup>25</sup> Telix is also progressing marketing authorisation applications for this investigational candidate in Europe<sup>26</sup> and Canada.<sup>27</sup>

## Telix Investor Relations

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*This announcement has been authorised for release by the Board of Directors.*

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*This announcement may include 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.*

*To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to publicly update or revise any forward-looking statements contained in this announcement, whether as a result of new information, future developments or a change in expectations or assumptions.*

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<sup>24</sup> ASX disclosure 20 December 2021.

<sup>25</sup> ASX disclosure 2 November 2021.

<sup>26</sup> ASX disclosure 10 December 2021.

<sup>27</sup> ASX disclosure 16 December 2020.