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Australia

Activities Report and Appendix 4C for June 2021 Quarter

Melbourne (Australia) – 22 July 2021. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today provides its Appendix 4C quarterly cash flow statement and accompanying Activities Report for the quarter ended 30 June 2021. All figures are in AUD unless otherwise stated.

Financial Summary

- Telix held cash reserves of $49.62 million on 30 June 2021 ($61.42 million held on 31 March 2021).
- Operating expenditure during the quarter was $12.80 million, in line with forecasts, with $8.25 million invested in R&D and clinical development activities.
- Cash runway for approximately 4 quarters of operations based on net cash used in operations in June 2021 quarter and exclusive of any anticipated revenue from sales of an approved product.
- Telix has sufficient cash reserves at hand to fund the commercial launch of Illuccix® (TLX591-CDx).[1]
- Australian Federal Government R&D tax return has been filed. Refund of ~$12 million expected during the September 2021 quarter.

Continued progress towards commercialisation made during Q2 2021

Telix has continued its progress in transitioning to a commercial-stage, revenue generating company. At a macro level, this included the establishment of an Asia-Pacific (APAC) operating region in May, a restructuring of the business designed to support this transition, and the Company's rapid commercial development.

With interest and activity building in the field of prostate cancer molecularly targeted radiation (MTR) for both diagnostic and therapeutic use, Telix has been working closely with suppliers and distribution partners to ensure that the roll-out of Illuccix®, its first commercial product, is delivered seamlessly and without delay, subject to requisite regulatory approvals worldwide.

Illuccix® – Commercial Launch Activities

Illuccix®, an investigational diagnostic imaging agent for PSMA[2]-PET[3] imaging of prostate cancer, will be Telix's first commercial product. PSMA-PET imaging represents the latest standard of care for prostate cancer imaging, having recently been included in clinical practice guidelines in the United States and Europe.[4]

As at the end of the quarter, marketing authorisation applications for Illuccix® were under review and progressing in 17 countries (United States, Canada, 13 European member states + UK, and Australia).

Key regulatory and clinical activity during the quarter, included a late-cycle review meeting with the U.S. Food and Drug Administration (FDA), which took place in June, regarding the ongoing review

[1] Subject to approvals in the relevant jurisdictions. None of Telix's products have attained a marketing authorisation in any country.
[2] Prostate specific membrane antigen.
[3] Positron Emission Tomography.
[4] Trabulsi EJ *et al.* J Clin Oncol. Jan 2020. European Association of Urology 2020.

of Telix's New Drug Application (NDA) for Illuccix®, with the FDA indicating that there are no outstanding substantive review issues with Telix's submission.

In April, the Australian Therapeutic Goods Administration (TGA) accepted the Company's submission for the registration of Illuccix® and commenced its priority evaluation process. The TGA has indicated a target decision date (approval date) for its priority evaluation of Illuccix® of 12 November 2021.

During May, a first patient was dosed in a clinical study in Japan using Illuccix®, in an academic collaboration between Telix and Kanazawa University. The study is the first clinical evaluation of gallium-based PSMA imaging in Japan, with the objective to obtain safety data in a representative Japanese patient population, and to demonstrate that the targeting and biodistribution of TLX591-CDx in Japanese patients is consistent with international experience.

As the company prepares for commercial launch, it continues to advance distribution partnerships. In May, Telix entered into an exclusive commercial distribution agreement with Berlin-based Eckert & Ziegler Strahlen und Medizintechnik AG (EZAG) for Illuccix® in the German market. Under the terms of the agreement, EZAG will be the exclusive commercial distributor of Illuccix® in Germany once marketing authorisation has been granted by the German health authorities, which is anticipated to occur in late 2021.

Telix and EZAG further reinforced their collaboration by announcing a co-promotion agreement in the United States in June, for the combination of Illuccix® and EZAG's GalliaPharm® (gallium-68 generator).

TLX250-CDx – for Renal Cancer Imaging (Second Commercial Product)

Telix expects that its second commercial product will be TLX250-CDx (^{89}Zr-girentuximab), the Company's PET imaging agent for the diagnosis and staging of clear cell renal cell carcinoma (ccRCC), the most common form of kidney cancer. TLX250-CDx has been granted Breakthrough Therapy (BT) designation by the FDA.[5] BT designation confers several benefits, including eligibility for Fast Track designation, more consultative interactions with the FDA, and the opportunity to submit a rolling Biological Licence Application (BLA) for TLX250-CDx.

During the quarter, Telix's Phase III ZIRCON study of TLX250-CDx for the imaging of renal cancer with PET exceeded 50% recruitment, with at least 80% of the study's 34 sites across EU, Turkey, Australia, US and Canada actively recruiting at the end of June following disruption due to the ongoing pandemic. With recent clarity on site re-openings and more predictable recruitment rates, we have been able to give updated guidance on timelines for completion[6] with the commencement of the Biologics Application Process (BLA) expected to commence with the FDA by year-end.

During April, the Phase I component of Telix's Phase I/II 'ZIRDAC-JP' study of TLX250-CDx reported initial results demonstrating the safety and tolerability of TLX250-CDx in Japanese patients. Importantly, the results of this study further demonstrated that the dosing and pharmacology of TLX250-CDx is comparable between Japanese and Caucasian patient populations. Such results provide Telix with a sound basis for consultation with the Pharmaceuticals and Medical Devices Agency (PMDA) to confirm the design of the next stage of development for TLX250-CDx for the Japanese market, with the objective being to bridge to the ZIRCON trial dataset when it becomes available.

TLX250-CDx – Indication Expansion

In June, a first patient was dosed in a Phase I study of TLX250-CDx in patients with urothelial carcinoma or bladder cancer.[7] 'ZiP-UP' is the first in a series of studies that will harness TLX250-CDx to evaluate carbonic anhydrase IX (CA9) expression in cancers other than renal cancer,

[5] ASX disclosure 1/07/20.
[6] ASX disclosure 20/07/21.
[7] ASX disclosure 23/06/21.

currently the focus of the ZIRCON (imaging) and STARLITE (therapy) studies. Other collaborative studies are in development for ovarian, triple negative breast, colorectal, head and neck, lung, and pancreatic cancers.

TLX591 and Other Clinical Activity Across the Pipeline

During the second quarter, Telix made significant progress in key clinical studies across the Company's portfolio:

Prostate Cancer:

- **TLX591:** In May, Telix's Phase III ProstACT trial of the Company's PSMA-targeted prostate cancer therapy candidate TLX591 (^{177}Lu-DOTA-rosopatamab) was granted Human Research Ethics Committee (HREC) approval and received Clinical Trial Notification (CTN) clearance by the TGA.[8] Telix has commenced the initiation of Australian ProstACT trial sites and will add global sites progressively during the second half of 2021, subject to the requisite approvals.
- **TLX592:** Study and site set-up activities for the first-in-human Phase I CUPID study of Telix's targeted alpha therapy (TAT) prostate cancer therapy candidate TLX592, in patients with advanced prostate cancer. The CUPID study, which will be led by principal investigator, Associate Professor Nat Lenzo, GenesisCare Group Clinical Director (Theranostics) is expected to enrol the first patient in late July or early August.
- **TLX599-CDx:** In April, the international NOBLE (Nobody Left Behind) Registry of Telix's 'rest of world' prostate cancer imaging agent TLX599-CDx (^{99m}Tc-HYNIC-iPSMA) was launched with the Oncidium Foundation, with sites in Nigeria and Egypt dosing their first patients. TLX599-CDx is being developed by Telix to facilitate patient access to advanced prostate cancer imaging in countries where single photon emission computed tomography (SPECT) imaging is predominant in healthcare facilities. Whereas Illuccix® utilises PET, TLX599-CDx employs SPECT, a diagnostic imaging technology that is widely available in healthcare facilities throughout the world.

Renal (Kidney) Cancer:

- **TLX250:** During the quarter, Telix's Phase II STARLITE-2 study of renal cancer therapeutic candidate TLX250 (^{177}Lu-girentuximab) plus nivolumab progressed at Memorial Sloan Kettering Cancer Center (MSKCC) (New York, U.S.A.) and received Institutional Review Board (IRB) approval to move forward as an Investigational New Drug (IND) to the FDA. MSKCC are anticipating IND approval in late August 2021 with patient recruitment to commence soon after. This study has experienced delays due to postponement of institutional research review processes during COVID-19.

Glioblastoma (Brain Cancer):

- **TLX101:** In June, an update was released for IPAX-1, Telix's glioblastoma (brain cancer) therapeutic investigational asset, with interim analysis of safety and preliminary efficacy sufficiently encouraging to warrant study in front-line therapy, where radiation therapy is more extensively used.[9] Complete safety and efficacy data will be released upon completion of the study report, and a follow-on study is currently in planning to accelerate the development of TLX101 in this important therapy area with high unmet medical need.

Rare Diseases / Bone Marrow Conditioning:

- **TLX66:** In May, initial results for safety and tolerability were reported for the Phase I/IIa TRALA trial of TLX66 (^{90}Y-besilesomab) in patients with Systemic Amyloid Light Chain Amyloidosis (AL amyloidosis). The study found that TLX66 was well-tolerated, enabling successful engraftment of the patients' own transplanted stem cells without the need for toxic chemotherapy. This indicates that TLX66 may offer a new approach to bone marrow conditioning in patients who could benefit from hematopoietic stem cell transplantation (HSCT). With all patients remaining alive, and most not requiring further therapy, the data

[8] ASX disclosure 10/05/21.
[9] ASX disclosure 24/11/20.

supports taking TLX66 forward into a pivotal registration study in this rare disease indication in collaboration with the amyloid community of patients and physicians.

During the quarter, Telix also completed additional high value research and commercial collaborations:

- Completion of a strategic manufacturing agreement with Global Medical Solutions, Ltd. (GMS) to manufacture and supply finished unit doses of Telix's MTR products for certain clinical development programs in Australia, including prostate cancer therapeutic investigational products TLX591 and TLX592 for Telix's planned ProstACT and CUPID clinical trials, respectively.
- Receipt of a €990K (~$1.56M) 'Eurostars-2' research grant awarded jointly to Telix and Swedish radiopharmaceutical production company Alpha Therapy Solutions ('ATS') by the EUREKA Association in Europe to develop a novel anti-cancer Targeted Alpha Therapy (TAT) using the alpha-particle emitting radioisotope; astatine-211.

People

Telix's mission is to help patients with cancer to live longer, better quality lives. To be able to optimally serve patients and the clinicians providing their care, Telix recognises it needs the best people, who possess the necessary qualifications and experience for late-stage drug development, and a commitment to delivering to market potentially life-changing new diagnostic and therapeutic options.

In May, Mr. Richard Valeix joined the Telix executive leadership team in the role of President, Europe, Middle East and Africa (EMEA). Richard joins with approximately twenty years of pharmaceutical industry experience, including radiopharmaceuticals, gained in senior executive leadership roles across a broad range of therapeutic product areas. Prior to joining Telix, Richard worked at Advanced Accelerator Applications, a Novartis Company (AAA) where he served for seven years in the roles of General Manager for France, Switzerland, Belgium, Netherlands and Luxembourg, and Global Head of Marketing and Sales. Earlier in his career, Richard held senior sales, marketing and strategy roles at Ipsen and Roche, where he gained extensive experience in European market access, reimbursement, regulatory affairs and commercial launch planning for first-in-class products.

Also in May, Telix appointed Dr. David Cade as President of Telix APAC, a new operating region for the Company. David, who has served as Telix's Chief Business Officer and Head of Investor Relations since joining Telix in 2019, will lead Telix's commercial activities across the Asia-Pacific region, including Telix's anticipated approval of Illuccix® in Australia and other regional territories.

As part of leadership changes announced in May, Dr. Tracey Brown, who joined Telix in February 2020, has been appointed Global Senior Vice President of Product Portfolio Management. Tracey will be responsible for driving the development of Telix's broad pipeline from early development through to commercialisation.

In June, Mr. Scott Law joined the business as Senior Vice President, Global Manufacturing Operations. Scott brings with him over 30 years' global pharmaceutical experience, including senior manufacturing roles at companies such as Baxter, Cognate BioServices, Emergent BioSolutions, Ferndale Laboratories, and Pfizer. Scott will lead Telix's global manufacturing operations through FDA approval of Illuccix® and the up-coming BLA submission for TLX250-CDx.

Quarterly Sales (Illuccix® / TLX591-CDx Kit)

In the June 2021 quarter, Telix delivered approximately 3,250 individual patient prostate cancer imaging doses, prepared from 1,300 TLX591-CDx prostate cancer imaging kits, representing a 63% increase compared to the corresponding quarter in 2020. The Company booked total sales for the quarter of $1.20 million and received $1.23 million in cash from TLX591-CDx kit sales. Pricing of the TLX591-CDx kit remained stable during the period.

Telix notes that the current sales of the TLX591-CDx kit are not indicative of a reimbursed diagnostic imaging product following marketing approval, given the Company sells the TLX591-CDx kit for

investigational, clinical trial, magisterial and compassionate use access only, not as a diagnostic imaging product in routine clinical practice.

Telix CEO Dr. Chris Behrenbruch stated, "We continue to make significant progress in a number of areas across the business, in preparation for commercial launch and towards our clinical and developmental milestones. As we anticipate FDA approval for our first commercial product Illuccix® Telix has demonstrated that our supply chain and distribution model has us positioned advantageously to move quickly to drive market adoption post-launch. The acceleration in recruitment of our ZIRCON trial after a period of unpredictability ensures we remain on track to complete the study this year and commence preparations for launch of our second commercial product."

Payments to Related Parties

Telix confirms that payments noted under section 6.1 of the accompanying Appendix 4C include payments of $602,000 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. Also included are payments of $214,000 to Directors for director fees and Managing Director salary.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan, 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 and follow Telix on Twitter (@TelixPharma) and LinkedIn.

About Illuccix®

Telix's lead investigational product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA[10], and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[11] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[12] and Canada.[13] None of Telix's products have attained a marketing authorisation in any jurisdiction.

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[10] ASX disclosure 24/11/20.
[11] ASX disclosure 14/04/21.
[12] ASX disclosure 1/05/20.
[13] ASX disclosure 16/12/20.

securities have been registered under the U.S. Securities Act or an exemption from the registration requirements of the U.S. Securities Act is available. None of the technologies or products described in this document have received a marketing authorisation in any jurisdiction. This announcement has been approved for release by the Disclosure Committee of Telix Pharmaceuticals Limited.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Telix Pharmaceuticals Limited	
ABN	**Quarter ended ("current quarter")**
85 616 620 369	June 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1,226	1,957
1.2	Payments for		
	(a) research and development	(8,248)	(19,733)
	(b) product manufacturing and operating costs	(1,102)	(1,674)
	(c) advertising and marketing	(319)	(524)
	(d) leased assets		
	(e) staff costs	(1,774)	(5,068)
	(f) administration and corporate costs	(2,582)	(4,891)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(6)	(6)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)		
	• Income received in advance	-	-
	• Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(12,805)**	**(29,939)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses	-	-
	(c) property, plant and equipment	(138)	(178)
	(d) investments	-	-
	(e) intellectual property	(3)	(3)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:	-	-
	(a) entities		
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(141)**	**(181)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	213	851
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(45)	(101)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Leased assets)	(286)	(574)
3.10	**Net cash from / (used in) financing activities**	**(118)**	**176**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	61,421	77,495
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(12,805)	(29,939)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(141)	(181)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(118)	176
4.5	Effect of movement in exchange rates on cash held	1,258	1,614
4.6	**Cash and cash equivalents at end of period**	**49,615**	**49,615**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	49,615	61,421
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**49,615**	**61,421**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	816
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: Payments in 6.1 include payments of $602k 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; and payments of $214k to Directors for director fees and salary.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	Nil	Nil
7.2	Credit standby arrangements	Nil	Nil
7.3	Other (please specify)	Nil	Nil
7.4	**Total financing facilities**	Nil	Nil

7.5	**Unused financing facilities available at quarter end**	Nil

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	**(12,805)**
8.2	Cash and cash equivalents at quarter end (item 4.6)	**49,615**
8.3	Unused finance facilities available at quarter end (item 7.5)	Nil
8.4	Total available funding (item 8.2 + item 8.3)	**49,615**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**3.9**

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 22 July 2021

Authorised by: The Disclosure Committee

(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.