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

ASX RELEASE

Activities Report and Appendix 4C for March quarter

Telix delivers its first $100M revenue quarter

Melbourne (Australia) – 17 April 2023. 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 31 March 2023 (Q1 2023). All figures are in AUD$ unless otherwise stated[1] and provided on an unaudited basis.

Summary

- Total revenue for the quarter reaches $100.1M, driven by global sales of Illuccix®, Telix's prostate cancer imaging agent
- Demand for Illuccix in the United States continues to increase with sales of $97.5M (up from $76.8M in the prior quarter)
- Second consecutive quarter of positive operating cash flow ($2.4M, an improvement of $0.8M on the prior quarter)
- Cash receipts from customers were $83.2M, up 15% from $72.2M in the prior quarter
- Closing cash balance of $121.4M at 31 March 2023 (compared to $116.3M at 31 December 2022)

Group CEO and Managing Director Dr Christian Behrenbruch commented, "In just under a year since the commercial launch of Illuccix and five years since listing on the ASX, Telix has delivered a significant milestone with its first $100M revenue quarter. We are making a meaningful difference in the lives of thousands of prostate cancer patients and delivering on our mission of global leadership in radiopharmaceuticals. Telix is able to fund the development of new imaging agents and novel therapeutics, evident in recent achievements and delivery of our second consecutive quarter of positive operating cash flow."

Commercial Activities Report

Americas region: U.S. sales growth trend continues, commercial launch underway in Canada

Revenue from U.S. sales of Illuccix (kit for the preparation of gallium Ga 68 gozetotide injection) increased to $97.5M (US$66.2M). Demand for Illuccix continues to grow in line with the increasing market adoption of PSMA-PET imaging from both existing accounts and new customer acquisition.

During the quarter the U.S. Food and Drug Administration (FDA) approved the supplemental new drug application (sNDA) for Illuccix, resulting in an expanded label indication to identify and select patients who are candidates for the only FDA-approved prostate-specific membrane antigen (PSMA)- directed radioligand therapy.[2]

"The demand for Illuccix continues to grow across all of our customer segments. Our focus on service and reliable delivery of doses is helping us to win and retain customers. Our recent focus on Illuccix's clinical differentiation and the expanded label to include patient selection for radioligand therapy is resonating with clinicians and helping to drive deeper engagement with our customers," stated Kevin Richardson, CEO of Telix Americas.

1. Conversion to AUD is at the average exchange rate for the period. AUD$1 = US$0.68; AUD$1 = €0.64
2. Telix ASX disclosure 16 March 2023. Illuccix is now approved for use for the selection of patients with metastatic prostate cancer, for whom lutetium-177 (^{177}Lu) PSMA-directed therapy is indicated, specifically lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy, marketed as Pluvicto® (Pluvicto is a registered trademark of Novartis AG and/or its affiliates).

During the quarter, the Company also launched Illuccix in Canada, where it is the first and only PSMA-PET imaging agent to have received regulatory approval. Illuccix is now available nationwide through Telix's partner, Isologic Innovative Radiopharmaceuticals.[1]

Worldwide revenue

Total revenue of $100.1M was generated during the quarter (including commercial sales of Illuccix in the U.S.). Ex-U.S. revenue (including sales of Illuccix / TLX591-CDx)[2] was $2.6M.

Net cash from operating activities

Telix delivered its second consecutive quarter of positive net operating cash inflow. The net operating cash inflow for the quarter was $2.4M, a $0.8M improvement on the prior quarter (Q4 2022, net operating cash inflow $1.6M). In line with increased revenue, cash receipts from customers improved 15% to $83.2M, up from $72.2M in the prior quarter. The closing cash balance at 31 March 2023 was $121.4M ($116.3M 31 December 2022).

Payments for product manufacturing and related costs reflect higher volume of sales and timing of supplier payments, with gross margin remaining in line with the previous quarter at 63%.

Illuccix global regulatory update

Telix is progressing marketing authorisations for Illuccix in a number of jurisdictions, with priority focus this past quarter on the United Kingdom (UK) and European Union (EU). On 3 April 2023, the Company provided a progress update on its European regulatory filings for Illuccix where a Marketing Authorisation Application (MAA) was submitted to the UK Medicines and Healthcare products Regulatory Agency (MHRA). The review period for the UK MAA follows a 150-day national application procedure.[3]

The process of submitting an EU MAA is underway. The German regulatory authority, BfArM Federal Institute for Drugs and Medical Devices has been selected to serve as Reference Competent Authority (CA). The Company will advise on the review timetable upon final acceptance of the dossier by the Reference CA and the corresponding member states.

Clinical Programs Update

Telix continues to progress its core therapeutic and diagnostic pipeline, with a focus on prostate cancer, renal (kidney) cancer, brain cancer (glioma) and rare diseases (bone marrow conditioning). The Company has over 20 clinical trials underway, including Telix-sponsored studies and collaborative investigator-initiated studies.

During the quarter, notable updates were published on the news section of the Company's website (www.telixpharma.com/news-views) and are summarised in this section of the Activities Report.

Priority focus for the clinical pipeline is in three key areas:

- **Preparation of a Biologics License Application (BLA) and commercialisation of TLX250-CDx, Telix's investigational kidney cancer imaging agent:** As supported under the Breakthrough Therapy Designation, the Company is actively engaging with the FDA as it prepares its regulatory filing. The Company expects to participate in a Type B meeting in the coming quarter to gain formal feedback on its submission. Further information on pre-commercialisation activity is detailed below.
- **Preparation of a New Drug Application (NDA) for TLX101-CDx, investigational brain cancer imaging agent:** During the quarter the Company participated in a successful consultation meeting with the FDA with the purpose of obtaining guidance and feedback on its proposed approach to the regulatory submission. Based on this positive discussion, the Company reconfirms its expectation to file an NDA during 2023.
- **Progression of the prostate cancer therapy program (TLX591):** Australian and New Zealand site engagement for recruitment into the ProstACT GLOBAL Phase III study has been a focus for the Company. Regulatory applications are in preparation to expand the study to the U.S. in H2 2023. Enrolment of the ProstACT SELECT study is complete (25 patients) with data to be reported in H2 2023.

1. 16 March 2023, joint media release with Isologic Innovative Radiopharmaceuticals.
2. 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).
3. With a period of up to 60 days during the review for the applicant to reply to requests for additional information.

Pre-commercialisation activities and regulatory submission for TLX250-CDx

Detailed positive results from the completed pivotal Phase III ZIRCON trial (ClinicalTrials.gov Identifier: NCT03849118)[1] were presented to the medical community for the first time at the American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium (ASCO GU)[2] in an oral presentation from Associate Professor Brian Shuch, MD, Director, Kidney Cancer Program, UCLA Institute of Urologic Oncology (Los Angeles, California) and a Principal Investigator in the study.

The results were also featured in a 'game-changing' oral presentation at the 38th Annual European Association of Urology (EAU) Congress, delivered by Professor Peter Mulders, Head of Urology at Radboud University Nijmegen Medical Centre and a Principal Investigator in the ZIRCON study. 'Game changing' sessions are reserved for Phase III trials or other developments that the EAU's Scientific Congress Office believes will have a large impact on daily practice.

The detailed analyses showed highly consistent results across three readers of an average 86% sensitivity and 87% specificity. This exceeded the pre-determined threshold required to demonstrate the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide an accurate and non-invasive method for identifying the presence and spread of clear cell renal cell carcinoma (ccRCC). Confidence intervals (CIs) exceeded expectations in all three readers showing high accuracy and consistency of image interpretation.[2]

The release of detailed results builds on the top-line data reported in November 2022, confirming the study has met its co-primary endpoint with sensitivity of ≥84% and specificity of ≥84% in all three readers.

The full data set also supported the accuracy of the imaging agent with 93% positive predictive value / 75% negative predictive value (secondary endpoints).

“The excellent results of the ZIRCON study are generating widespread interest in the urology field. Physicians can foresee the clinical utility in this non-invasive tool that exceeds conventional imaging in its ability to detect and characterise ccRCC and enables physicians to make an informed decision on optimal treatment pathways”, stated Dr Colin Hayward, Chief Medical Officer at Telix.

Telix is currently rolling out an early access program to provide this important diagnostic to patients and physicians as well as planning new research into other areas of high unmet need in cancers expressing carbonic anhydrase IX (CAIX).

TLX101 brain cancer (glioblastoma) therapy program sites initiated

The Company has initiated the IPAX-2 study (ClinicalTrials.gov Identifier: NCT05450744) to confirm the safety profile of TLX101 as a front-line therapy in combination with standard of care treatment, ahead of progressing to a label-indicating Phase II/III study in a larger patient population, IPAX-3.[3] The IPAX-2 study, which will enrol 12 patients, is expected to imminently commence dosing patients at Australian sites.

Partnership with Grand Pharma advances multiple programs into the clinic

The Company’s partnership with Grand Pharmaceutical Group Limited (Grand Pharma), Telix’s development partner in Greater China is making progress across multiple programs. In China, sites are being prepared for studies of TLX591-CDx and TLX250-CDx - which will bridge to FDA approval of Illuccix and the ZIRCON study for kidney cancer imaging, respectively - to establish equivalent efficacy in Chinese and Western populations. It is anticipated that first patients will be dosed in both studies during Q2 2023.

Subsequent to quarter end, the Chinese National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE) approved a Phase I study of TLX101 investigational therapy (4-L-[^{131}I] iodo-phenylalanine, or ^{131}I-IPA) in Chinese patients with newly diagnosed glioblastoma (GBM) that will bridge to Telix’s planned global Phase II/III IPAX-3 study.[4] This is the first of Telix’s investigational therapies to move into a clinical trial with Grand Pharma.

1. Top line data released to ASX on 7 November 2022.
2. Telix media release 20 February 2023.
3. Telix ASX disclosure 22 March 2023.
4. Telix media release 11 April 2023.

Research and Innovation (R&I) Highlights

Telix remains at the forefront of innovation in radiopharmaceuticals by investing a small proportion of its R&D budget into the development of new targets and technologies. The goals of Telix's R&I programs are to enhance existing product candidates through innovation and life-cycle management and identify promising new clinical targets and assets for introduction into the product candidate pipeline. Key highlights include:

Antibody in-licensed from Lilly progresses to clinical studies

Subsequent to quarter-end, on 17 April 2023, Telix announced the successful preclinical development of radiolabelled olaratumab, an antibody licensed from Eli Lilly and Company (Lilly) in April 2022.[1] Olaratumab was originally developed as a naked (non-radiolabelled) monoclonal antibody targeting Platelet Derived Growth Factor Receptor Alpha (PDGFRα), a target expressed in multiple tumour types. Telix has demonstrated preclinical proof-of-concept by using olaratumab to selectively deliver both diagnostic and therapeutic radiation to tumours as a radiopharmaceutical moiety and has produced a candidate for clinical translation.

The program will now progress to first-in-human clinical studies based on these highly encouraging results with the agent assigned formal candidate status in Telix's development pipeline (to be denoted as TLX300-CDx/TLX300 for the diagnostic/patient selection tool and therapeutic, respectively).

Related Party Transactions

Telix confirms that payments noted under section 6.1 of the accompanying Appendix 4C include payments of $0.5M to ABX-CRO advanced pharmaceutical services (of which Non-Executive Director Dr Andreas Kluge is Managing Director)[2] for the provision of clinical and analytical services for the Company's development programs. Payments of $0.4M were made to Directors for Director fees and Managing Director salary.

Investor Call

An investor conference call and webcast will be held at 9.00am AEST on Tuesday 18 April (7.00pm EDT, Monday 17 April)

Participants can register for the conference call at this link: https://s1.c-conf.com/diamondpass/10030024-t5emod.html

< ENDS >

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals. 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-stage products that aims to address significant unmet medical need in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX).

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 Twitter (@TelixPharma) and LinkedIn.

TLX250-CDx (^{89}Zr-DFO-girentuximab) has not received a marketing authorisation in any jurisdiction. Telix's lead product, Illuccix® or kit for preparation of gallium-68 (^{68}Ga) gozetotide (also known as ^{68}Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),[3] by the Australian Therapeutic Goods Administration (TGA),[4] and by Health Canada.[5] Telix is also progressing a marketing authorisation application for this investigational candidate in the United Kingdom.[6]

1. Telix ASX disclosure 17 April 2023.
2. Dr Andreas Kluge is currently on a temporary leave of absence from his role as Non-Executive Director of Telix - Telix ASX disclosure 29 March 2023.
3. Telix ASX disclosure 20 December 2021.
4. Telix ASX disclosure 2 November 2021.
5. Telix ASX disclosure 14 October 2022.
6. Telix ASX disclosure 3 April 2023.

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

This announcement has been authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

Legal Notices

This announcement is not intended as promotion or advertising directed to any healthcare professional or other audience in any country worldwide (including Australia, United States and the United Kingdom). 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.

Except as required by applicable laws or regulations, Telix does not undertake to publicly update or review any forward-looking statements. Past performance cannot be relied on as a guide to future performance. Readers should read this announcement together with our material risks, as disclosed in our most recently filed reports with the ASX and on our website.

Rule 4.7B

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	31 March 2023

	Consolidated statement of cash flows	Current quarter	Year to date (3 months)
		$A'000	$A'000
1	**Cash flows from operating activities**		
1.1	Receipts from customers	83,169	83,169
1.2	Payments for		
1.2 (a)	- research and development	(23,045)	(23,045)
1.2 (b)	- product manufacturing and operating costs	(31,609)	(31,609)
1.2 (c)	- advertising and marketing	(4,475)	(4,475)
1.2 (d)	- leased assets	-	-
1.2 (e)	- staff costs	(17,025)	(17,025)
1.2 (f)	- administration and corporate costs	(4,658)	(4,658)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	132	132
1.5	Interest and other costs of finance paid	(27)	(27)
1.6	Income taxes paid	(14)	(14)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**2,448**	**2,448**

2	Cash flows from investing activities	Current quarter	Year to date (3 months)
2.1	Payments to acquire or for:		
2.1 (a)	- entities	-	-
2.1 (b)	- businesses	-	-
2.1 (c)	- property, plant and equipment	(1,636)	(1,636)
2.1 (d)	- investments	-	-
2.1 (e)	- intellectual property	-	-
2.1 (f)	- other non-current assets	-	-
2.2	Proceeds from disposal of:		
2.2 (a)	- entities	-	-
2.2 (b)	- businesses	-	-
2.2 (c)	- property, plant and equipment	-	-
2.2 (d)	- investments	-	-
2.2 (e)	- intellectual property	-	-
2.2 (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 used in investing activities**	**(1,636)**	**(1,636)**

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	759	759
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	1,460	1,460
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (leased assets)	(317)	(317)
3.10	**Net cash from financing activities**	**1,902**	**1,902**

4	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	116,329	116,329
4.2	Net cash from / (used in) operating activities (item 1.9 above)	2,448	2,448
4.3	Net cash used in investing activities (item 2.6 above)	(1,636)	(1,636)
4.4	Net cash from financing activities (item 3.10 above)	1,902	1,902
4.5	Effect of movement in exchange rates on cash held	2,311	2,311
4.6	**Cash and cash equivalents at end of period**	**121,354**	**121,354**

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	121,354	116,329
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)**	**121,354**	**116,329**

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	916
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
6.1 Note	Note: Payments in 6.1 include payments of $543k 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 $373k 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	19,614	4,925
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	19,614	4,925
7.5	**Unused financing facilities available at quarter end**		**14,689**
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.	Telix entered into loan agreements with BNP Paribas and IMBC Group totalling €10.1 million on a 10-year term, and a loan with BNP Paribas totalling €2 million on a two-year, extendable term. All three loans are to fund the construction of the Brussels South manufacturing facility. All loans have a two-year repayment holiday period, with repayments due to commence from March 2024. As at 31 March 2023, Telix has drawn down on €3.0 million of these loan facilities.	

8	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	**2,448**
8.2	Cash and cash equivalents at quarter end (item 4.6)	**121,354**
8.3	Unused finance facilities available at quarter end (item 7.5)	**14,689**
8.4	Total available funding (item 8.2 + item 8.3)	**136,044**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**N/A**
	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:	17 April 2023

Authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

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.