Telix Pharmaceuticals Limited
ACN 616 620 369
Suite 401, 55 Flemington Road
North Melbourne
Victoria, 3051
Australia

Activity Report and Sales Note to Accompany Appendix 4C

Melbourne (Australia) – 30th October 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today provides its Appendix 4C for the quarter ending 30th September 2020 and a Q3 2020 sales update for its prostate cancer imaging product, the TLX591-CDx kit (Kit for the preparation of ^{68}Ga-PSMA-11 Injection).

Significant achievements for the quarter ending 30th September 2020:

- First formal interaction with the U.S. Food and Drug Administration (FDA) on the design of Phase III PROSTACT trial of TLX591 prostate cancer therapeutic product (7th July)
- Pre-investigational new drug (IND) meeting for TLX591 scheduled with the FDA for 24th November to review final proposed PROSTACT trial design
- New Drug Application (NDA) for TLX591-CDx prostate cancer imaging product lodged with the FDA (23rd September)

Financial Summary:

- The Company held cash reserves at the end of the quarter of $25.70 million
- Operating expenditure during the quarter was $9.2 million, up from $6.9 million in the prior quarter
- Increased operating expenditure was associated with finalisation and lodgement of NDA for the TLX591-CDx prostate cancer imaging product with U.S. FDA and implementation of Enterprise Resource Planning (ERP), Customer Relationship Management (CRM) and Electronic Quality Management Systems (EQMS) in preparation for 2021 product launch
- Australian Federal Government R&D tax refund of $11.4 million was received in July
- Cash runway for three further quarters of operations

Prostate Cancer Program – Overview

Prostate cancer is the second most common cancer in men following skin cancer and, in 2018, 1.3 million men were diagnosed with prostate cancer for the first time.[1] Despite advances in treatment, prostate cancer still accounts for a large number of deaths and in 2018 more than 365,000 men died from their disease. Rates of diagnosis are increasing and the highest levels of prostate cancer are found in Europe, the U.S., Europe and Australia and New Zealand.

Typically, men receive local therapy (prostatectomy and/or radiotherapy) and adjuvant androgen deprivation therapy (ADT) for early stage disease, which provides a favourable long-term prognosis. However, approximately 15% of men ultimately will develop advanced stage disease.[2] In this setting, effective new systemic therapies represent a significant medical need.

Telix's prostate cancer program comprises the prostate cancer imaging product TLX591-CDx (^{68}Ga-PSMA-11) and the prostate cancer therapeutic product TLX591 (^{177}Lu-DOTA-rosopatamab). Each of these products targets prostate specific membrane antigen (PSMA), which is an important and well-validated drug target in prostate cancer.

[1] GLOBOCAN 2018.
[2] Scher HI et al. Prevalence of Prostate Cancer Clinical States and Mortality in the United States: Estimates Using a Dynamic Progression Model. PLoS ONE 10(10), 2015.

Prostate Cancer Imaging – TLX591-CDx

Telix's prostate cancer imaging product TLX591-CDx is the Company's most developmentally advanced product and is presently used under investigational (IND), clinical trial and special access use in the United States and Europe.[3]

During September, Telix submitted a New Drug Application (NDA) to the U.S. FDA, which included:

- Clinical data from over 600 patients obtained from both prospective and retrospective clinical studies performed by Telix or in collaboration with research partners
- Extensive clinical evidence reported in peer-reviewed medical literature, a significant proportion of which originated from research conducted at leading academic centres including the University of California, Los Angeles (USA), the Peter MacCallum Cancer Centre (Australia) and Heidelberg University Hospital (Germany)

The submission of the NDA to the FDA for Telix's first product represents a major commercial milestone for the Company and follows the submission of Telix's European marketing authorisation application (MAA) in April 2020. Telix's FDA submission was the first commercial NDA for PSMA imaging in the United States. The Company has engaged with the FDA in relation to its NDA for TLX591-CDx since July 2019, with valuable guidance resulting in what Telix considers to be a comprehensive submission.

Also in September, the Company entered into an exclusive distribution agreement with Fleurus (Belgium) based IRE Elit S.A. (IRE ELiT) to distribute TLX591-CDx in France and French overseas territories, during both the initial period of 'autorisation d'exploitation temporaire' (temporary authorisation) and once full European marketing authorisation is granted, which is anticipated to occur during 2021.

Prostate Cancer Therapy – TLX591

In July, the U.S. FDA provided feedback on the design of Telix's Phase III PROSTACT trial of TLX591 for the treatment of patients with PSMA-expressing metastatic castration-resistant prostate cancer (mCRPC). The feedback represented Telix's first formal interaction with the FDA for the Company's Phase III prostate cancer therapy program and provided valuable guidance on key study design considerations, statistical methods, dosing strategy and safety monitoring to be employed in the PROSTACT trial.

Patient selection for the PROSTACT trial will be enriched via the use of TLX591-CDx companion diagnostic imaging, to identify patients with PSMA-expressing prostate cancers. Telix has integrated the FDA's recommendations into the protocol for the PROSTACT trial and a further pre-IND meeting is scheduled with the FDA for 23rd November to review the final proposed study design.

Renal Cancer Program – Overview

More than 400,000 people worldwide were diagnosed with kidney cancer and more than 175,000 people died from their disease in 2018.[4] Kidney cancer is approximately twice as common in men than women and the risk of developing kidney cancer is increased by smoking, obesity, high blood pressure and diabetes. While the advent of immunotherapy agents has improved outcomes for a significant proportion of patients with renal cell carcinoma, the most common form of kidney cancer, it remains that many patients fail to respond to

[3] TLX591-CDx is an investigational product and has not received marketing authorisation in any jurisdiction.
[4] GLOBOCAN 2018.

immunotherapies, or develop resistance following initial treatment response. For such patients, there is a significant need for new therapeutic approaches.

Telix's renal cancer program comprises the kidney cancer imaging product TLX250-CDx (^{89}Zr-girentuximab) and the kidney cancer therapeutic product TLX250 (^{177}Lu-girentuximab).

Each of these products target carbonic anhydrase IX (CA9), a cancer target highly expressed by several tumour types including clear cell renal cell carcinoma (ccRCC), the most common form of kidney cancer. Telix expects TLX250-CDx to be the first diagnostic imaging agent specifically intended for the non-invasive assessment of patients with suspected ccRCC.

The FDA granted Breakthrough Therapy (BT) designation for TLX250-CDx in July. Under BT status, the FDA will work closely with the Company to provide guidance on the development of TLX250-CDx for the diagnosis of 'indeterminate renal masses' that have been identified on computed tomography (CT) or magnetic resonance imaging (MRI). The criteria for BT designation require preliminary clinical evidence that demonstrates the product may have substantial improvement on at least one clinically significant endpoint over the currently available care.

TLX250-CDx is being developed for the initial clinical application of determining whether an indeterminate renal mass is either ccRCC or non-ccRCC, using Positron Emission Tomography (PET) imaging. BT designation offers a number of significant benefits to Telix, including eligibility for Fast Track designation, more frequent and intensive interactions with the FDA, and the opportunity to submit a 'rolling' Biological Licence Application (BLA) for the TLX250-CDx product, with the benefit being the application may be submitted in separate modules to increase the efficiency of the FDA review process.

During August, Telix commenced the 'ZIRDAC-JP' (Zirconium Dosing and Comparison in Japan) study of TLX250-CDx in Japan, dosing the first patients at Yokohama City University Hospital:

- The ZIRDAC-JP study is a Japanese multi-centre Phase I/II study that will recruit approximately 40 patients in total, with the objective being to confirm the safety and tolerability, as well as sensitivity and specificity of PET imaging with TLX250-CDx to detect ccRCC in Japanese patients.

- The patient population in the ZIRDAC-JP trial has been selected to be identical to Telix's global Phase III ZIRCON trial, which is currently recruiting patients at 35 sites internationally and is expected to complete recruitment during Q1 2021.

- The ZIRDAC-JP study has been designed in consultation with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to collect the necessary data to potentially bridge to the ZIRCON study, by confirming that the dosing and pharmacology of TLX250-CDx in Japanese patients is equivalent to non-Japanese patients.

- Following consultation with the PMDA, Telix expects to commence the Phase II component of the ZIRDAC-JP study in Q1 2021.

Glioblastoma Program – Overview

Glioblastoma, also known as glioblastoma multiforme or GBM, is the most aggressive form of primary brain cancer, with approximately 10,500 new cases diagnosed annually in the United States in 2010.[5] The mainstay of treatment for GBM typically comprises surgical resection,

[5] Ostrom QT *et al.* CBTRUS statistical report: Primary brain and central nervous system tumors diagnosed in the United States in 2006–2010. Neuro Oncol. 2013.

followed by radiotherapy and the chemotherapy agent temozolomide. However, despite these treatment options the majority of patients experience recurrence of their GBM and median survival stubbornly remains at approximately 14 months from diagnosis.[6]

Telix's GBM therapeutic product TLX101 (^{131}I-IPA) targets LAT-1, a promising target in a number of cancer types, including glioblastoma. TLX101 is a novel approach that is readily able to pass through the blood-brain barrier, a normal physiological barrier that protects the brain and excludes many other potential drug candidates. TLX101 is presently undergoing Phase I/II development in the IPAX-1 clinical trial in combination with external beam radiation therapy (EBRT).[7] IPAX-1 is recruiting at five sites in Europe and Australia, and Telix expects to present preliminary study data prior to the end of 2020.

During August, Telix submitted a Drug Master File (DMF) to the U.S. FDA for TLX101, thus enabling academic and pharmaceutical collaborators to initiate investigator-led studies with TLX101 in the United States, as well as potentially expanded access use in the longer term, subject to the requisite FDA approvals.[8] TLX101 has previously been granted orphan drug status by the FDA and the filing of the DMF for TLX101 potentially enables the generation of further independent clinical data in both glioblastoma and other LAT-1 expressing cancers.

Future Pipeline Development and Other Cancers

TLX102:

- In August Telix was granted Orphan Drug Designation (ODD) by the FDA for 4-[^{211}At] astato-l-phenylalanine (designated as TLX102), for the treatment of multiple myeloma. TLX102 represents an evolution of Telix's existing investigational glioblastoma treatment TLX101, utilising new chemistry and rapid synthesis methods to replace ^{131}I (iodine-131) with ^{211}At (astatine-211). TLX102 is a form of Targeted Alpha Therapy (TAT), a cutting-edge future field of radiopharmaceutical development. Telix has one of the most extensive TAT R&D pipelines.

- Astatine-211 is a high-energy, very short-range radioisotope known as an 'alpha emitter'. The short-range of alpha radiation is potentially suited to the treatment of blood cancers such as multiple myeloma, which are typically comprised of widely disseminated cancer cells that require highly targeted radiation to minimise damage to adjacent normal tissues, such as the bone marrow. Multiple myeloma arises from plasma cells, the white blood cells responsible for antibody production and typically portends a poor prognosis, with a 5-year survival of around 50%, despite recent advances in treatment.

- TLX102 has demonstrated promising efficacy in standard pre-clinical models of multiple myeloma and is expected to be evaluated in human patients in the second half of 2021. The granting of an ODD for TLX102 qualifies Telix for various drug development incentives which may include FDA-administered market exclusivity for seven years, waived FDA prescription drug user fees, and tax credits for R&D and clinical development costs.

APOMAB™:

- During September, the first patients were dosed in a Phase I study of a novel lung and ovarian cancer theranostic agent (APOMAB™) at the Royal Adelaide Hospital (RAH). This clinical study, which is being conducted by the Central Adelaide Local Health Network (CALHN) is co-funded by Telix and its strategic partner, AusHealth®.

[6] Ohgaki H *et al.* Epidemiology and etiology of gliomas. Acta Neuropathol 2005; 109:93–108.

[7] ClinicalTrials.gov Identifier: NCT03849105

[8] TLX101 does not have a marketing authorization in any jurisdiction.

- This Phase I clinical proof of concept study is evaluating APOMAB™, an antibody that targets the La/SSB protein, which is specifically expressed by cancer cells that have been treated with chemotherapy and/or radiation. APOMAB™ will initially be labelled with Zirconium-89 (^{89}Zr-APOMAB) to enable the biological and targeting properties of the antibody to be evaluated using PET imaging.

- The ultimate research objective of the study will be to determine how effectively APOMAB™ is able to deliver diagnostic and therapeutic targeted radiation to advanced lung or ovarian cancers and will enrol 18 patients in total.[9]

Strategic Collaborations

RefleXion Medical (Hayward, California, USA):

- In July, Telix entered into a strategic collaboration agreement with RefleXion Medical, a Hayward, California (USA) based radiation oncology company pioneering the development of biology-guided radiotherapy (BgRT) as a new approach for treating advanced cancers. The strategic collaboration will initially evaluate Telix's PET imaging tracers TLX591-CDx (^{68}Ga-PSMA-11) and TLX250-CDx (^{89}Zr-Girentuximab) to guide BgRT for the treatment of prostate and kidney cancers, respectively.

- BgRT is an innovative method of delivering radiation therapy, that utilises the biological emissions from a patient's cancer cells created by injecting a small amount of a PET tracer (such as TLX591-CDx or TLX250-CDx), to guide external-beam radiotherapy (EBRT). Once the PET tracer binds to the cancer cells, it produces emissions that signal the cancer's location, enabling RefleXion's BgRT linear accelerator device to detect these emissions using PET detectors and respond in real time to direct BgRT to the cancer location.

- Presently, the most commonly used PET tracer, ^{18}F-FDG can detect many different cancer types, however its performance in certain tumour types and organs remains limited, particularly for kidney and prostate cancers. Telix's PET tracers, which are designed to target specific cancer types may thus enable more accurate guidance of BgRT for prostate and kidney cancers. In the longer term, the collaboration with RefleXion may enable Telix to expand the indications for TLX 591-CDx and TLX-250-CDx to use in BgRT.

Varian Medical Systems (Palo Alto, California, USA):

- During the quarter, Telix entered into a second significant strategic collaboration with Palo Alto, California (USA) based market leading cancer therapy company Varian Medical Systems, to evaluate the use of advanced prostate cancer imaging within Varian's radiation treatment planning platform.

- The collaboration initially aims to leverage Telix's extensive clinical data for imaging prostate-specific membrane antigen (PSMA) via PET imaging, to potentially develop new image-guided treatment planning functions, automated analysis and artificial intelligence capabilities within Varian's radiation treatment planning technology platforms. The goal of the collaboration is to ensure that the latest standard of care in prostate imaging, PSMA PET/CT imaging, is able to be an integral part of radiation treatment planning.

- The collaboration with Varian will formally investigate the potential to incorporate the invaluable diagnostic and cancer staging information provided by PSMA PET/CT imaging

[9] Australian New Zealand Clinical Trials Registry registration number: ACTRN12620000622909

into Varian's bioinformatics and radiation treatment planning platforms to generate highly personalized and targeted radiation therapy for patients with prostate cancer.

Quarterly Sales (TLX591-CDx / illumet® Kit)

During the quarter, Telix delivered approximately 2,000 individual patient doses prepared from 800 TLX591-CDx prostate cancer imaging kits. The Company received A$0.82M in cash from (pre-marketing approval) kit sales for the quarter, down 14% on the previous quarter and reflective of the impact of COVID-19.

It should be noted that these sales are not indicative of a reimbursed product following marketing approval, as TLX591-CDx kits are currently being sold for investigational, research, magisterial and compassionate use access only, not as part of routine clinical care. Thus, unit sales are particularly vulnerable in the COVID-19 environment. Pricing of the TLX591-CDx kit remained stable during the period.

Payments to Related Parties

Telix confirms that payments noted under section 6.1 of the accompanying Appendix 4C include payments to ABX-CRO advanced pharmaceutical services Forschungsgesellschaft [10] for the provision of clinical and analytical services for its programs, and to Directors for director fees.

About Telix Pharmaceuticals Limited

Telix is a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne with international operations in Belgium, Japan and the United States. Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical need in prostate, kidney and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

Telix Corporate Contact

Dr Christian Behrenbruch
Telix Pharmaceuticals Limited
CEO
Email: chris@telixpharma.com

Telix Investor Relations

Dr David N. Cade
Telix Pharmaceuticals Limited
CBO and Head of Investor Relations
Email: david.cade@telixpharma.com

[10] Dr Andreas Kluge is a Non-Executive Director of Telix Pharmaceuticals Limited and General Manager of ABX-CRO advanced pharmaceutical services Forschungsgesellschaft.

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	September 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	823	2,912
1.2	Payments for		
	(a) research and development	(5,538)	(20,357)
	(b) product manufacturing and operating costs	(392)	(1,622)
	(c) advertising and marketing	(78)	(176)
	(d) leased assets		
	(e) staff costs	(2,344)	(7,080)
	(f) administration and corporate costs	(1,682)	(4,239)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	18	66
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	11,386	11,386
1.8	Other (provide details if material)	(8)	(83)
1.9	**Net cash from / (used in) operating activities**	**2,185**	**(19,193)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses	-	-
	(c) property, plant and equipment	-	(66)
	(d) investments	-	-
	(e) intellectual property	(36)	(36)
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
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**	**(36)**	**(102)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	170	589
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	458
3.6	Repayment of borrowings	(50)	(232)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Leased assets)	(290)	(622)
3.10	**Net cash from / (used in) financing activities**	**(170)**	**193**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	24,378	44,598
4.2	Net cash from / (used in) operating activities (item 1.9 above)	2,185	(19,193)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(36)	(102)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(170)	193
4.5	Effect of movement in exchange rates on cash held	(656)	205
4.6	**Cash and cash equivalents at end of period**	**25,701**	**25,701**

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	25,701	24,378
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)**	**25,701**	**24,378**

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	370
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: Payments in 6.1 include payments to ABX-CRO advanced pharmaceutical services Forschungsgesellschaft for the provision of clinical and analytical services for its programs, and to Directors for director fees

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)	**2,185**
8.2	Cash and cash equivalents at quarter end (item 4.6)	**25,701**
8.3	Unused finance facilities available at quarter end (item 7.5)	Nil
8.4	Total available funding (item 8.2 + item 8.3)	**25,701**
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: 30 October 2020

Authorised by: TLX 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.