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Australia

Activity Report and Appendix 4C for Q4 2020

Melbourne (Australia) – 29 January 2021. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today provides its Appendix 4C quarterly cash flow statement and accompanying Activity Report for the quarter ending 31 December 2020. All figures are in $AUD unless otherwise stated.

Financial Summary

- The Company held cash reserves of $79.09 million on 31 December 2020.
- An up-front non-refundable prepayment of $33.81 million, plus an equity investment of $35.1 million were received during the quarter following completion of a strategic licence and commercial partnership with China Grand Pharmaceutical and Healthcare Holdings Limited (CGP) for Greater China.[1]
- Operating expenditure during the quarter included $7.93 million for R&D and clinical trial costs, as well as regulatory filing costs for Telix's first product Illuccix® (TLX591-CDx), for the Positron Emission Tomography (PET) imaging of prostate cancer.
- Telix has sufficient capital reserves to launch its first two products Illuccix® (TLX591-CDx) and TLX250-CDx for prostate and renal cancer imaging, respectively[2], and to fund ongoing clinical development costs in 2021 and 2022.[3]

Major progress achieved during Q4

During the December quarter, Telix made major progress on its mission to help patients with cancer live longer, better quality lives, and towards its key 2021 objective of transitioning to a commercial-stage pharmaceutical company. While progress occurred across all facets of the Company's operations, the most significant developments included:

1. Advancing Illuccix® (TLX591-CDx) towards commercial launch in 2021. We note that Illuccix® is the product name agreed with the FDA and supersedes the use of Illumet®.

2. Completing commercial transactions, financing and technology collaborations

3. Advancing the TLX591 (prostate cancer therapy) program, as Telix's most advanced-stage therapeutics program

4. Executing clinical activity across the pipeline, both diagnostic and therapeutic programs.

Advancing Illuccix® towards commercial launch in 2021

Telix's first commercial product is Illuccix® (TLX591-CDx), a diagnostic imaging agent for the PET imaging of prostate cancer. In December, the U.S. Food and Drug Administration (FDA)

[1] ASX disclosure 2/11/20.
[2] Subject to approvals in the relevant jurisdictions. None of Telix's products have attained a marketing authorisation in any country.
[3] Subject to timely commencement of revenues from product launch of Illuccix® (TLX591-CDx) in the US/EU.

informed Telix that the Company's New Drug Application (NDA) for Illuccix® would proceed to a substantive review, with a mid-cycle review meeting planned for 16 February 2021 and a label review date proposed for 30 May 2021. The FDA also indicated that no major issues had been identified in Telix's NDA and that it did not plan to hold an advisory committee meeting to discuss Telix's application.[4]

During the quarter, Telix also made significant progress towards commercial launch of Illuccix® in other important markets:

- New Drug Submission (NDS) for Illuccix® submitted to Health Canada, representing the first commercial NDS for Prostate Specific Membrane Antigen (PSMA) imaging in Canada[5]
- Australian Therapeutic Goods Administration (TGA) granted Priority Review status for Illuccix®, providing a 150 working day timeline for product dossier review and approval.[6]

Together with the Marketing Authorisation Application for Illuccix® made in the European Union earlier in 2020[7], Telix expects the regulatory submissions for its first product to continue to progress during the first half of 2021, with commercial launch plans well advanced in each of these markets.

Completing commercial transactions, financing and technology collaborations

During the quarter, Telix completed two key transactions and entered into several important collaborations, delivering $68.91 million of additional financial resources, securing access to the Greater China market, and broadening the clinical stage product portfolio to include hematology and rare disease applications.

China Grand Pharma Partnership

In November, Telix entered into a long-term commercial partnership with China Grand Pharmaceutical and Healthcare Holdings Limited ('CGP')[8], granting exclusive rights to a portion of Telix's diagnostic and therapeutic Molecularly Targeted Radiation (MTR) product portfolio for Greater China.[9] Central to Telix's objective of building an Asian commercial presence, the Telix-CGP Partnership represents more than $400 million in value to Telix, plus royalties on product sales over the life of the partnership.

Importantly, the transaction with CGP delivered an immediate cash injection of $68.91 million from the up-front, non-refundable prepayment of $33.81 million for future regulatory and commercial milestones, and a strategic equity investment in Telix of $35.1 million. Following the CGP transaction, Telix has sufficient capital to:

- Undertake the global commercial launch of its first two products Illuccix® (TLX591-CDx) and TLX250-CDx for prostate and renal cancer imaging, respectively
- Fund ongoing clinical development costs in 2021 and 2022, across the wider portfolio.

TheraPharm GmbH Acquisition

In December, Telix acquired Swiss-German biotechnology company TheraPharm GmbH (TheraPharm), for a total consideration of €10.2 million (~$16.5 million) upfront plus €10.0

[4] ASX disclosure 9/12/20.
[5] ASX disclosure 16/12/20.
[6] ASX disclosure 7/12/20.
[7] ASX disclosure 1/05/20.
[8] ASX disclosure 2/11/20.
[9] Greater China comprises Mainland China, Hong Kong SAR, Macau SAR, Taiwan.

million (~$16.2 million) in future earn-out and royalty payments.[10] The acquisition of TheraPharm extends Telix's MTR capabilities into major new applications, comprising:

- Hematologic oncology (blood cancers)
- Transplant medicine
- Several high-value, under-served rare diseases including amyloidosis.

By acquiring TheraPharm, Telix gained access to the diagnostic product, Scintimun® (^{99m}Tc-besilesomab) which is approved in Europe for the indication of locating suspected bone infection (osteomyelitis). Scintimun®, which is currently marketed by Curium Pharma in Europe, is revenue generating and has considerable potential for expanded clinical use.

Telix also gained access to the clinical-stage therapeutic program (^{90}Y-besilesomab), including rights to the clinical data from the University of Southampton, U.K. demonstrating excellent clinical safety and efficacy data from Phase I & II trials. ^{90}Y-besilesomab has been granted orphan drug designation (ODD) status in Europe for the broad indication of Bone Marrow Conditioning (BMC) for Hematopoietic Stem Cell Transplantation (HSCT), providing significant potential for the fast-track development of ^{90}Y-besilesomab for the treatment of systemic amyloid light chain amyloidosis (SALA).

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

- Exclusive IP licence agreement with the German Cancer Research Centre (DKFZ) for a 'dual-labelled' PSMA tracer that enables both PET and optical imaging of prostate cancer, and has significant applications in the field of image-guided prostate cancer surgery[11]
- Exclusive scientific and clinical research collaboration with Paris-based Mauna Kea Technologies (Mauna Kea) to develop advanced image-guided surgical technologies in the field of urologic oncology.[12] The focus of the collaboration, which has been named the "*Imaging and Robotics in Surgery*" (IRiS) Alliance, is to combine the use of Telix's dual-labelled PSMA tracer with Mauna Kea's Cellvizio® confocal laser endomicroscopy (CLE) in vivo cellular imaging platform. The IRiS Alliance aims to develop advanced capabilities for pre-operative planning, intra-operative guidance, surgical margin assessment and other surgical parameters, with initial applications in prostate and renal cancer
- Receipt by Telix of a €545,000 (~$893,000) research grant awarded by the Walloon regional government in Belgium to support the preclinical R&D and early clinical development of Telix's prostate cancer imaging agent[13]
- Exclusive commercialisation and partnership agreement with leading South Korean radiopharmaceutical company DuChemBio Co, Ltd. (DuChemBio) for Illuccix® in South Korea.[14] Under this agreement, Telix and DuChemBio will collaborate to obtain a marketing authorisation for Illuccix® from South Korea's Ministry of Food and Drug Safety (MFDS).

Advancing the prostate cancer therapy program

During the quarter, Telix completed a pre-Investigational New Drug (IND) meeting with the U.S. FDA, at which the Company and the Agency reviewed key aspects of the Phase III ProstACT clinical study for Telix's prostate cancer therapy product TLX591 (^{177}Lu-DOTA-rosopatamab).[15] Following the pre-IND meeting, Telix confirmed its intention to proceed with the ProstACT

[10] ASX disclosure 30/11/20.
[11] ASX disclosure 28/10/20.
[12] ASX disclosure 16/12/20.
[13] ASX disclosure 19/11/20.
[14] ASX disclosure 3/12/20.
[15] ASX disclosure 3/12/20.

study as an international, multi-centre, randomised controlled trial (RCT) that will compare best standard of care with and without TLX591, in patients with PSMA-expressing metastatic castration-resistant prostate cancer (mCRPC), who have progressed following prior treatment with a novel androgen axis drug (NAAD).

Based on the clear guidance received from the Agency, Telix plans to commence the ProstACT study in Australia and is in the process of submitting a Clinical Trial Notification (CTN) to the Australian TGA. Based on the ProstACT trial requirements indicated by the FDA, Telix expects to add US patients to the ProstACT study during the second half of 2021, subject to allowance by the FDA.

Executing clinical activity across the pipeline

During the quarter, Telix also made significant progress in a number of clinical studies, both with the Company's existing clinical stage portfolio, as well as with an earlier R&D stage asset:

- Completion of patient enrolment into the Phase I component of the Phase I/II ZIRDAC-JP trial of Telix's renal cancer diagnostic imaging agent TLX250-CDx in Japan.[16] The ZIRDAC-JP study is a Japanese multi-centre Phase I/II study recruiting approximately 40 patients in total that has been designed in consultation with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to collect the necessary data to potentially bridge to Telix's international Phase III ZIRCON study. Following review of these Phase I data and consultation with the PMDA, Telix expects to commence the Phase II component of the ZIRDAC-JP study in early 2021.
- Entry into a clinical study collaboration with Kanazawa University in Japan to conduct a Phase I trial of TLX591-CDx (^{68}Ga-PSMA-11) in patients with advanced prostate cancer.[17] The objective of this study, which is the first clinical trial involving the use of gallium-based PSMA imaging in Japan, is to obtain preliminary Japanese ethnicity data to demonstrate to the Japanese PMDA that the targeting and biodistribution of TLX591-CDx is comparable to the rest of the world in order to facilitate planning discussions for product approval in Japan.
- Approval in Australia to commence the first-in-human Phase I CUPID study of Telix's next generation prostate cancer therapeutic product TLX592, in patients with advanced prostate cancer.[18] Using Telix's proprietary RADmAb® antibody technology, TLX592 has been designed to clear more rapidly from a patient's circulation, making it suitable for use as a targeting agent for ^{225}Ac (actinium-225). Actinium is a potent therapeutic alpha-emitting radioisotope, considered to be suitable for "Targeted Alpha Therapy" (TAT).

Quarterly Sales (Illuccix® / TLX591-CDx Kit)

During the December quarter, Telix delivered approximately 2,700 individual patient doses prepared from 1,100 TLX591-CDx prostate cancer imaging kits. The Company received $0.87M in cash from TLX591-CDx kit sales for the quarter, representing a slight increase on the prior quarter and in line with Company expectations for TLX591-CDx kit sales prior to marketing approval being granted, which is expected during 2021.

Telix notes that these sales are not indicative of a reimbursed product following marketing approval, given the Company sells TLX591-CDx kits for clinical trial, research, magisterial and compassionate use access only, not as a diagnostic imaging agent in routine clinical practice. Pricing of the TLX591-CDx kit remained stable during the period.

Telix CEO Dr. Chris Behrenbruch stated, "We are pleased with the substantial progress Telix made across the business during the last quarter of 2020. Going into 2021, Telix is a stronger

[16] ASX disclosure 27/10/20.
[17] ASX disclosure 14/12/20.
[18] ASX disclosure 2/12/20.

company, in a sound financial position, with its first two products continuing to achieve their various milestones on the path to commercial launch. The whole team is highly energised by the outlook for 2021, as we transition to commercialisation and deliver on our mission to help patients with cancer live longer, better quality lives."

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 [19] 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, 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 needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information, please follow Telix on Twitter @TelixPharma and LinkedIn, and visit www.telixpharma.com.

About Illuccix®

Telix's lead commercial product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA[20], and has been granted Priority Review status by the Therapeutic Goods Administration (TGA) in Australia.[21] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[22] and Canada.[23] None of Telix's products have currently received a marketing authorisation in any jurisdiction.

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[19] Dr Andreas Kluge is a Non-Executive Director of Telix Pharmaceuticals Limited and General Manager of ABX-CRO advanced pharmaceutical services Forschungsgesellschaft.
[20] ASX disclosure 24/11/20.
[21] ASX disclosure 7/12/20.
[22] ASX disclosure 1/05/20.
[23] ASX disclosure 16/12/20.

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	December 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	952	3,864
1.2	Payments for		
	(a) research and development	(7,926)	(28,283)
	(b) product manufacturing and operating costs	(887)	(2,509)
	(c) advertising and marketing	(310)	(486)
	(d) leased assets		
	(e) staff costs	(2,597)	(9,677)
	(f) administration and corporate costs	(1,751)	(5,990)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	67
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	11,386
1.8	Other (provide details if material)		
	• Income received in advance	33,807	33,807
	• Other		(83)
1.9	**Net cash from / (used in) operating activities**	**21,289**	**2,096**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses	-	-
	(c) property, plant and equipment	(28)	(94)
	(d) investments	(320)	(320)
	(e) intellectual property	(37)	(73)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**(385)**	**(487)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	35,315	35,904
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	(69)	(69)
3.5	Proceeds from borrowings	-	458
3.6	Repayment of borrowings	680	448
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Leased assets)	(288)	(910)
3.10	**Net cash from / (used in) financing activities**	**35,638**	**35,831**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	25,701	44,598
4.2	Net cash from / (used in) operating activities (item 1.9 above)	21,289	2,096
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(385)	(487)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	35,638	35,831
4.5	Effect of movement in exchange rates on cash held	(3,154)	(2,949)
4.6	**Cash and cash equivalents at end of period** *Note:*. Unfavourable exchange movements result from impact of strengthening of AUD FX rates on significant USD bank balances held in last quarter.	**79,089**	**79,089**

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	79,089	25,701
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)**	**79,089**	**25,701**

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	944
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 of $767k Forschungsgesellschaft for the provision of clinical and analytical services for its programs, and to Directors for director fees of $177k.

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)	**21,289**
8.2	Cash and cash equivalents at quarter end (item 4.6)	**79,089**
8.3	Unused finance facilities available at quarter end (item 7.5)	Nil
8.4	Total available funding (item 8.2 + item 8.3)	**79,089**
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: 29 January 2021

Authorised by: CFO and Continuous Disclosure Committee of the Board

(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.