

Activities Report and Appendix 4C for March 2021 Quarter

Melbourne (Australia) – 22 April 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 31 March 2021. All figures are in \$AUD unless otherwise stated.

Financial Summary

- Telix held cash reserves of \$61.42 million on 31 March 2021 (\$77.95 million held on 31 December 2020).
- Operating expenditure during the quarter was \$17.13 million, in line with forecasts, with \$11.49 million invested in R&D and clinical development activities.
- Operating expenditure during the quarter included the payment of \$3.50 million for expenses accrued in 2020, giving underlying cash utilisation of \$13.63 million.
- Cash runway for approximately 5 quarters of operations¹, based on underlying cash utilisation and exclusive of any anticipated revenue from approved product sales.
- Telix has sufficient cash reserves at hand to fund the commercial launch of Illuccix® (TLX591-CDx).²

Continued progress towards commercialisation made during Q1 2021

In the first quarter of 2021, Telix has continued to make significant progress towards its objective of transitioning to a commercial-stage pharmaceutical company. While the Company has set comprehensive objectives for 2021 that aim to advance all aspects of the business, the three most important milestones Telix aims to achieve this year are:

1. **Commence** the international, multi-centre, Phase III ProstACT randomised controlled trial (RCT) of TLX591 (¹⁷⁷Lu-rosapatamab), Telix's lead prostate cancer therapy product.
2. **Complete** the Company's Phase III ZIRCON trial of its renal cancer positron emission tomography (PET) imaging product.
3. **Launch** Illuccix® (TLX591-CDx, Kit for the preparation of ⁶⁸Ga-PSMA-11), Telix's lead prostate cancer PET imaging product.

Illuccix® – Commercial Launch Activities

Telix's first commercial product will be Illuccix® (formerly referred to as TLX591-CDx or *illumet*®), a diagnostic imaging agent for PSMA-PET imaging of prostate cancer. PSMA-PET

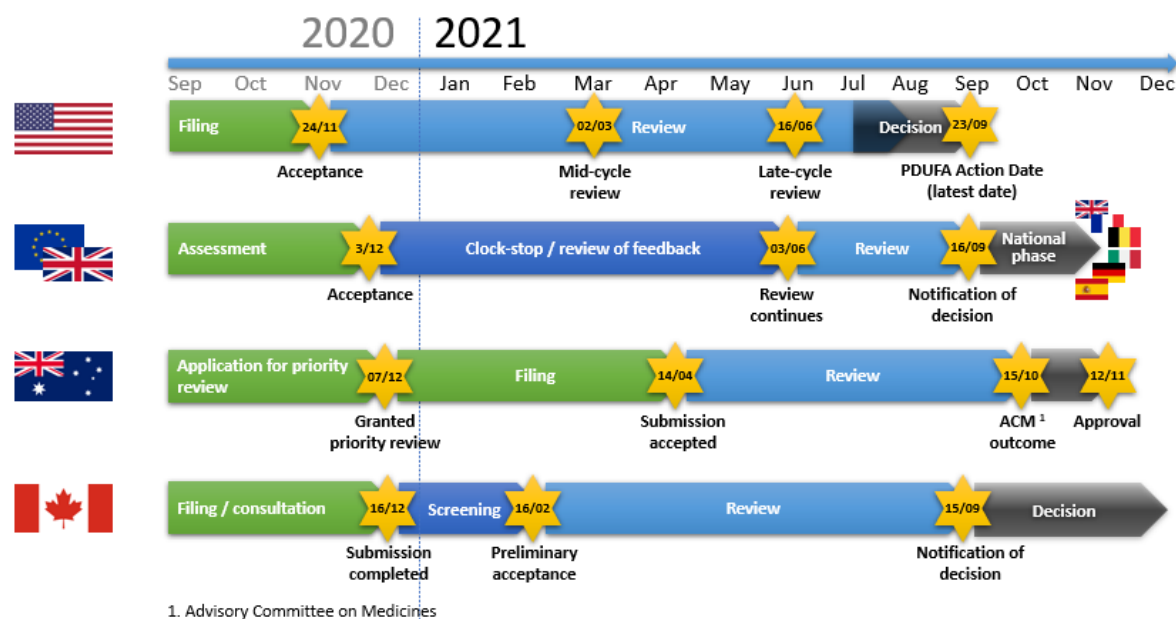
¹ This is the approximate number of quarters remaining based on underlying cash spend being actual spend for the quarter less \$3.5M of spend associated with the previous year. When \$3.5M is deducted the number of quarters remaining is over 4.5 which has been rounded to 5 quarters in the Financial Summary.

² Subject to approvals in the relevant jurisdictions. None of Telix's products have attained a marketing authorisation in any country.

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.³

As at the end of the quarter, marketing authorisation applications for Illuccix[®] were under review and progressing in 16 countries (United States, Canada, 13 European member states + UK), with the Australian Therapeutic Goods Administration (TGA) accepting the Company's submission for the registration of Illuccix[®] and commencing its priority evaluation process after the end of the quarter (on 14 April). The TGA has indicated a target decision date (approval date) for its priority evaluation of Illuccix[®] of 12 November 2021.⁴

Illuccix[®]: anticipated regulatory timelines by market



The U.S. Food and Drug Administration (FDA) has scheduled its late-cycle review meeting for Illuccix[®] for 16 June 2021, prior to which the FDA intends to communicate to Telix the proposed product labelling for Illuccix[®], which may include the indications for use statement.

In February, the Czech Republic became the first European country to grant a national authorisation allowing the use of Illuccix[®] by Czech physicians under the country's Specific Therapeutic Programme (STP). Under the STP, which is valid until 31 December 2022, Illuccix[®] is allowed to be used for a broad range of indications comprising:

1. Primary staging of high-risk disease with a view to early identification of metastases
2. Localisation of prostate cancer in patients that are progressing following radical treatment (also known as 'biochemical recurrence')
3. Identification of patients with extensive generalised prostate cancer for who radical life-saving treatment is not indicated

Telex is collaboratively pursuing similar temporary authorisations for Illuccix[®] in several other European countries in parallel with its primary marketing authorisation application submitted in April 2020.⁵

³ Trabulsi EJ *et al.* J Clin Oncol. Jan 2020. European Association of Urology 2020.

⁴ ASX disclosure 14/04/21.

⁵ ASX disclosure 1/05/20.

In Japan, Telix and its collaboration partner, Kanazawa University received Clinical Trial Notification (CTN) clearance from the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to commence a Phase I study of Illuccix[®] in 10 patients with advanced prostate cancer. While Illuccix[®] is at a much earlier stage of development in Japan relative to other markets, the aim of this study is to obtain preliminary Japanese clinical data to demonstrate that the targeting and pharmacology of Illuccix[®] is equivalent to Caucasian patients. Telix then intends to use this data to support regulatory consultation with the PMDA to confirm and formalise an approval pathway for the product in Japan.

Anticipating regulatory decisions for Illuccix[®] in 17 countries during the second half of 2021, Telix entered an agreement in March with contract development and manufacturing organisation Grand River Aseptic Manufacturing (GRAM) to perform commercial-scale Good Manufacturing Practice (GMP) manufacturing of Illuccix[®]. Under the terms of this agreement, GRAM will perform advanced aseptic fill and finish services for Illuccix[®] at its Grand Rapids, Michigan, U.S.A. facility for the United States, Canada, European Union and Australian markets.

TLX250-CDx – Second Product for Renal Cancer Imaging

Telix expects that its second product to be commercialised will be TLX250-CDx (⁸⁹Zr-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.⁶ 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.

In January, Telix's international, multi-centre, Phase III ZIRCON trial of TLX250-CDx enrolled and dosed its first patients in the U.S. after a period of delay due to the COVID-19 pandemic. The ZIRCON trial includes twelve participating sites in the U.S. and Canada, and 36 participating sites globally, which the Company anticipates will achieve a patient enrolment rate to enable completion of enrolment around mid-year. Given that the duration of study participation for patients on the ZIRCON trial is 42 days, Telix anticipates commencing its BLA preparation activities in the fourth quarter of 2021, with the goal of scheduling a pre-BLA meeting with the FDA prior to the end of 2021.

As reported after the end of the quarter (on 21 April 2021), 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.⁷ Importantly, the results of this study furthermore 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 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 Phase III ZIRCON trial data-set when it becomes available in late 2021.

TLX591 and Other Clinical Activity Across the Pipeline

In late 2020, Telix met with the FDA for a pre-Investigational New Drug (IND) meeting, enabling the design of its Phase III ProstACT trial of Telix' prostate cancer therapy product TLX591 (¹⁷⁷Lu-rosopatamab) to be finalised.⁸ During the quarter, Telix advanced its ProstACT trial Australian launch preparation, with Australian TGA Clinical Trial Notification (CTN) acceptance anticipated in May.

⁶ ASX disclosure 1/07/20.

⁷ ASX disclosure 20/07/21.

⁸ ASX disclosure 3/12/20.

In March, Telix extended its global clinical and commercial supply agreements with Isotopen Technologien München AG (ITM) for the supply of high purity lutetium-177 (¹⁷⁷Lu), the therapeutic isotope used in both TLX591 and TLX250 for prostate and renal cancer therapy, respectively. As the leading global supplier that has established significant production capacity for ¹⁷⁷Lu, the supply agreements with ITM will support both the near-term clinical trial programs in prostate and renal cancer therapy, as well as commercial-scale activity in the future, subject to regulatory approval of Telix's drug candidates.

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

- Finalisation of the design of the Phase II STARLITE-2 trial of TLX250 (¹⁷⁷Lu-girentuximab) plus nivolumab in up to 30 patients with ccRCC who have progressed following prior immunotherapy. Patient enrolment onto the STARLITE-2 trial is expected to commence at Memorial Sloan Kettering Cancer Center (MSKCC) (New York, U.S.A.) in May, pending the FDA's granting of an IND.
- Completion of study 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. TLX592 (²²⁵Ac-RADmAb[®]) employs Telix's proprietary RADmAb[®] engineered antibody technology and targets prostate specific membrane antigen (PSMA), as does the Company's existing TLX591 (¹⁷⁷Lu-rosapatamab) prostate cancer therapy program. Compared to TLX591 however, TLX592 has been engineered to clear far more rapidly from a patient's circulation, rendering it more suitable for use as a targeting agent for ²²⁵Ac, a potent therapeutic alpha emitting radionuclide.⁹ The CUPID study, which will be led by principal investigator, Associate Professor Nat Lenzo, GenesisCare Group Clinical Director (Theranostics) is expected to commence patient enrolment in April.
- Telix has progressed the post-merger integration of TheraPharm GmbH, which was acquired by Telix in December 2020¹⁰, including planning and development of a proposed pivotal trial design for TLX66 (⁹⁰Y-besilesomab) for the indication of bone marrow conditioning prior to hematopoietic stem cell transplantation in patients with systemic amyloid light chain amyloidosis. The Company plans to consult with European regulators following the read-out of the TRALA (Targeted Radiotherapy for AL-Amyloidosis) trial, a Phase I/IIa trial that has completed at the University of Southampton, United Kingdom and is currently undergoing final data safety monitoring board review, and is expected to read-out in May.

Quarterly Sales (Illuccix[®] / TLX591-CDx Kit)

In the March 2021 quarter, Telix delivered approximately 3,000 individual patient prostate cancer imaging doses, prepared from 1,200 TLX591-CDx prostate cancer imaging kits, representing a 15% increase compared to the corresponding quarter in 2020. The Company booked total sales for the quarter of \$0.90 million and received \$0.73 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 Chief Executive Officer Dr. Chris Behrenbruch stated, "We are pleased with the progress we have continued to make across the business since the start of 2021. This is an exciting year in which we expect to achieve major commercial and developmental milestones that will fundamentally transform the prospects of the Company and our ability to deliver growth

⁹ Refer to ASX disclosure 2/12/2020 for detailed briefing on CUPID study, TLX592 and targeted alpha therapy.

¹⁰ ASX disclosure 14/12/20.

through revenue generation. Telix is on the cusp of being able to materially deliver on our stated 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 of \$242,000 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 \$300,000 to Directors for director fees and Managing Director salary.

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 visit www.telixpharma.com and follow Telix on Twitter @TelixPharma and LinkedIn.

About Illuccix®

Telix's lead investigational product, Illuccix® (TLX591-CDx, Kit for the preparation of ⁶⁸Ga-PSMA-11 injection) for prostate cancer imaging, has been accepted for filing by the U.S. FDA¹¹, and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).¹² Telix is also progressing marketing authorisation applications for Illuccix® in the European Union¹³ and Canada.¹⁴ None of Telix's products have attained a marketing authorisation in any jurisdiction.

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Important Information

This announcement does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States, or in any other jurisdiction in which such an offer would be illegal. The securities referred to herein have not been and will not be registered under the United States Securities Act of 1933 (the "U.S. Securities Act"), or under the securities laws of any state or other jurisdiction of the United States and may not be offered or sold within the United States, unless the 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.

¹¹ ASX disclosure 24/11/20.

¹² ASX disclosure 14/04/21.

¹³ ASX disclosure 1/05/20.

¹⁴ 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

85 616 620 369

Quarter ended ("current quarter")

31 March 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	731	731
1.2 Payments for		
(a) research and development	(11,485)	(11,485)
(b) product manufacturing and operating costs	(572)	(572)
(c) advertising and marketing	(205)	(205)
(d) leased assets		
(e) staff costs	(3,294)	(3,294)
(f) administration and corporate costs	(2,309)	(2,309)
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	-	-
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	(17,134)	(17,134)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses	-	-
(c) property, plant and equipment	(40)	(40)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 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	(40)	(40)

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	638	638
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	(56)	(56)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (Leased assets)	(288)	(288)
3.10 Net cash from / (used in) financing activities	294	294

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	77,945	77,495
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(17,134)	(17,134)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(40)	(40)

Appendix 4C

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

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	294	294
4.5	Effect of movement in exchange rates on cash held	356	356
4.6	Cash and cash equivalents at end of period	61,421	61,421

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	61,421	77,945
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)	61,421	77,945

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	542
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note:</i> Payments in 6.1 include payments of \$242k 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 \$300k to Directors for director fees and salary.		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	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)	(17,134)
8.2	Cash and cash equivalents at quarter end (item 4.6)	61,421
8.3	Unused finance facilities available at quarter end (item 7.5)	Nil
8.4	Total available funding (item 8.2 + item 8.3)	61,421
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.6
	<i>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.</i>	
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	
	<i>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.</i>	

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 April 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.