

## **Activities Report and Sales Note to Accompany Appendix 4C**

Melbourne (Australia) – 27<sup>th</sup> July 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today provides its Activities Report and Appendix 4C for the quarter ending 30<sup>th</sup> June 2020 and a Q2 2020 sales update for its prostate cancer imaging product, the TLX591-CDx kit (Kit for the preparation of <sup>68</sup>Ga-PSMA-11 Injection).

### **Financial Summary**

- The Company held cash reserves at the end of the quarter of \$24.38 million.
- Operating expenditure during the quarter was \$6.90 million, down from \$14.48 million in the prior quarter, reflecting reduced R&D, clinical trial, drug product manufacturing and staff costs.
- R&D tax refund of \$11.4 million received after the end of Q2, resulting in funds sufficient for at least five further quarters of operations (based on June quarter expenditure).
- The Company does not anticipate the need for additional public market capital during the remainder of 2020.

As previously disclosed, the Company expected a reduction in the rate of R&D, clinical trial and drug product manufacturing expenditure in Q2, due to the impact of the COVID-19 pandemic on elective healthcare activities, including clinical trials, in tertiary hospitals and medical centres.<sup>1</sup> The Company maintains the view that the statutorily reported "estimated quarters of funding available" remains conservative. Having received an \$11.4 million R&D tax refund after the end of Q2,<sup>2</sup> Telix affirms that, based on June quarter expenditure, it has adequate cash reserves to fund its operations for at least five quarters and to enable the first two commercial product launches.

Telix confirms that payments noted under section 6.1 of the accompanying Appendix 4C include payments to ABX-CRO advanced pharmaceutical services Forschungsgesellschaft<sup>3</sup> for the provision of clinical and analytical services for its programs, and to Directors for director fees.

### **Prostate Cancer Imaging and Therapy Program**

Telix's prostate cancer program comprises the prostate cancer imaging product TLX591-CDx (<sup>68</sup>Ga-PSMA-11) and the prostate cancer therapeutic product TLX591 (<sup>177</sup>Lu-DOTA-rosopitamab). Both the imaging and therapeutic products target prostate specific membrane antigen (PSMA), an important and well-validated drug target in prostate cancer.

The TLX591-CDx program is the Company's most advanced program, with the product currently used under investigational (IND), clinical trial and special access use in the United States and Europe.<sup>4</sup> In April, Telix submitted a marketing authorisation application (MAA) in Europe for TLX591-CDx. The submission was made to the Danish Medicines Agency (DKMA)

<sup>1</sup> ASX disclosure 22/04/20.

<sup>2</sup> ASX disclosure 21/07/20.

<sup>3</sup> Dr Andreas Kluge is a Non-Executive Director of Telix Pharmaceuticals Limited and General Manager of ABX-CRO advanced pharmaceutical services Forschungsgesellschaft.

<sup>4</sup> TLX591-CDx is an investigational product and has not received marketing authorisation in any jurisdiction.

in its capacity as a reference Competent Authority of a European member state. The DKMA will coordinate and lead the evaluation of Telix's MAA for TLX591-CDx on behalf of Denmark as well as a basket of 13 additional European member states that have been nominated by Telix.

Consistent with the current European Association of Urology (EAU) guidelines on prostate cancer imaging, Telix has applied for a MAA in Europe for TLX591-CDx for the clinical indication of imaging patients with elevated prostate-specific antigen (PSA) after radical prostatectomy or radiation therapy. This indication, which is broadly termed "biochemical recurrence" (BCR), is reported to occur in 20-40% and 30-50% of men who have undergone prostatectomy or radiation therapy with curative intent, respectively.

In June, Telix provided an update on the progress of its New Drug Application (NDA) for TLX591-CDx to the US Food and Drug Administration (FDA).<sup>5</sup> The Company indicated that new data reporting the superiority of <sup>68</sup>Ga-PSMA-11 prostate cancer imaging compared to conventional imaging in men with newly diagnosed high-risk prostate cancer had recently been published and that as a consequence, the Company was considering a broader dataset in its NDA submission. At this time, most modules of the NDA submission have been completed and the Company is currently preparing for filing (completion during Q3).

### **Renal Cancer Imaging and Therapy Program**

Telix's renal (kidney) cancer program comprises the kidney cancer imaging product TLX250-CDx (<sup>89</sup>Zr-girentuximab) and the kidney cancer therapeutic product TLX250 (<sup>177</sup>Lu-girentuximab). These products target carbonic anhydrase IX (CA9), which is highly expressed by clear cell renal cell carcinoma (ccRCC), the most common and aggressive form of kidney cancer. Telix expects TLX250-CDx to be the first diagnostic imaging agent to enable the non-invasive assessment of patients with suspected ccRCC.

Telix's ZIRCON trial is an international, multi-centre Phase III trial that compares pre-surgical imaging using TLX250-CDx in detecting ccRCC, with tissue histology in patients undergoing surgical resection. The ZIRCON trial is being conducted at 33 sites globally and will enrol approximately 250 patients. During the quarter, the Company successfully applied for FDA Breakthrough Designation (granted subsequent to the quarter<sup>6</sup>), an important accomplishment for the Company as it will potentially accelerate the FDA product review and approval process upon completion of the ZIRCON study.

While ZIRCON trial activity was paused during the period March to May due to the impact of COVID-19, the Company indicated in June<sup>7</sup> that the ZIRCON trial had recommenced patient recruitment in Europe, approximately 2-3 months ahead of expectation. Further sites in Australia, Canada, Turkey and USA are in the process of restarting clinical trial operations and are expected to resume patient enrolment during Q3.

### **Glioblastoma Program**

Glioblastoma multiforme (GBM) is the most common form of brain cancer and carries a poor prognosis, primarily due to there being few effective treatment options. Telix's GBM therapeutic product TLX101 (<sup>131</sup>I-IPA) targets LAT-1, a promising target in numerous cancer settings, 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.

<sup>5</sup> ASX disclosure 10/06/2020.

<sup>6</sup> ASX disclosure 01/07/2020.

<sup>7</sup> ASX disclosure 18/06/2020.

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Telix's IPAX-1 trial is an international, multi-centre Phase I/II trial that combines TLX101 with external beam radiation (XRT) in patients with recurrent GBM. The trial is being conducted at 6 sites in Europe and Australia and is currently completing the dose-escalation component of the study (22 out of 48 patients). Like the ZIRCON trial, trial activity was paused March-May due to COVID-19, but recruitment has now resumed in Europe with preliminary read-out expected end-2020.

### **Commercialisation Activities**

In April, Telix entered into a definitive commercial distribution agreement with Columbus, Ohio (USA) based Cardinal Health to provide radio-pharmacy and logistics services to support Telix's prostate cancer imaging product TLX591-CDx.<sup>8</sup> Under the terms of this agreement, Cardinal Health will prepare and deliver patient-specific unit-doses of TLX591-CDx for the US market, pending regulatory approval from the FDA.

Telix entered into a further commercial distribution agreement in May with Boca Raton, Florida (USA) based Pharmalogic Holdings Corp. to provide nuclear pharmacy and logistics services to support Telix's prostate cancer imaging product TLX591-CDx. Under the terms of this agreement, Pharmalogic will prepare and deliver patient-specific unit-doses of TLX591-CDx, for the US market through its network of 27 nuclear medicine pharmacies. Pharmalogic's nuclear medicine pharmacy network services predominantly regional and rural areas in the Midwest and Northeast regions of the United States.

Also in the quarter, Telix completed the acquisition of a licensed radiopharmaceutical production facility in Seneffe, Belgium from German company Eckert & Ziegler Strahlen und Medizintechnik AG (EZAG).<sup>9</sup> The Seneffe facility has one of the most extensive private sector medical isotope licences in Europe, which delivers significant operational flexibility to Telix and the ability to meet the Company's commercial production needs for its product portfolio in Europe. Completion of this acquisition required approval from Belgium's Federal Agency for Nuclear Control (FANC) for the transfer of the site's active radiation licence to Telix, as well as an amendment of the radiation licence to enable production and R&D activities to commence using the isotopes represented within Telix's product portfolio.

### **People**

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

In June, Dr Colin Hayward joined Telix as Chief Medical Officer, based in Raleigh, North Carolina (USA). Colin, who holds a Bachelor of Medicine degree from the University of London and is a Fellow of the Faculty of Pharmaceutical Medicine (UK) brings over 20 years of global pharmaceutical, biotechnology and drug development experience to Telix. Colin will lead the Company's medical affairs, regulatory, clinical operations and pharmacovigilance activities on a global basis.

In Europe, Telix's commercial team was strengthened significantly with the appointment of Mr Christian Davis as Vice President of Sales and Marketing, EMEA, based in the Frankfurt area (Germany). Christian, who brings to Telix over 20 years medical sales experience gained in the areas of oncology, radiology and nuclear medicine will lead Telix's European, Middle East

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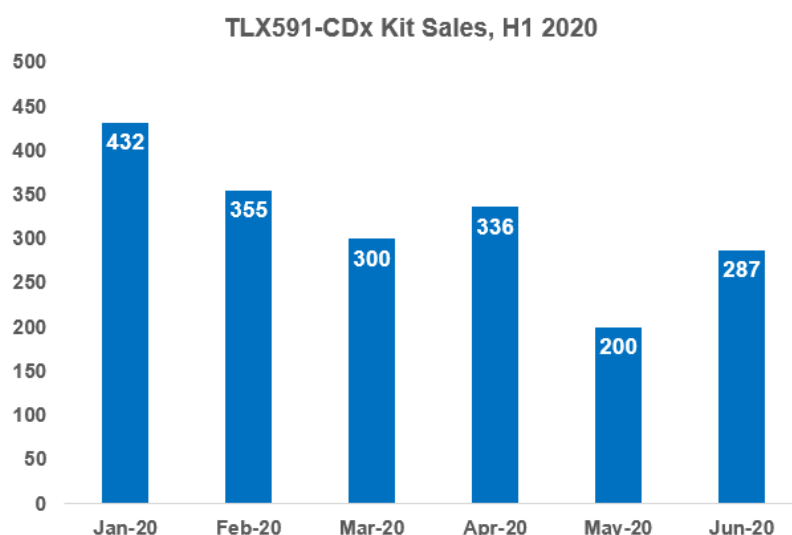
<sup>8</sup> ASX disclosure 08/04/2020.

<sup>9</sup> ASX disclosure 03/04/2020.

and African (EMEA) commercial activities, including via both direct and distributor sales channels.

### **Quarterly Sales (TLX591-CDx / illumet® Kit)**

During the quarter, Telix delivered approximately 2,000 individual patient doses prepared from TLX591-CDx prostate cancer imaging kits. The Company received A\$0.95M in cash from kit sales for the quarter, down 16% on the first quarter while pricing of the kit remained stable during the period.



Telix CEO Dr. Chris Behrenbruch stated, “In line with the guidance we provided in April <sup>10</sup>, COVID-19 has resulted in an expected reduction in prostate cancer imaging kit sales this quarter as many oncology and radiology services, including non-urgent surgeries were deferred to manage patient risk. Given the ongoing nature of the pandemic we expect that this trend will continue into the third quarter with fairly flat sales. While the revenue from these sales is not material to Telix’s cash runway, these sales do provide an important opportunity for early customer engagement and preparation ahead of commercial product launch.”

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### **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](http://www.telixpharma.com).

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<sup>10</sup> ASX Disclosure 22/04/2020.

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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 authorised for release by Dr Christian Behrenbruch, Managing Director and Chief Executive Officer.*

## 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")**

June 2020

| <b>Consolidated statement of cash flows</b>               | <b>Current quarter<br/>\$A'000</b> | <b>Year to date<br/>(6 months)<br/>\$A'000</b> |
|---|------------------------------------|--|
| <b>1. Cash flows from operating activities</b>            |                                    |  |
| 1.1 Receipts from customers                               | 954                                | 2,089  |
| 1.2 Payments for  |                                    |  |
| (a) research and development                              | (3,954)                            | (14,819)                                       |
| (b) product manufacturing and operating costs             | (266)                              | (1,230)  |
| (c) advertising and marketing                             | (31)                               | (98)   |
| (d) leased assets   | -                                  | -  |
| (e) staff costs   | (2,126)                            | (4,736)  |
| (f) administration and corporate costs                    | (1,395)                            | (2,557)  |
| 1.3 Dividends received (see note 3)                       | -                                  | -  |
| 1.4 Interest received                                     | 1                                  | 48   |
| 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)                   | (85)                               | (75)   |
| <b>1.9 Net cash from / (used in) operating activities</b> | <b>(6,902)</b>                     | <b>(21,378)</b>                                |

|  |    |      |
|--|----|------|
| <b>2. Cash flows from investing activities</b> |    |      |
| 2.1 Payments to acquire:                       |    |      |
| (a) entities                                   | -  | -    |
| (b) businesses                                 | -  | -    |
| (c) property, plant and equipment              | 49 | (66) |
| (d) investments                                | -  | -    |
| (e) intellectual property                      | -  | -    |

| Consolidated statement of cash flows |   | Current quarter<br>\$A'000 | Year to date<br>(6 months)<br>\$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                                  | <b>Net cash from / (used in) investing activities</b> | <b>49</b>                  | <b>(66)</b>                           |

|           |   |              |            |
|-----------|---|--------------|------------|
| <b>3.</b> | <b>Cash flows from financing activities</b>   |              |            |
| 3.1       | Proceeds from issues of equity securities (excluding convertible debt securities)       | 279          | 419        |
| 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   | (158)        | (182)      |
| 3.7       | Transaction costs related to loans and borrowings                                       | -            | -          |
| 3.8       | Dividends paid  | -            | -          |
| 3.9       | Other (Leased assets)   | (274)        | (333)      |
| 3.10      | <b>Net cash from / (used in) financing activities</b>                                   | <b>(153)</b> | <b>363</b> |

|           |  |         |          |
|-----------|--|---------|----------|
| <b>4.</b> | <b>Net increase / (decrease) in cash and cash equivalents for the period</b> |         |          |
| 4.1       | Cash and cash equivalents at beginning of period                             | 34,491  | 44,598   |
| 4.2       | Net cash from / (used in) operating activities (item 1.9 above)              | (6,902) | (21,378) |

| Consolidated statement of cash flows |   | Current quarter<br>\$A'000 | Year to date<br>(6 months)<br>\$A'000 |
|--------------------------------------|---|----------------------------|---------------------------------------|
| 4.3                                  | Net cash from / (used in) investing activities<br>(item 2.6 above)  | 49                         | (66)                                  |
| 4.4                                  | Net cash from / (used in) financing activities<br>(item 3.10 above) | (153)                      | 363                                   |
| 4.5                                  | Effect of movement in exchange rates on<br>cash held                | (3,107)                    | 861                                   |
| 4.6                                  | <b>Cash and cash equivalents at end of<br/>period</b>               | <b>24,378</b>              | <b>24,378</b>                         |

| 5.  | Reconciliation of cash and cash<br>equivalents<br>at the end of the quarter (as shown in the<br>consolidated statement of cash flows) to the<br>related items in the accounts | Current quarter<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances   | 24,378                     | 34,491                      |
| 5.2 | Call deposits   | -                          | -                           |
| 5.3 | Bank overdrafts   | -                          | -                           |
| 5.4 | Other (provide details)   | -                          | -                           |
| 5.5 | <b>Cash and cash equivalents at end of<br/>quarter (should equal item 4.6 above)</b>  | <b>24,378</b>              | <b>34,491</b>               |

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

| Current quarter<br>\$A'000 |
|----------------------------|
| 619                        |
| -                          |

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.*

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

| Total facility amount at quarter end<br>\$A'000 | Amount drawn at quarter end<br>\$A'000 |
|---|--|
| Nil   | Nil                                    |
| Nil   | Nil                                    |
| Nil   | Nil                                    |
| 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.

N/A

**8. Estimated cash available for future operating activities**

**\$A'000**

|     |   |         |
|-----|---|---------|
| 8.1 | Net cash from / (used in) operating activities (Item 1.9)                     | (6,902) |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6)                           | 24,378  |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5)                 | Nil     |
| 8.4 | Total available funding (Item 8.2 + Item 8.3)                                 | 24,378  |
| 8.5 | <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b> | 3.5     |

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

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

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

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

### 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: 27 July 2020

Authorised by: Mr Doug Cubbin, Chief Financial Officer

(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.