

**Telix Pharmaceuticals Limited** 

Suite 401, 55 Flemington Road North Melbourne, VIC, 3051

ABN: 85 616 620 369

# Appendix 4D Half-year report for the six months ended 30 June 2021

#### Results for announcement to the market

Current Reporting Period: 30 June 2021
Previous Reporting Period: 30 June 2020

	6 months to 30 June 2021 \$000	6 months to 30 June 2020 \$000	Movement \$000	Movement %
Revenue from continuing operations	2,910	1,607	1,303	81%
Other income: R&D tax incentive income	4,598	5,850	(1,252)	(21%)
Loss after income tax for the half-year attributable to members	(32,514)	(18,301)	(14,213)	78%
Total comprehensive loss for the half- year attributable to members	(33,436)	(17,622)	(15,814)	90%

NTA backing	30 June 2021 \$	30 June 2020 \$
Net tangible asset backing per ordinary security	(0.03)	0.04

#### Events subsequent to the end of the half-year

Refer page 8 of the Interim Financial Report for details of events subsequent to 30 June 2021 and at the date of this report.

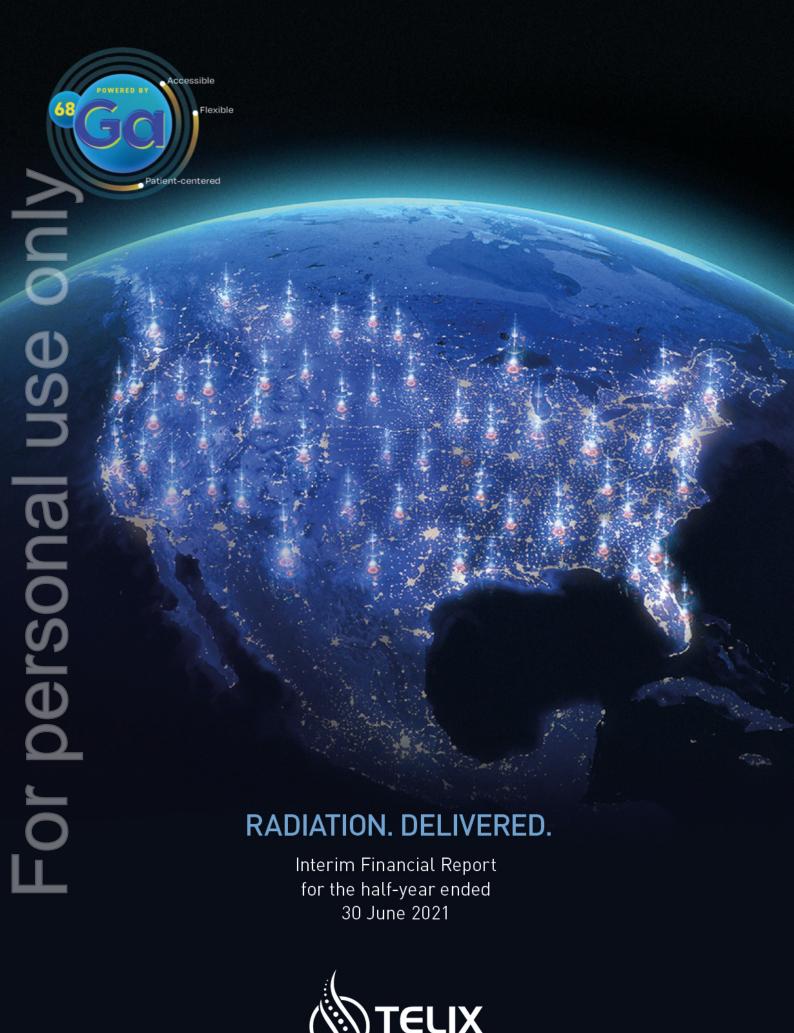
#### **Review of results**

The Directors' Report attached to this Appendix 4D details the review of results. This information should be read in conjunction with the most recent Annual Financial Report (31 December 2020).

#### **Auditor's Review**

This report is based on the Interim Financial Report for the half-year ended 30 June 2021 of Telix Pharmaceuticals Limited and its controlled entities, which has been reviewed by PricewaterhouseCoopers (PwC). The Independent Auditor's Review Report provided by PwC is included in the Interim Financial Report.

The Appendix 4D and Interim Financial Report for the half-year ended 30 June 2021 have been approved for release by the Board of Directors.



# **COMPANY DIRECTORY**

#### **Directors**

H Kevin McCann AO (Chairman)
Christian P Behrenbruch PhD MBA (MD and CEO)
Oliver Buck
Andreas Kluge MD PhD
Mark Nelson PhD
Jann Skinner

#### **Company Secretary**

Melanie Farris

#### Registered Office

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#### Australian Business Number

85 616 620 369

#### Securities Exchange Listing

Australian Securities Exchange ASX Code: TLX

#### Auditor

PricewaterhouseCoopers
2 Riverside Quay
Southbank VIC 3006

#### **Share Registry**

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Your Directors present their interim report on Telix Pharmaceuticals Limited (Telix or the Company) and its subsidiaries (collectively, the Group) for the half-year ended 30 June 2021.

The names of the Company's Directors in office during the half-year and until the date of this report are set out below. Directors were in office for this entire period.

H Kevin McCann AO Chairman

Christian P Behrenbruch PhD MBA Managing Director and Chief Executive Officer

Oliver Buck Non-Executive Director Andreas Kluge MD PhD Non-Executive Director Mark Nelson PhD Non-Executive Director Jann Skinner Non-Executive Director

#### **REVIEW OF RESULTS**

Telix Pharmaceuticals Limited is a radiopharmaceutical 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 products that address significant unmet medical need in oncology and rare diseases. Telix was established on 3 January 2017 and listed on the Australian Securities Exchange on 15 November 2017.

The total comprehensive loss for the half-year ended 30 June 2021 was \$33,436,000 (2020: \$17,622,000). No dividend was proposed or paid during the period.

Telix made significant progress towards its objective of transitioning to a commercial-stage, financially sustainable, revenue-generating company. While the Company's corporate objectives aim to advance all aspects of the business, the three most important milestones Telix aims to achieve this financial year are:

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

With interest and activity building in the field of prostate cancer MTR for both diagnostic and therapeutic use, Telix has been working closely with suppliers and distribution partners to ensure that the roll-out of illuccix®, its first planned commercial product, is delivered seamlessly and without delay, subject to requisite regulatory approvals worldwide.

Activities during the half-year were directed to advancing each of the Group's four lead programs in prostate, kidney, brain, and hematologic (blood) cancers and rare diseases, as well as strengthening strategic commercial global partnerships.

#### **Program Achievements H121**



- Illuccix®, TLX591-CDx

  ✓ Marketing authorisation submissions progressing in 17 countries
- Czech temporary national authorisation (Feb)
- TGA commenced priority evaluation (Apr)
- First patient dosed in Japanese study (May) ✓ FDA late-cycle review meeting (Jun)

#### TI X599-CDx

√ NOBLE Registry launched and FPI (Apr)

# Prostate cancer therapy

TI X591

ProstACT Ph III study granted HREC approval and CTN clearance by the TGA (May)



#### Kidney cancer imaging

TLX250-CDx

- √ First US patients dosed in ZIRCON trial (Jan)
- ✓ ZIRDAC-JP study reports safety and tolerability in Japanese patients (Apr)
- Indication expansion first patient dosed in Ph I 'ZiP-UP' study of patients with urothelia carcinoma or bladder cancer (June)

## Kidney cancer therapy

✓ Design finalised for Ph II STARLITE-2 trial



TLX101

Encouraging interim analysis of safety and preliminary efficacy reported in the IPAX-1 study (Jun)



#### Rare disease & bone marrow conditioning

Initial positive results reported for safety and tolerability in the TRALA study (May)

#### **REVIEW OF OPERATIONS**

#### 1. COMMERCIALISATION ACTIVITIES

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 Goods 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, United States facility for the United States, Canada, European Union and Australian markets.

Also in March 2021, 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 April 2021, a strategic manufacturing agreement was completed with Global Medical Solutions, Ltd. (GMS) to manufacture and supply finished unit doses of Telix's MTR products for certain clinical development programs in Australia, including TLX591 and TLX592 for Telix's planned ProstACT and CUPID clinical trials, respectively.

In May 2021, Telix entered into an exclusive commercial distribution agreement with Berlin-based Eckert & Ziegler Strahlen und Medizintechnik AG (EZAG) for illuccix® in the German market. Under the terms of the agreement, EZAG will be the exclusive commercial distributor of illuccix® in Germany once the marketing authorisation has been granted by the German health authorities, which is anticipated to occur in late 2021.

Telix and EZAG further reinforced their collaboration by announcing a co-promotion agreement in the United States in June 2021, for the combination of illuccix® and EZAG's GalliaPharm® (gallium-68 generator).

#### 2. PROSTATE CANCER PROGRAM

Telix's core prostate cancer research portfolio comprises the investigational prostate cancer imaging products illuccix® and TLX599-CDx (99mTc-PSMA-11), and the prostate cancer therapy candidate TLX591 (177Lu-DOTA-rosopatamab). Each of these products targets prostate specific membrane antigen (PSMA), which is an important and well-validated drug target in prostate cancer.

Illuccix®, an investigational diagnostic imaging agent for PSMA-PET imaging of prostate cancer, will be Telix's first commercial product. PSMA-PET 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.

Telix anticipates that illuccix® will be the first <sup>68</sup>Ga-PSMA based imaging agent to receive full United States Food and Drug Administration (FDA) approval, following limited institutional approvals at University of California, Los Angeles (UCLA), and University of California, San Francisco (UCSF) in late 2020. A key competitive advantage of gallium-based radiopharmaceuticals is that the isotope can be produced by either cyclotron or generator, offering greater flexibility and opportunity for scale than other purely cyclotron-based isotopes. Subject to marketing authorisation, illuccix® will be able to rapidly scale to deliver state of the art prostate cancer imaging to ~95% of men in the United States via nationwide nuclear pharmacy and logistics agreements with Cardinal Health (NYSE: CAH) and Pharmalogic Holdings Corp.

# Prostate cancer imaging

#### Illuccix® - commercial launch activities

As at the end of June, marketing authorisation applications for illuccix® were under review and progressing in 17 countries (United States, Canada, 13 European Union member states, United Kingdom, Australia).

In February 2021, 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 lifesaving treatment is not indicated

Telix is collaboratively pursuing similar temporary authorisations for illuccix<sup>®</sup> in several other European countries in parallel with its primary marketing authorisation application submitted in April 2020.

In April 2021, the Australian Therapeutic Goods Administration (TGA) accepted the Company's submission for the registration of illuccix<sup>®</sup> and commenced its priority evaluation process. The TGA has indicated a target decision date (approval date) for its priority evaluation of illuccix<sup>®</sup> of 12 November 2021.

During May 2021, a first patient was dosed in a clinical study in Japan using illuccix<sup>®</sup>, in an academic collaboration between Telix and Kanazawa University. The study is the first clinical evaluation of gallium-based PSMA imaging in Japan, with the objective to obtain safety data in a representative Japanese patient population, and to demonstrate that the targeting and biodistribution of TLX591-CDx in Japanese patients is consistent with international experience. Clinical data may facilitate development planning discussions with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and other Asian regulators.

In June 2021, a late-cycle review meeting took place with the FDA regarding the ongoing review of the New Drug Application (NDA) for illuccix<sup>®</sup>, with the FDA indicating that there are no outstanding substantive review issues with Telix's submission.

#### TLX599-CDx - NOBLE Registry

In April 2021, the international NOBLE (Nobody Left Behind) Registry of Telix's 'rest of world' prostate cancer imaging agent TLX599-CDx (99mTc-HYNIC-iPSMA) was launched with the Oncidium Foundation, with sites in Nigeria and Egypt dosing their first patients. TLX599-CDx is being developed by Telix to facilitate patient access to advanced prostate cancer imaging in countries where single photon emission computed tomography (SPECT) imaging is predominant in healthcare facilities. Whereas illuccix® utilises PET, TLX599-CDx employs SPECT, a diagnostic imaging technology that is widely available in healthcare facilities throughout the world.

#### Prostate cancer therapy

Telix's ProstACT trial of TLX591 was granted Human Research Ethics Committee (HREC) approval and received Clinical Trial Notification (CTN) clearance by the TGA in May 2021. The Phase III trial is an international, multi-centre, randomised controlled trial (RCT) in patients with PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC), experiencing disease progression following prior treatment with a novel androgen axis drug (NAAD). The ProstACT trial will enrol approximately 390 patients and incorporates patient selection using <sup>68</sup>Ga-PSMA imaging with illuccix®. The trial will compare standard of care therapy alone versus standard of care therapy plus TLX591, with a primary endpoint of radiographic progression-free survival (rPFS). Trial secondary endpoints will include overall survival and quality-of-life assessment. Telix has commenced the initiation of Australian ProstACT trial sites and will add global sites progressively during the second half of 2021, subject to the requisite approvals.

#### **TLX592**

During the first half of 2021, study set-up activities were completed 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 (<sup>225</sup>Ac-RADmAb®) employs Telix's proprietary RADmAb® engineered antibody technology and, as with TLX591, targets PSMA. 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 <sup>225</sup>Ac, a potent therapeutic alpha emitting radionuclide.

#### 3. RENAL CANCER PROGRAM

#### Renal cancer imaging

Telix's investigational kidney cancer imaging product TLX250-CDx (89Zr-DFO-girentuximab) and the kidney cancer therapeutic candidate TLX250 (177Lu-girentuximab), represent the key assets in the Company's kidney cancer program. Each of these products targets carbonic anhydrase IX (CA9), a cancer target that is highly expressed by several tumour types including clear cell renal cell carcinoma (ccRCC), the most common and aggressive form of kidney cancer.

Telix expects that TLX250-CDx will be its second product to be commercialised, becoming the first PET imaging agent to enable the non-invasive assessment of patients with suspected ccRCC. Improved detection of ccRCC (including metastatic disease, which also expresses CA9) with PET/CT imaging could lead to more accurate staging. This could reduce the need for renal biopsy and the proportion of partial or radical nephrectomies performed to remove localised renal masses that are subsequently shown to have benign or indolent histopathology. TLX250-CDx has been granted Breakthrough Therapy (BT) designation by the FDA, conferring 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).

In January 2021, Telix's international, multi-centre, Phase III ZIRCON trial of TLX250-CDx enrolled and dosed its first patients in the United States after a period of delay due to the COVID-19 pandemic. The ZIRCON trial includes twelve participating sites in the United States and Canada, and 34 participating sites globally.

During 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. Importantly, the results of this study further 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.

#### TLX250-CDx indication expansion

In June 2021, a first patient was dosed in a Phase I study of TLX250-CDx in patients with urothelial carcinoma or bladder cancer. ZiP-UP is the first in a series of studies that will harness TLX250-CDx to evaluate CA9 expression in cancers other than renal cancer, currently the focus of the ZIRCON (imaging) and STARLITE (therapy) studies. Other collaborative studies are in development for ovarian, triple negative breast, colorectal, head and neck, lung, and pancreatic cancers.

#### Renal cancer therapy

During the first half of 2021, the design was finalised for 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, United States) in 3Q21, pending the FDA's granting of an Investigational New Drug Application (IND).

#### 4. GLIOBLASTOMA PROGRAM

Glioblastoma, also known as glioblastoma multiforme (GBM), is the most common and aggressive form of brain cancer and carries a poor prognosis, primarily due to there being few effective treatment options. Telix's GBM therapeutic product TLX101 (131I-IPA) targets LAT-1, a promising target in several cancer types, including glioblastoma. TLX101 is a novel approach that is readily able to pass through the blood-brain barrier, the normal protective barrier prevents many other potential drug candidates from entering the brain.

Telix's IPAX-1 trial is an international, multi-centre Phase I/II trial that combines TLX101 with external beam radiation therapy (EBRT) in patients with recurrent GBM.

In June 2021, an update was released for IPAX-1, with interim analysis of safety and preliminary efficacy sufficiently encouraging to warrant study in front-line therapy, where radiation therapy is more extensively used. Complete safety and efficacy data will be released upon completion of the study report, and a follow-on study is currently in planning to accelerate the development of TLX101 in this important therapy area with high unmet medical need.

#### 5. RARE DISEASE AND BONE MARROW CONDITIONING PROGRAM

In December 2020, Telix acquired Swiss-German biotechnology company TheraPharm GmbH, expanding the Company's pipeline to hematologic oncology, bone marrow transplantation and rare diseases. TLX66 (90Y-besilesomab) targets CD66, a receptor expressed on specific types of immune/blood cells, and has been granted orphan drug designation (ODD) status in Europe for bone marrow conditioning (BMC) for hematopoietic stem cell transplantation (HSCT), a broad clinical indication.

Prior Phase I and II clinical studies of TLX66 have demonstrated encouraging efficacy and safety data in multiple myeloma, pediatric leukemia and systemic amyloid light chain amyloidosis (SALA), a rare disease with a poor prognosis characterised by abnormal protein deposition in the organs of the body.

During May 2021, initial results for safety and tolerability were reported for the TRALA (Targeted Radiotherapy for AL-amyloidosis) trial, a Phase I/IIa trial at the University of Southampton, United Kingdom. The study found that TLX66 was well-tolerated, enabling successful engraftment of the patients' own transplanted stem cells without the need for toxic chemotherapy. This indicates that TLX66 may offer a new approach to bone marrow conditioning in patients who could benefit from HSCT such as those with AL-amyloidosis. With all patients remaining alive, and most not requiring further therapy, the data supports taking TLX66 forward into a pivotal registration study in this rare disease indication in collaboration with the amyloid community of patients and physicians.

#### 6. RESEARCH PARTNERSHIPS

During February 2021, Telix formalised its strengthening relationship with Heidelberg University Hospital in Germany (UKHD) by the signing of a research cooperation agreement to develop next generation theranostic radiopharmaceuticals for urologic oncology. The goal of the collaboration is to identify candidates and generate sufficient data to proceed to first-in-human trials, with all candidates being evaluated in a pre-clinical study (in vitro and in vivo analysis, toxicology, and manufacturing suitable for clinical translation).

In June, the Company was jointly awarded a €990K (\$1,560,000) Eurostars-2 research grant with Swedish radiopharmaceutical production company Alpha Therapy Solutions (ATS) from the EUREKA Association in Europe. The Eurostars program supports international innovative projects involving at least two different participants from

different Eurostars countries and led by R&D-performing small and medium-sized enterprises. Eurostars projects are awarded access to public funding, which originates from participating countries' national budgets and the European Union Horizon 2020 framework.

Funding has been awarded to Telix and ATS to develop a novel anti-cancer TAT using the alpha-particle emitting radioisotope; astatine-211. The scope of the project, with a budget of €990K over three years, comprises scale up radiochemistry, preclinical studies and support for a clinical proof-of-concept study. The efficient scale-up production of astatinated radiopharmaceuticals is made possible through the use of ATS' novel automated astatine production platform.

#### 7. PEOPLE

As Telix transitions to a commercial stage, revenue-generating company it is vitally important for the Company to continue to recruit and develop its outstanding team, and harness the strength of diversity and talent that is present worldwide.

In May 2021, Richard Valeix joined Telix as President, Europe, Middle East and Africa (EMEA). Richard brings twenty years of pharmaceutical industry experience, including radiopharmaceuticals, gained in senior executive leadership roles across a broad range of therapeutic product areas. Prior to joining Telix, Richard worked at Advanced Accelerator Applications (AAA), a Novartis Company, where he served for seven years in the roles of General Manager for France, Switzerland, Belgium, Netherlands and Luxembourg, and Global Head of Marketing and Sales.

Also in May, Telix announced the establishment of an Asia-Pacific (APAC) operating region, with David Cade MD as President. David, who has served as Telix's Chief Business Officer and Head of Investor Relations since joining Telix in 2019, will lead Telix's commercial activities across the Asia-Pacific region, including the anticipated approval of illuccix® in Australia and other regional territories.

#### **CHANGES TO ISSUED CAPITAL**

#### Issue of unlisted share options

On 28 January 2021, the Company agreed to issue 2,226,856 unlisted share options with an exercise price of \$4.38 each and an expiry date of 27 January 2026 (TLXO009). The options were issued to staff and key advisors to the Company. This number includes 100,708 options agreed to be issued to Managing Director and CEO, Christian Behrenbruch following shareholder approval at the Company's Annual General Meeting of Shareholders on 12 May 2021.

#### Exercise of unlisted share options

A total of 1,218,086 fully paid ordinary shares were issued upon exercise of 1,266,600 unlisted share options during the half-year ended 30 June 2021:

- On 2 March 2021, 550,000 options with an exercise price of \$0.85 each and an expiry date of 14 October 2021 were exercised
- On 9 March 2021, 100,000 options with an exercise price of \$0.85 each and an expiry date of 14 October 2021 were exercised
- On 25 March 2021, 366,600 options with an exercise price of \$0.85 each and an expiry date of 14 October 2021 were exercised
- On 30 June 2021, 250,000 options with an exercise price of \$0.85 each and an expiry date of 14 October 2021 were exercised

#### Subsequent to the end of the half-year

On 19 July 2021, a total of 1,018,574 share options lapsed unexercised. These options lapsed following the cessation of employment of the option holder and the subsequent cancellation of options in accordance with the terms of their grant:

- 200,000 options with an exercise price of \$1.09 and an expiry date of 24 January 2023 (TLXO004)
- 400,000 options with an exercise price of \$2.30 and an expiry date of 3 November 2023 (TLXO005)
- 330,000 options with an exercise price of \$2.23 and an expiry date of 12 January 2024 (TLXO006)
- 50,000 options with an exercise price of \$1.83 and an expiry date of 30 June 2024 (TLXO007)
- 38,574 options with an exercise price of \$4.38 and an expiry date of 27 January 2026 (TLXO009)

On 21 July 2021 the Company issued 1,292,992 unlisted share options to new employees. Options have an exercise price of \$5.37 each (being the 10 day volume weighted average price of shares to 20 July 2021), and an expiry date of 20 July 2026 (TLXO010). All options vest and become exercisable upon the achievement of \$100M in cumulative revenue (before cost of goods sold) from product sales.

Also on 21 July 2021, the Company issued 225,000 unlisted Rights to acquire fully paid ordinary TLX shares. Each Right was issued for nil consideration and has a nil exercise price. Subject to performance and other conditions being met, Rights will vest and become exercisable on or before 20 July 2026. Rights lapse on 19 July 2026 (TLXO011). TLX shares to be allocated following vesting of Rights are currently on issue and held in the Telix Employee Share Trust. Rights were issued in line with the Company's Equity Incentive Plan and long-term incentive policy for key employees.

#### TOTAL NUMBER OF SHARES AND OPTIONS ON ISSUE

	31 December 2020	30 June 2021	At the date of this Report
Shares on issue	280,405,322	281,623,408	281,623,408
Options on issue	20,226,000	21,967,679	22,467,097

#### **EVENTS AFTER THE REPORTING PERIOD**

In July 2021, Telix reported that the Phase III ZIRCON trial of renal imaging investigational product TLX250-CDx had exceeded 50% recruitment, with more than 80% of study sites back recruiting into clinical trials. Recruitment has significantly accelerated in recent months and indicative patient recruitment is 5-10 patients per week. Given that the duration of study participation for patients on the ZIRCON trial is 42 days, Telix expects to commence the FDA BLA consultation process before end-calendar year, as planned.

Also in July 2021, Telix received authorisation from the Belgian Agence Fédérale de Contrôle Nucléaire (AFCN) to decommission the first of two cyclotrons housed at the Company's licensed radiopharmaceutical production facility in Seneffe, Belgium. The authorisation means that the AFCN has accepted Telix's decommissioning dossier, submitted with the support of SCK-CEN (the Belgian Nuclear Research Centre), and is satisfied that safety and operational requirements will be met. This represents a significant milestone for Telix since it will enable the build-out of a state-of-the-art nuclear facility that will ultimately serve as the Company's primary European manufacturing site.

In August 2021, a first patient was dosed in a first-in-human Phase I CUPID study of the Company's next generation prostate cancer therapy candidate TLX592. This investigational agent will become Telix's first targeted alpha therapy (TAT) for the treatment of patients with advanced prostate cancer. The CUPID study, which is being conducted in collaboration with GenesisCare, will recruit up to 15 patients and will initially use copper-64 (64Cu)-labelled TLX592, as a PET imaging agent, to evaluate biodistribution and dosing, before proceeding to studies with actinium-225 (225Ac) TAT

Also in August 2021, Telix announced that the London-based Great Ormond Street Hospital (GOSH), an international centre of excellence in child healthcare, received ethics approval to commence a Phase II academic study of Telix's investigational product, TLX66 (90Y-DTPA-besilesomab), in children with high-risk leukemia. The open label Phase II study is being carried out by GOSH to evaluate safety and efficacy of TLX66 as part of a reduced toxicity conditioning regimen in children and adolescents undergoing allogeneic HSCT. The independent trial will enrol 25 patients and follows the successful completion of a Phase I study, full results of which are expected to be published in late 2021.

During August 2021, Telix announced a pan-cancer clinical collaboration with Merck KGaA, Darmstadt, Germany (Merck), to conduct combination studies with one of Merck's investigational proprietary DNA Damage Response Inhibitor (DDRi) molecules in combination with each of Telix's TLX591 and TLX250 therapeutic programs. This clinical collaboration builds on encouraging pre-clinical data derived from the initial strategic research collaboration between Telix and Merck announced in August 2019.

In August 2021, Telix also announced an indication expansion into breast cancer with two new investigator-led studies initiated to evaluate the potential utility of TLX591-CDx and TLX250-CDx in invasive lobular carcinoma (ILC) and triple negative breast cancer (TNBC), respectively. The study of TLX591-CDx at Winship Cancer Institute of Emory University will recruit 20 patients over two years. TLX591-CDx targets glutamate carboxypeptidase II (GCPII), more generally known as PSMA, a protein that is highly expressed in many cancers, including ILC. While Telix has filed for regulatory approval of TLX591-CDx in prostate cancer imaging (investigational product *illuccix*® kit), this study marks the first formal clinical investigation of TLX591-CDx in another indication of interest. The study of TLX250-CDx in TNBC (OPALESCENCE) will be conducted at the Institut de Cancérologie de l'Ouest in St Herblain, France, and will recruit 12 patients. OPALESCENCE follows ZiP-UP as the second of a comprehensive series of studies that will evaluate CA9 expression in cancers other than ccRCC. Both ILC and TNBC can be extremely aggressive with unmet medical need

in both accurate staging and therapeutic delivery. These studies support Telix's goal of rapid indication expansion, alongside executing the Company's near-term commercial and clinical goals for TLX591-CDx and TLX250-CDx.

No other matter or circumstance has arisen since 30 June 2021 that has significantly affected the Group's operations, results or state of affairs.

#### **ROUNDING OF AMOUNTS**

The company is of a kind referred to in ASIC Legislative Instrument 2016/191, relating to the 'rounding off' of amounts in the Directors' Report. Amounts in the Directors' Report have been rounded off in accordance with the instrument to the nearest thousand dollars, or in certain cases, to the nearest dollar.

#### **AUDITOR INDEPENDENCE**

A statement of independence has been provided by the Company's auditor, PricewaterhouseCoopers, and is included in this report.

This report is made in accordance with a resolution of Directors.

H Kevin McCann AO

Chairman

19 August 2021

Christian P Behrenbruch PhD MBA
Managing Director and Chief Executive Officer

19 August 2021



# Auditor's Independence Declaration

As lead auditor for the review of Telix Pharmaceuticals Limited for the half-year ended 30 June 2021, I declare that to the best of my knowledge and belief, there have been:

- (a) no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- (b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Telix Pharmaceuticals Limited and the entities it controlled during the period.

Brad Peake Partner

PricewaterhouseCoopers

Melbourne 19 August 2021

PricewaterhouseCoopers, ABN 52 780 433 757

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# INTERIM CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

for the half-year ended 30 June 2021

	Note	30 June 2021 \$'000	30 June 2020 \$'000
Continuing operations			
Revenue	5.1	2,910	1,607
Cost of inventory sold		(875)	(917)
Research and development costs	5.2	(13,670)	(8,605)
Administration and corporate costs	5.2	(6,519)	(2,690)
Depreciation and amortisation	5.2	(2,546)	(2,335)
Employment costs	5.2	(10,631)	(7,169)
Remeasurement of provisions	12	(3,394)	(4,641)
Finance costs	5.2	(2,505)	(1,246)
Other income and expenses	5.3	4,782	6,750
Loss before income tax		(32,448)	(19,246)
Income tax (expense)/benefit	5.4	(66)	945
Loss for the half-year		(32,514)	(18,301)
Loss is attributable to:			
Owners of Telix Pharmaceuticals Limited		(32,514)	(18,301)
Other comprehensive income Items to be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		(922)	679
Total comprehensive loss for the half-year		(33,436)	(17,622)
Total comprehensive loss for the half-year is attributable to:			
Owners of Telix Pharmaceuticals Limited		(33,436)	(17,622)
Basic loss per share from continuing operations		Cents	Cents
attributable to the ordinary equity holders of the company		(11.56)	(7.22)
Diluted loss per share from continuing operations attributable to the ordinary equity holders of the company		(11.56)	(7.22)

The interim consolidated statement of total comprehensive income is to be read in conjunction with the accompanying notes.

# INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION as at 30 June 2021

	Note	30 June 2021 \$'000	31 December 2020 \$'000
Current assets			
Cash and cash equivalents		49,615	77,945
Trade and other receivables	6	17,203	12,399
Inventories		889	633
Other current assets		2,598	2,651
Total current assets		70,305	93,628
Non-current assets			
Property, plant and equipment	7	4,582	4,821
Intangible assets	8	53,773	59,189
Non-current trade and other receivables		183	183
Total non-current assets		58,538	64,193
Total assets		128,843	157,821
Current liabilities			
Trade and other payables	9	11,144	10,892
Borrowings		43	264
Lease liabilities	10	509	503
Contract liabilities	11	3,038	3,235
Provisions	12	5,831	3,053
Employee benefit obligations		1,723	2,009
Total current liabilities		22,288	19,956
Non-current liabilities			
Borrowings		-	95
Lease liabilities	10	1,144	1,345
Contract liabilities	11	27,993	27,515
Provisions	12	29,365	29,894
Employee benefit obligations		123	-
Total non-current liabilities		58,625	58,849
Total liabilities		80,913	78,805
Net assets		47,930	79,016
Equity			
Share capital	14	167,908	167,058
Foreign currency translation reserve		(623)	299
Share-based payments reserve	14	6,120	4,620
Accumulated losses		(125,475)	(92,961)
Total equity		47,930	79,016

The interim consolidated statement of financial position is to be read in conjunction with the accompanying notes.

# INTERIM CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

for the half-year ended 30 June 2021

Total \$'000	Share-based payments reserve \$'000	Foreign currency translation reserve \$'000	Accumulated losses \$'000	Share capital
\$ 000	\$ 000	\$ 000	<del>\$ 000</del>	\$ 000
79,016	4,620	299	(92,961)	167,058
(32,514)	-	-	(32,514)	-
(922)	-	(922)	-	-
(33,436)	-	(922)	(32,514)	-
850	-	-	-	850
1,500	1,500	-	-	-
47,930	6,120	(623)	(125,475)	167,908

	Share capital \$'000	Accumulated losses \$'000	Foreign currency translation reserve \$'000	Share-based payments reserve \$'000	Total equity \$'000
Balance at 1 January 2020	115,943	(48,074)	(62)	2,274	70,081
Loss for the half-year	-	(18,301)	-	-	(18,301)
Other comprehensive income	-	-	679	-	679
Total comprehensive loss for the half-year	-	(18,301)	679	-	(17,622)
Issue of shares on exercise of options	419	-	-	-	419
Movements in share-based payments reserve	-	-	-	843	843
Balance at 30 June 2020	116,362	(66,375)	617	3,117	53,721

Balance at 1 January 2021

Other comprehensive loss

Total comprehensive loss

Issue of shares on exercise

Movements in share-based

Balance at 30 June 2021

Loss for the half-year

for the half-year

payments reserve

of options

The interim consolidated statement of changes in equity is to be read in conjunction with the accompanying notes.

# INTERIM CONSOLIDATED STATEMENT OF CASH FLOWS

for the half-year ended 30 June 2021

	30 June 2021 \$'000	30 June 2020 \$'000
Cash flows from operating activities		
Receipts from customers	1,813	2,079
Payments to suppliers and employees	(30,376)	(20,571)
Interest received	-	48
Interest paid	(85)	(28)
Net cash outflow from operating activities	(28,648)	(18,472)
Cash flows from investing activities		
Purchase of plant and equipment	(329)	(200)
Purchase of intangible assets	(3)	-
Payments reducing decommissioning liability	(446)	(444)
Net cash outflow from investing activities	(778)	(644)
Cash flows from financing activities		
Proceeds from issues of shares and other equity	850	419
Proceeds from borrowings	-	573
Repayment of borrowings	(316)	(288)
Principal element of lease payments	(195)	(218)
Net cash inflow from financing activities	339	486
	(00.007)	(40,000)
Net decrease in cash held	(29,087)	(18,630)
Cash and cash equivalents at beginning of the half- year	77,945	44,598
Net foreign exchange differences	757	(1,590)
Cash and cash equivalents at end of the half-year	49,615	24,378

The interim consolidated statement of cash flows is to be read in conjunction with the accompanying notes.

#### 1. CORPORATE INFORMATION

Telix Pharmaceuticals Limited (Telix or the Company) is a for profit company limited by shares incorporated in Australia whose shares have been publicly traded on the Australian Securities Exchange since its listing on 15 November 2017 (ASX: TLX). Telix is an oncology company that is developing a pipeline of MTR products for unmet needs in cancer care. Telix is the Parent company of the Telix Pharmaceuticals Group (the Group).

This consolidated financial report of Telix Pharmaceuticals Limited for the half-year ended 30 June 2021 was authorised for issue in accordance with a resolution of the Directors on 19 August 2021.

#### 2. SIGNIFICANT CHANGES IN THE CURRENT REPORTING PERIOD

Although global market conditions have affected market confidence, the Group remains well placed to deliver on its corporate objectives. The Group has reviewed its exposure to COVID-19 and other business risks. At the date of this report the Group has not identified any risks, other than those described in the report, that could impact the financial performance or position of the Group.

#### 3. SEGMENT REPORTING

The Telix Pharmaceuticals Group is an oncology group with operations in Australia, the United States, Belgium and Japan. The Group does not currently consider that the risks and returns of the Group are affected by differences in either the products or services it provides, nor the geographical areas in which the Group operates. As such the Group operates as one segment. Group performance is evaluated based on operating profit or loss and is measured consistently with profit or loss in the financial statements. Group financing (including finance costs and finance income) and income taxes are managed on a Group basis.

#### 4. BASIS OF PREPARATION AND CHANGES TO THE COMPANY'S ACCOUNTING POLICIES

This consolidated interim financial report for the half-year reporting period ended 30 June 2021 has been prepared in accordance with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Act 2001 (Cth). This interim report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 31 December 2020 and any public announcements made by Telix Pharmaceuticals Limited during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act. The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

A number of new or amended standards became applicable for the current reporting period, including amendments to the guidance in IFRS 3 *Business Combinations* that revises the definition of a business. The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these standards. The Group has identified that there is no impact of new standards issued but not yet applied.

#### 4.1 Going concern

These financial statements have been prepared on the basis that the Company is a going concern.

Telix is transitioning from a development stage, medical biotechnology company to a commercial-stage, financially sustainable, revenue-generating company. For the half-year ended 30 June 2021 the Company (on a consolidated basis) incurred a loss after income tax of \$32,514,000 (30 June 2020: \$18,301,000) and operating cash outflows of \$28,648,000 (30 June 2020: \$18,472,000). As at 30 June 2021 the net assets of the Group were \$47,930,000 (31 December 2020: \$79,016,000) with cash and cash equivalents of \$49,615,000 (31 December 2020: \$77,945,000).

The Company (on a consolidated basis) has recorded current trade and other receivables of \$12,239,000 from the Australian Taxation Office in respect of its FY2020 research and development (R&D) tax incentive claim for eligible R&D activities. The Company reasonably anticipates the imminent receipt of this tax incentive claim. A further R&D tax incentive claim is expected to be submitted in Q2 2022 for eligible R&D activities undertaken in FY2021.

In forming the view that the Company is a going concern, the Directors, in consultation with Management, have considered the anticipated receipt of regulatory approval from the US Food and Drug Administration

# NOTES TO THE INTERIM CONSOLIDATED FINANCIAL STATEMENTS for the half-year ended 30 June 2021

(FDA) and European regulatory authorities for the sale and marketing of illuccix® in the United States and European Union states (respectively), as well as progress against regulatory approval processes underway in other commercially important jurisdictions, including Australia and Canada.

The Directors are satisfied that there is sufficient working capital to support committed research activities over the coming 12 months. The Directors, in consultation with Management, have identified a number of active capital management strategies that could be implemented to ensure the Company's ability to continue as a going concern and to ensure the Company will have the ability to realise its assets and pay its liabilities and commitments in the normal course of business should some or all regulatory approvals above not occur or be significantly delayed.

On this basis, the directors are satisfied that the Group continues to be a going concern as at the date of this Report.

The Directors are of the opinion that no asset is likely to be realised for an amount less than the carrying amount at which it is recorded in the consolidated statement of financial position as at 30 June 2021.

As such, no adjustment has been made to the interim financial report relating to the recoverability and classification of the asset carrying amounts or the classification of liabilities that might be necessary should the Group not continue as a going concern.

#### 5. PROFIT AND LOSS INFORMATION

The Group has identified a number of items which are material due to the significance of their nature and/or amount. These are listed separately here to provide a better understanding of the financial performance of the Group.

#### 5.1 Revenue

The Group derives revenue from the sale and transfer of goods and services over time and at a point in time under the following major business activities:

Sale of goods
Research and development services
Total revenue

30 June 2021 \$'000	30 June 2020 \$'000
2,072	1,607
838	-
2,910	1,607

Research and

Timing of revenue recognition
At a point in time
Over time
Total revenue

Sale of	f goods	developr	nent services
30 June 2021	30 June 2020	30 June 2021	30 June 2020
\$'000	\$'000	\$'000	\$'000
2,072	1,607	-	-
-	-	838	-
2,072	1,607	838	-

### 5.2 Expenses

	30 June 2021 \$'000	30 June 2020 \$'000
Research and development costs		
Preclinical	26	128
Clinical	4,411	3,123
Manufacturing	7,742	3,470
Research and development related costs	1,491	1,884
	13,670	8,605
Administration and corporate costs		
Rent and insurance	623	305
Marketing and sponsorship	992	173
Product launch	1,395	122
Professional fees	2,469	1,380
Travel, training and conference	474	461
Other administration expenses	566	248
	6,519	2,690
Depreciation and amortisation		
Depreciation	457	334
Amortisation of intangible assets	2,089	2,001
	2,546	2,335
Employment costs		
Directors' fees	235	190
Salaries and wages	8,071	5,266
Superannuation	236	154
Share based payments and incentives	2,089	1,559
	10,631	7,169
Finance costs		
Bank fees	11	13
Interest expense	74	96
Unwind of discount	2,420	1,137
	2,505	1,246

The Group recognised an unwind of discount on provisions of \$1,836,000 (30 June 2020: \$1,137,000) and contract liabilities of \$584,000 (30 June 2020: \$NIL).

# NOTES TO THE INTERIM CONSOLIDATED FINANCIAL STATEMENTS for the half-year ended 30 June 2021

#### 5.3 Other income and expense items

Research and development tax incentive income
Realised currency gain
Unrealised currency gain
Interest income
Other income

30 June 2021 \$'000	30 June 2020 \$'000
4,598	5,850
79	-
4	593
-	48
101	259
4,782	6,750

#### 5.4 Income tax (expense)/benefit

The Group recognises unused tax losses as an income tax benefit only to the extent that the tax losses can be set off against probable future taxable profits. A deferred tax asset of \$5,942,000 has not been recognised for tax losses incurred for the half-year ended 30 June 2021 (30 June 2020: \$2,248,000). Income tax expense is recognised based on Management's estimate of tax payable by subsidiaries. The net income tax (expense)/benefit recognised for the half-year ended 30 June 2021 is \$(66,000) (2019: \$945,000).

#### 6. TRADE AND OTHER RECEIVABLES

Trade receivables

Research and development tax incentive receivable

Total trade and other receivables

30 June 2021 \$'000	31 December 2020 \$'000
365	160
16,838	12,239
17,203	12,399

### 7. PROPERTY, PLANT AND EQUIPMENT

	Land and buildings \$'000	Plant and equipment \$'000	Furniture, fittings and equipment \$'000	Leasehold improvements \$'000	Right-of- use assets \$'000	Total \$'000
Half-year ended 30 June 2021	<del>-                                    </del>	<b>\$ 000</b>	<del></del>	Ψ 000	<u> </u>	<b>\$ 500</b>
Opening net book amount	2,402	250	225	187	1,757	4,821
Additions	-	2	199	14	114	329
Depreciation charge	(44)	(19)	(60)	(15)	(319)	(457)
Exchange differences	(85)	(4)	(2)	(4)	(16)	(111)
Net book amount	2,273	229	362	182	1,536	4,582
At 30 June 2021						
Cost or fair value	2,374	320	509	240	2,646	6,089
Accumulated depreciation	(101)	(91)	(147)	(58)	(1,110)	(1,507)
Net book amount	2,273	229	362	182	1,536	4,582

	Land and buildings \$'000	Plant and equipment \$'000	Furniture, fittings and equipment \$'000	Leasehold improvements \$'000	Right-of- use assets \$'000	Total \$'000
Year ended 31 December 2020 Opening net book						
amount	-	177	164	211	1,347	1,899
Additions	2,463	112	120	6	950	3,651
Depreciation	(61)	(39)	(77)	(30)	(570)	(777)
Exchange differences	-	-	18	-	30	48
Net book amount	2,402	250	225	187	1,757	4,821
At 31 December 2020						
Cost or fair value	2,463	324	313	230	2,560	5,890
Accumulated depreciation	(61)	(74)	(88)	(43)	(803)	(1,069)
Net book amount	2,402	250	225	187	1,757	4,821

#### 8. INTANGIBLE ASSETS

		Intellectual			
	Goodwill \$'000	property \$'000	Patents \$'000	Licence \$'000	Total \$'000
Half-year ended 30 June 2021					¥ 000
Opening net book amount	4,224	50,377	249	4,339	59,189
Additions	-	-	3	-	3
Amortisation charge	-	(1,937)	(8)	(144)	(2,089)
Changes in provisions	-	9	-	(2,105)	(2,096)
Exchange differences	(57)	(1,017)	-	(160)	(1,234)
Net book amount	4,167	47,432	244	1,930	53,773
At 30 June 2021					
Cost	4,167	56,876	368	2,250	63,661
Accumulated amortisation	-	(9,444)	(124)	(320)	(9,888)
Net book amount	4,167	47,432	244	1,930	53,773

	Goodwill \$'000	Intellectual property \$'000	Patents \$'000	Licence \$'000	Total \$'000
Year ended 31 December 2020					
Opening net book amount	4,224	37,527	197	-	41,948
Additions	-	16,586	72	4,540	21,198
Amortisation charge	-	(3,881)	(22)	(202)	(4,105)
Exchange differences	-	145	2	1	148
Net book amount	4,224	50,377	249	4,339	59,189
At 31 December 2020					
Cost	4,224	58,088	365	4,541	67,218
Accumulated amortisation	-	(7,711)	(116)	(202)	(8,029)
Net book amount	4,224	50,377	249	4,339	59,189

### 8. INTANGIBLE ASSETS (CONTINUED)

The allocation of intangible assets to each cash-generating unit (CGU) is summarised below:

		30 June 2021	31 December 2020
CGU	Entity name	\$'000	\$'000
illuccix <sup>®</sup> (previously illumet <sup>®</sup> )	ANMI	20,834	23,134
TLX591-t	Atlab	13,182	13,440
TLX101	Therapeia	1,356	1,441
TheraPharm Therapeutic	TheraPharm	15,177	15,476
TheraPharm Diagnostic	TheraPharm	1,049	1,110
Seneffe manufacturing facility licence	Telix Belgium	1,930	4,339
Patents	Corporate	245	249
		53,773	59,189

#### Impairment test for goodwill and indefinite life intangible assets:

There were no indicators for impairment of any of the CGUs at 30 June 2021.

#### 9. TRADE AND OTHER PAYABLES

	30 June 2021 \$'000	31 December 2020 \$'000
Trade payables	4,463	5,808
Payroll liabilities	6,339	4,600
Other creditors and accruals	342	484
Total trade and other payables	11,144	10,892

#### 10. LEASE LIABILITIES

The interim consolidated statement of financial position shows the following amounts relating to leases:

30 June 2021

31 December 2020

	\$'000	\$'000
Right-of-use assets		
Properties	1,174	1,380
Motor vehicles	362	377
Total right-of-use-assets	1,536	1,757
Lease liabilities		
Current	509	503
Non-current	1,144	1,345
Total lease liabilities	1,653	1,848

### 10. LEASE LIABILITIES (CONTINUED)

Interest expense (included in finance cost)
Depreciation charge on right-of-use assets
Properties
Motor vehicles

30 June 2021 \$'000	30 June 2020 \$'000
72	68
251	199
68	51
319	250

The total cash outflow for leases is \$267,000 (2020: \$267,000). This is made up of \$195,000 (2020: \$199,000) principal and \$72,000 (2020: \$68,000) interest payments.

#### 11. CONTRACT LIABILITIES

The Group has recognised the following liabilities related to contracts with customers in licensing arrangements:

	30 June 2021 \$'000	31 December 2020 \$'000
Current	3,038	3,235
Non-current	27,993	27,515
Total contract liabilities	31,031	30,750

	Contract
	liabilities
	\$'000
Opening balance	30,750
Charged or credited to profit or loss	
Revenue recognised for research and development services	(838)
Unwind of discount	584
Exchange differences	535
Closing balance	31,031

### China Grand Pharma strategic partnership

On 2 November 2020, the Group entered into a strategic commercial partnership with China Grand Pharmaceutical and Healthcare Holdings Limited (CGP) for the Group's portfolio of MTR products. A non-refundable upfront payment of US\$25,000,000 was received upon signing of the contract with CGP. The strategic partnership with CGP includes a licence of existing intellectual property and the provision of research and development services. The Group has recorded its contractual liability to undertake the identified performance obligations relating to research and development services using a cost-plus margin approach.

#### 12. PROVISIONS

Government grant liability
Contingent consideration
Decommissioning liability

Total provisions - current

Government grant liability
Contingent consideration
Decommissioning liability
Total provisions – non-current
Total provisions

30 June 2021 \$'000	31 December 2020 \$'000
128	73
2,715	1,294
2,988	1,686
5,831	3,053

30 June 2021 \$'000	31 December 2020 \$'000
1,054	982
26,788	23,802
1,523	5,110
29,365	29,894
35,196	32,947

Opening balance
Charged to profit or loss
Additional provisions recognised
Unwind of discount
Exchange differences
Amounts deducted from intangible assets
Provision utilised in the half-year
Closing balance

Total \$'000	Decommiss- ioning liability \$'000	Contingent consideration \$'000	Government grant liability \$'000
32,947	6,796	25,096	1,055
3,394	-	3,309	85
1,836	269	1,504	63
(439)	(3)	(415)	(21)
(2,096)	(2,105)	9	-
(446)	(446)	-	-
35,196	4,511	29,503	1,182

#### 12.1 Government grant liability

ANMI has received grants from the Walloon regional government in Belgium. The grants are repayable to the Walloon government based on a split between fixed and variable repayments. The fixed proportion is based on contractual cash flows agreed with the Walloon government. The variable cash flows are based on a fixed percentage of future sales and are capped at an agreed upon level.

The Group has estimated that the full variable repayments will be made up to the pre-agreed capped amount. The key inputs into this calculation are the risk adjusted post-tax discount rate, the expected sales volumes and the net sales price per unit.

## 12.2 Contingent consideration

The Group is liable for future variable payments to previous ANMI shareholders which are calculated based on the percentage of net sales for five years following the achievement of market authorisation of the product. The percentage of net sales varies depending on the net sales achieved in Europe and the United States. The Group also holds an option to buy-out the remaining future variable payments in the third year following the achievement of market authorisation, if specified sales thresholds are met. Additional provisions were recognised as a net result of changes to the key assumptions of the contingent consideration valuation such as an increase in sale volumes and net sales price per unit in certain jurisdictions over the forecast period.

# NOTES TO THE INTERIM CONSOLIDATED FINANCIAL STATEMENTS for the half-year ended 30 June 2021

#### 12. PROVISIONS (CONTINUED)

#### 12.2 Contingent consideration (continued)

The Group is liable for future milestone payments to previous TheraPharm shareholders which are contingent upon successful completion of a Phase II pivotal registration trial and achievement of marketing authorisation in Europe or the United States, and variable payments based on a percentage of net sales for the first three years following marketing authorisation in Europe or the United States.

The contingent consideration liability has been remeasured by discounted cash flow analysis utilising an adjusted post-tax discount rate of 12.0% (31 December 2020: 12.3%).

#### 12.3 Decommissioning liability

The Group recognised a provision for its obligation to decommission its nuclear product manufacturing plant facility over its operating life. During the period, a decision was taken by Management to accelerate certain decommissioning works to 2021 – 2022. Other decommissioning costs not required to upgrade the manufacturing plant facility have been deferred to the end of the operating life of the facility in 2041. The decommissioning costs expected to be incurred in 2041 of \$9,904,000 has been discounted at a rate of 8.0% and translated to Australian dollars at the exchange rate at 30 June 2021.

#### 12.4 Fair value

Provisions are categorised as Level 3 financial liabilities and remeasured at each reporting date with movements recognised in profit or loss, except in instances where changes are permitted to be added to / reduce an associated asset. The inputs used in fair value calculations are determined by Management.

The carrying amount of financial liabilities measured at fair value is principally calculated based on inputs other than quoted prices that are observable for these financial liabilities, either directly (i.e. as unquoted prices) or indirectly (i.e. derived from prices). Where no price information is available from a quoted market source, alternative market mechanisms or recent comparable transactions, fair value is estimated based on the Group's views on relevant future prices, net of valuation allowances to accommodate liquidity, modelling and other risks implicit in such estimates.

Sensitivity of Level 3 financial liabilities

The potential effect of using reasonably possible alternative assumptions in valuation models, based on a change in the most significant input, such as sales volumes, by an increase/(decrease) of 10 per cent while holding all other variables constant will increase/(decrease) profit before tax by \$2,607,000 (30 June 2020: \$2,209,000).

#### Valuation processes

The finance team of the Group performs the valuations of provisions required for financial reporting purposes, including Level 3 fair values. This team reports directly to the Chief Financial Officer (CFO). Discussions of valuation processes and results are held between the CFO and Board at least once every six months, in line with the Group's half-yearly reporting periods.

The main Level 3 inputs used by the Group in measuring the fair value of provisions are derived and evaluated as follows:

- Discount rates are determined by an independent third party using a weighted average cost of capital
  model to calculate a post-tax rate that reflects current market assessments of the time value of
  money and the risk specific to the asset.
- Regulatory/marketing authorisation approval dates and approval for marketing authorisation probability risk factors are derived in consultation with the Group's regulatory team.
- Expected sales volumes and net sales price per unit are estimated based on market information on annual incidence rates and information for similar products and expected market penetration.
- · Contingent consideration cash flows are estimated based on the terms of the sale contract.

Changes in fair values are analysed at the end of each reporting period during the half-yearly valuation discussion between the CFO and Board. As part of this discussion the CFO presents a report that explains the reason for the fair value movements.

#### 13. CONTRACTUAL MATURITIES OF FINANCIAL LIABILITIES

As at 30 June 2021, the contractual maturities of the Group's non-derivative financial liabilities were as follows:

	Note	1 - 6 months \$'000	6 - 12 months \$'000	1 – 5 years \$'000	Over 5 years \$'000	Total contract- ual cash flows \$'000	Carrying amount of liabilities \$'000
Trade and other payables	9	11,144	-	-	-	11,144	11,144
Borrowings		21	22	-	-	43	43
Lease liabilities	10	333	289	1,041	329	1,992	1,653
Government grant liability	12	117	49	1,596	118	1,879	1,182
Contingent consideration	12	406	2,124	38,231	-	40,761	29,503
Decommissioning liability	12	2,975	90	-	6,839	9,904	4,511
Total non-derivative financial liabilities		14,996	2,574	40,868	7,286	65,723	48,036

As at 31 December 2020, the contractual maturities of the Group's non-derivative financial liabilities were as follows:

	Note	1 - 6 months \$'000	6 - 12 months \$'000	1 – 5 years \$'000	Over 5 years \$'000	Total contract- ual cash flows \$'000	Carrying amount of liabilities \$'000
Trade and other payables	9	10,892	-	-	-	10,892	10,892
Borrowings		132	132	95	-	359	359
Lease liabilities	10	334	298	1,210	406	2,248	1,848
Government grant liability	12	-	129	2480	-	2,609	1,055
Contingent consideration	12	-	1,453	33,445	-	34,898	25,096
Decommissioning liability	12	-	1,738	6,393	-	8,131	6,796
Total non-derivative financial liabilities	<del>-</del>	11,358	3,750	43,623	406	59,137	46,046

#### 14. EQUITY

#### 14.1 Share capital

			31 December	31 December
	30 June 2021	30 June 2021	2020	2020
	Number	\$'000	Number	\$'000
Movements in shares on				_
issue				
Opening balance	280,405,322	167,058	253,279,999	115,943
Shares issued through the exercise of share options <sup>(i)</sup>	1,218,086	850	1,865,991	838
Shares issued CGP (ii)	-	-	20,947,181	35,401
Shares issued TheraPharm		-	4,312,151	15,006
Less transaction costs	-	-	-	(130)
Closing balance	281,623,408	167,908	280,405,322	167,058

- (i) Options exercised under the employee incentive plan in the half-year ended 30 June 2021 resulted in 1,218,086 shares being issued for \$850,000.
- (ii) On 2 November 2020, the Group entered into a strategic commercial partnership with China Grand Pharmaceutical and Healthcare Holdings Limited (CGP) for the Group's portfolio of MTR products. CGP made an equity investment of \$35,401,000 (US\$25,000,000) in the form of a placement to CGP of 20,947,181 fully paid ordinary Telix shares, issued at a price of \$1.69 per share
- (iii) On 14 December 2020, Telix acquired all of the issued capital of TheraPharm for consideration which included \$15,006,000 (€10,200,000) comprising 4,312,151 fully paid ordinary Telix shares, issued at a price of \$3.48 per share

The weighted average ordinary shares for the period 1 January 2021 to 30 June 2021 is 281,019,987 (2020: 257,271,000). The Company does not have a limited amount of authorised capital.

#### 14.2 Share-based payments reserve

	30 June 2021 Number	30 June 2021 \$'000	31 December 2020 Number	31 December 2020 \$'000
Movements				
Opening balance	20,226	4,620	17,814	2,274
Options issued (i)	2,227	1,500	5,530	2,435
Options exercised	(1,267)	-	(2,710)	-
Options lapsed	-	-	(408)	(89)
Closing balance (ii)	21,186	6,120	20,226	4,620

- (i) Options have an expiry date of 27 January 2026 and an exercise price of \$4.38 per option
- (ii) Excludes 780,923 warrants issued on 11 September 2018 on completion of the acquisition of Atlab. The consideration for the acquisition comprised \$12,612,000 in Telix shares at a fair value of \$0.85 per share (14,837,531 Telix shares) and warrants over Telix shares at a fair value of \$184,000 (780,923 warrants). The warrants have an expiry date of 11 September 2022 and an exercise price of \$1.34 per warrant.

# NOTES TO THE INTERIM CONSOLIDATED FINANCIAL STATEMENTS for the half-year ended 30 June 2021

#### 15. COMMITMENTS AND CONTINGENT LIABILITY

**Capital commitments**: At 30 June 2021 the company's capital commitments are \$NIL (31 December 2020: \$NIL).

Research and development commitments: At 30 June 2021 the company has \$28,383,000 (31 December 2020: \$21,087,000) commitments against existing research and development and clinical development related contracts. These contracts have typical termination provisions to limit the commitment to the time and materials expended at termination, the orderly close out of activities or up to an approved work order amount.

**Contingent liability:** On 18 March 2021 the Group entered into a non-exclusive global clinical and commercial supply agreement with Garching-based ITM Isotopen Technologien München AG (ITM) for the supply of highly pure no-carrier-added lutetium-177, a therapeutic isotope. ITM will supply the product for use in the Group's investigational programs in prostate and renal cancer therapy and subject to approval of the Group's drug candidates for therapeutic use, also provide the product for scale-up and commercialisation.

At 30 June 2021 there is a possible obligation for the Group to pay \$1,581,000 (€1,000,000) to ITM on the approval of the product for therapeutic use by the relevant regulatory authority in either United States, France, Germany, Spain, Italy or the UK and \$1,581,000 (€1,000,000) when the Group makes a commercial armslength sale of the product. The existence of the obligation will be confirmed only by the occurrence of one or more uncertain future events not wholly within the control of the Group.

#### 16. RELATED PARTY TRANSACTIONS

#### Transactions with other related parties

ABX-CRO is a clinical research organisation (CRO) that specialises in radiopharmaceutical product development. Telix has entered into a master services agreement with ABX-CRO for the provision of clinical and analytical services for its programs. Non-Executive Director, Dr. Andreas Kluge, is the principal owner and Geschäftsführer (Managing Director) of ABX-CRO. Fees for services provided during the half-year to 30 June 2021 total \$843,661 (30 June 2020: \$658,536). The amount payable at 30 June 2021 was \$524,971 (31 December 2020: \$177,110).

### 17. EVENTS AFTER THE REPORTING PERIOD

In July 2021, Telix reported that the Phase III ZIRCON trial of renal imaging investigational product TLX250-CDx had exceeded 50% recruitment, with more than 80% of study sites back recruiting into clinical trials. Recruitment has significantly accelerated in recent months and indicative patient recruitment is 5-10 patients per week. Given that the duration of study participation for patients on the ZIRCON trial is 42 days, Telix expects to commence the FDA BLA consultation process before end-calendar year, as planned.

Also in July 2021, Telix received authorisation from the Belgian Agence Fédérale de Contrôle Nucléaire (AFCN) to decommission the first of two cyclotrons housed at the Company's licensed radiopharmaceutical production facility in Seneffe, Belgium. The authorisation means that the AFCN has accepted Telix's decommissioning dossier, submitted with the support of SCK-CEN (the Belgian Nuclear Research Centre), and is satisfied that safety and operational requirements will be met. This represents a significant milestone for Telix since it will enable the build-out of a state-of-the-art nuclear facility that will ultimately serve as the Company's primary European manufacturing site.

In August 2021, a first patient was dosed in a first-in-human Phase I CUPID study of the Company's next generation prostate cancer therapy candidate TLX592. This investigational agent will become Telix's first targeted alpha therapy (TAT) for the treatment of patients with advanced prostate cancer. The CUPID study, which is being conducted in collaboration with GenesisCare, will recruit up to 15 patients and will initially use copper-64 (64Cu)-labelled TLX592, as a PET imaging agent, to evaluate biodistribution and dosing, before proceeding to studies with actinium-225 (<sup>225</sup>Ac) TAT.

Also in August 2021, Telix announced that the London-based Great Ormond Street Hospital (GOSH), an international centre of excellence in child healthcare, received ethics approval to commence a Phase II academic study of Telix's investigational product, TLX66 (90Y-DTPA-besilesomab), in children with high-risk leukemia. The open label Phase II study is being carried out by GOSH to evaluate safety and efficacy of TLX66 as part of a reduced toxicity conditioning regimen in children and adolescents undergoing allogeneic HSCT.

# NOTES TO THE INTERIM CONSOLIDATED FINANCIAL STATEMENTS for the half-year ended 30 June 2021

The independent trial will enrol 25 patients and follows the successful completion of a Phase I study, full results of which are expected to be published in late 2021.

During August 2021, Telix announced a pan-cancer clinical collaboration with Merck KGaA, Darmstadt, Germany (Merck), to conduct combination studies with one of Merck's investigational proprietary DNA Damage Response Inhibitor (DDRi) molecules in combination with each of Telix's TLX591 and TLX250 therapeutic programs. This clinical collaboration builds on encouraging pre-clinical data derived from the initial strategic research collaboration between Telix and Merck announced in August 2019.

In August 2021, Telix also announced an indication expansion into breast cancer with two new investigator-led studies initiated to evaluate the potential utility of TLX591-CDx and TLX250-CDx in invasive lobular carcinoma (ILC) and triple negative breast cancer (TNBC), respectively. The study of TLX591-CDx at Winship Cancer Institute of Emory University will recruit 20 patients over two years. TLX591-CDx targets glutamate carboxypeptidase II (GCPII), more generally known as PSMA, a protein that is highly expressed in many cancers, including ILC. While Telix has filed for regulatory approval of TLX591-CDx in prostate cancer imaging (investigational product *illuccix*® kit), this study marks the first formal clinical investigation of TLX591-CDx in another indication of interest. The study of TLX250-CDx in TNBC (OPALESCENCE) will be conducted at the Institut de Cancérologie de l'Ouest in St Herblain, France, and will recruit 12 patients. OPALESCENCE follows ZiP-UP as the second of a comprehensive series of studies that will evaluate CA9 expression in cancers other than ccRCC. Both ILC and TNBC can be extremely aggressive with unmet medical need in both accurate staging and therapeutic delivery. These studies support Telix's goal of rapid indication expansion, alongside executing the Company's near-term commercial and clinical goals for TLX591-CDx and TLX250-CDx.

No other matter or circumstance has arisen since 30 June 2021 that has significantly affected the Group's operations, results or state of affairs.

In accordance with a resolution of the Directors of Telix Pharmaceuticals Limited, we state that:

In the opinion of the Directors:

- the financial statements and notes of the Group are in accordance with the *Corporations Act* 2001 (Cth), including:
  - giving a true and fair view of the Group's financial position as at 30 June 2021 and of its performance for the period ended on that date; and
  - ii. complying with Australian Accounting Standards (including the Australian Accounting Interpretations) and the Corporations Regulations 2001;
- there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration has been made after receiving the declarations by the Chief Executive Officer and Chief Financial Officer recommended to be made under the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations for the half-year ended 30 June 2021.

Signed in Sydney on 19 August 2021

On behalf of the Board

In Galin

H Kevin McCann AO Chairman Christian P Behrenbruch PhD MBA
Managing Director and Chief Executive Officer



# Independent auditor's review report to the members of Telix Pharmaceuticals Limited

# Report on the half-year financial report

#### Conclusion

We have reviewed the half-year financial report of Telix Pharmaceuticals Limited (the Company) and the entities it controlled during the half-year (together the Group), which comprises the consolidated statement of financial position as at 30 June 2021, the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, significant accounting policies and explanatory notes and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Telix Pharmaceuticals Limited does not comply with the *Corporations Act 2001* including:

- 1. giving a true and fair view of the Group's financial position as at 30 June 2021 and of its performance for the half-year ended on that date
- 2. complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

# Basis for conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity* (ASRE 2410). Our responsibilities are further described in the *Auditor's responsibilities for the review of the half-year financial report* section of our report.

We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional & Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to the audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

### Responsibilities of the directors for the half-year financial report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement whether due to fraud or error.

PricewaterhouseCoopers, ABN 52 780 433 757

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# Auditor's responsibilities for the review of the half-year financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 30 June 2021 and of its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Pricewaterhouse Coopers

PricewaterhouseCoopers

Brad Peake Partner Melbourne 19 August 2021